There are going to be two bills on the suspension calendar that I worked on very hard for the last several years.

The first bill is a comprehensive FDA reform bill to reform the Food and Drug Administration. It is the culmination of a series of 3 years of work on a bipartisan basis to bring the American people the safest food and the most technologically advanced drugs and medical devices in the world.

The second bill is the suspension bill that will ratify low-level nuclear waste compact between my State, Texas, and the great States of Maine and Vermont. Again, this bill is a culmination of 5 years of work between those States' Governors and State delegations on a bipartisan basis.

So we are going to have two bills on the floor today, both good public policy, and I would encourage all of my colleagues to vote for them.

FOOD AND DRUG ADMINISTRATION REGULATORY MODERNIZATION ACT OF 1997

Mr. BLILEY. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 1411) to amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to facilitate the development and approval of new drugs and biological products, and for other purposes, as amended.

The Clerk read as follows:

H.R. 1411

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; REFERENCES; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Food and Drug Administration Regulatory Modernization Act of 1997''.

(b) REFERENCES.—Except as otherwise specified, whenever in this Act an amendment is expressed in terms of an amendment to a section or other provision, the reference shall be considered to be made to that section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.).

(c) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

TITLE I—IMPROVING REGULATION OF DRUGS

SEC. 101. FEES RELATING TO DRUGS.

(a) FINDINGS.—Congress finds that—

(1) prompt approval of safe and effective new drugs and other therapies is critical to the improvement of the public health so that patients may enjoy the benefits provided by these therapies to treat and prevent illness and disease;

(2) the public health will be served by making additional funds available for the purpose of augmenting the resources of the Food and Drug Administration that are devoted to the process for review of human drug applications;

(3) the provisions added by the Prescription Drug User Fee Act of 1992 have been successful in substantially reducing review times for human drug applications and should be—

(A) reauthorized for an additional 5 years, with certain technical improvements; and

(B) carried out by the Food and Drug Administration with new commitments to implement more ambitious and comprehensive improvements in regulatory processes of the Food and Drug Administration; and

(4) the fees authorized by amendments made in this title will be dedicated toward expediting the drug development process and the review of human drug applications as set forth in the goals identified in the letters of _____, and _____, from the Secretary of Health and Human Services to the chairman of the Committee on Commerce of the House of Representatives and the chairman of the Committee on Labor and Human Resources of the Senate, as set forth at ____ Cong. Rec. _____ (daily ed. _____, 1997).

(b) DEFINITIONS.—Section 735 (21 U.S.C. 379g) is amended—

(1) in the second sentence of paragraph (1)—

(A) by striking ''Service Act, and'' and inserting ''Service Act,''; and

(B) by striking ''September 1, 1992.'' and inserting the following: ''September 1, 1992, does not include an application for a licensure of a biological product for further manufacturing use only, and does not include an application or supplement submitted by a State or Federal Government entity for a drug that is not distributed commercially. Such term does include an application for licensure, as described in subparagraph (D), of a large volume biological product intended for single dose injection for intravenous use or infusion.'';

(2) in the second sentence of paragraph (3)—

(A) by striking ''Service Act, and'' and inserting ''Service Act,''; and

(B) by striking ''September 1, 1992.'' and inserting the following: ''September 1, 1992, does not include a biological product that is licensed for further manufacturing use only, and does not include a drug that is not distributed commercially and is the subject of an application or supplement submitted by a State or Federal Government entity. Such term does include a large volume biological product intended for single dose injection for intravenous use or infusion.'';

(3) in paragraph (4), by striking ''without'' and inserting ''without substantial'';

(4) by amending the first sentence of paragraph (5) to read as follows:

''(5) The term 'prescription drug establishment' means a foreign or domestic place of business which is at one general physical location consisting of one or more buildings all of which are within 5 miles of each other and at which one or more prescription drug products are manufactured in final dosage form.'';

(5) in paragraph (7)(A)—

(A) by striking ''employees under contract'' and all that follows through ''Administration,'' the second time it occurs and inserting ''contractors of the Food and Drug Administration,''; and

(B) by striking ''and committees,'' and inserting ''and committees and to contracts with such contractors,'';

(6) in paragraph (8)—

(A) in subparagraph (A)—

(i) by striking ''August of'' and inserting ''April of''; and

(ii) by striking ''August 1992'' and inserting ''April 1997'';

(B) in subparagraph (B), by striking ''1992'' and inserting ''1997''; and

(C) by striking the second sentence; and

(7) by adding at the end the following:

''(9) The term 'affiliate' means a business entity that has a relationship with a second business entity if, directly or indirectly—

''(A) one business entity controls, or has the power to control, the other business entity; or

''(B) a third party controls, or has power to control, both of the business entities.''.

(c) AUTHORITY TO ASSESS AND USE DRUG FEES.—

(1) TYPES OF FEES.—Section 736(a) (21 U.S.C. 379h(a)) is amended—

(A) by striking ''Beginning in fiscal year 1993'' and inserting ''Beginning in fiscal year 1998'';

(B) in paragraph (1)—

(i) by striking subparagraph (B) and inserting the following:

''(B) PAYMENT.—The fee required by subparagraph (A) shall be due upon submission of the application or supplement.'';

(ii) in subparagraph (D)—

(I) in the subparagraph heading, by striking ''NOT ACCEPTED'' and inserting ''REFUSED'';

(II) by striking ''50 percent'' and inserting ''75 percent'';

(III) by striking ''subparagraph (B)(i)'' and inserting ''subparagraph (B)''; and

(IV) by striking ''not accepted'' and inserting ''refused''; and

(iii) by adding at the end the following:

''(E) EXCEPTION FOR DESIGNATED ORPHAN DRUG OR INDICATION.—A human drug application for a prescription drug product that has been designated as a drug for a rare disease or condition pursuant to section 526 shall not be subject to a fee under subparagraph (A), unless the human drug application includes indications for other than rare diseases or conditions. A supplement proposing to include a new indication for a rare disease or condition in a human drug application shall not be subject to a fee under subparagraph (A), if the drug has been designated pursuant to section 526 as a drug for a rare disease or condition with regard to the indication proposed in such supplement.

''(F) EXCEPTION FOR SUPPLEMENTS FOR PEDIATRIC INDICATIONS.—A supplement to a human drug application for an indication for use in pediatric populations shall not be assessed a fee under subparagraph (A).

''(G) REFUND OF FEE IF APPLICATION WITHDRAWN.—If an application or supplement is withdrawn after the application or supplement is filed, the Secretary may waive and refund the fee or a portion of the fee if no substantial work was performed on the application or supplement after the application or supplement was filed. The Secretary shall have the sole discretion to waive and refund a fee or a portion of the fee under this subparagraph. A determination by the Secretary concerning a waiver or refund under this paragraph shall not be reviewable.'';

(C) by striking paragraph (2) and inserting in lieu the following:

''(2) PRESCRIPTION DRUG ESTABLISHMENT FEE.—

''(A) IN GENERAL.—Except as provided in subparagraph (B), each person that is named as the applicant in a human drug application, and after September 1, 1992, had pending before the Secretary a human drug application or supplement, shall be assessed an annual fee established in subsection (b) for each prescription drug establishment listed in its approved human drug application as an establishment that manufactures the prescription drug product named in the application. The annual establishment fee shall be assessed in each fiscal year in which the prescription drug product named in the application is assessed a fee under paragraph (3) unless the prescription drug establishment listed in the application does not engage in the manufacture of the prescription drug product during the fiscal year. The establishment fee shall be payable on or before January 31 of each year. Each such establishment shall be assessed only one fee per establishment, notwithstanding the number of prescription drug products manufactured at the establishment. In the event an establishment is listed in a human drug application by more than 1 applicant, the establishment fee for the fiscal year shall be divided equally and assessed among the applicants whose prescription drug products are manufactured by the establishment during the fiscal year and assessed product fees under paragraph (3).

''(B) EXCEPTION.—If, during the fiscal year, an applicant initiates or causes to be initiated the manufacture of a prescription drug product at an establishment listed in its human drug application—

''(i) that did not manufacture the product in the previous fiscal year; and

''(ii) for which the full establishment fee has been assessed in the fiscal year at a time before manufacture of the prescription drug product was begun;

the applicant will not be assessed a share of the establishment fee for the fiscal year in which the manufacture of the product began.''.

(D) in paragraph (3)—

(i) in subparagraph (A)—

(I) in clause (i), by striking ''is listed'' and inserting ''has been submitted for listing''; and

(II) by striking ''Such fee shall be paid'' and all that follows through ''section 510.'' and inserting the following: ''Such fee shall be payable for the fiscal year in which the product is first submitted for listing under section 510, or for relisting under section 510 if the product has been withdrawn from listing and relisted. After such fee is paid for that fiscal year, such fee shall be payable on or before January 31 of each year. Such fee shall be paid only once for each product for a fiscal year in which the fee is payable.''; and

(ii) in subparagraph (B), by striking ''505(j).'' and inserting the following: ''505(j), under an abbreviated application filed under section 507, or under an abbreviated new drug application pursuant to regulations in effect prior to the implementation of the Drug Price Competition and Patent Term Restoration Act of 1984.''.

(2) FEE AMOUNTS.—Section 736(b) (21 U.S.C. 379h(b)) is amended to read as follows:

''(b) FEE AMOUNTS.—Except as provided in subsections (c), (d), (f), and (g), the fees required under subsection (a) shall be determined and assessed as follows:

''(1) APPLICATION AND SUPPLEMENT FEES.—

''(A) FULL FEES.—The application fee under subsection (a)(1)(A)(i) shall be $250,704 in fiscal year 1998, $256,338 in each of fiscal years 1999 and 2000, $267,606 in fiscal year 2001, and $258,451 in fiscal year 2002.

''(B) OTHER FEES.—The fee under subsection (a)(1)(A)(ii) shall be $125,352 in fiscal year 1998, $128,169 in each of fiscal years 1999 and 2000, $133,803 in fiscal year 2001, and $129,226 in fiscal year 2002.

''(2) FEE REVENUES FOR ESTABLISHMENT FEES.—The total fee revenues to be collected in establishment fees under subsection (a)(2) shall be $35,600,000 in fiscal year 1998, $36,400,000 in each of fiscal years 1999 and 2000, $38,000,000 in fiscal year 2001, and $36,700,000 in fiscal year 2002.

''(3) TOTAL FEE REVENUES FOR PRODUCT FEES.—The total fee revenues to be collected in product fees under subsection (a)(3) in a fiscal year shall be equal to the total fee revenues collected in establishment fees under subsection (a)(2) in that fiscal year.''.

(3) INCREASES AND ADJUSTMENTS.—Section 736(c) (21 U.S.C. 379h(c)) is amended—

(A) in the subsection heading, by striking ''INCREASES AND'';

(B) in paragraph (1)—

(i) by striking ''(1) REVENUE'' and all that follows through ''increased by the Secretary'' and inserting the following: ''(1) INFLATION ADJUSTMENT.—The fees and total fee revenues established in subsection (b) shall be adjusted by the Secretary'';

(ii) in subparagraph (A), by striking ''increase'' and inserting ''change'';

(iii) in subparagraph (B), by striking ''increase'' and inserting ''change''; and

(iv) by adding at the end the following flush sentence:

''The adjustment made each fiscal year by this subsection will be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 1997 under this subsection.'';

(C) in paragraph (2), by striking ''October 1, 1992,'' and all that follows through ''such schedule.'' and inserting the following: ''September 30, 1997, adjust the establishment and product fees described in subsection (b) for the fiscal year in which the adjustment occurs so that the revenues collected from each of the categories of fees described in paragraphs (2) and (3) of subsection (b) shall be set to be equal to the revenues collected from the category of application and supplement fees described in paragraph (1) of subsection (b).''; and

(D) in paragraph (3), by striking ''paragraph (2)'' and inserting ''this subsection''.

(4) FEE WAIVER OR REDUCTION.—Section 736(d) (21 U.S.C. 379h(d)) is amended—

(A) by redesignating paragraphs (1), (2), (3), and (4) as subparagraphs (A), (B), (C), and (D), respectively and indenting appropriately;

(B) by striking ''The Secretary shall grant a'' and all that follows through ''finds that—'' and inserting the following:

''(1) IN GENERAL.—The Secretary shall grant a waiver from or a reduction of one or more fees assessed under subsection (a) where the Secretary finds that—'';

(C) in subparagraph (C) (as so redesignated by subparagraph (A)), by striking '', or'' and inserting a comma;

(D) in subparagraph (D) (as so redesignated by subparagraph (A)), by striking the period and inserting '', or'';

(E) by inserting after subparagraph (D) (as so redesignated by subparagraph (A)) the following:

''(E) the applicant is a small business submitting its first human drug application to the Secretary for review.''; and

(F) by striking ''In making the finding in paragraph (3),'' and all that follows through ''standard costs.'' and inserting the following:

''(2) USE OF STANDARD COSTS.—In making the finding in paragraph (1)(C), the Secretary may use standard costs.

''(3) RULES RELATING TO SMALL BUSINESSES.—

''(A) DEFINITION.—In paragraph (1)(E), the term 'small business' means an entity that has fewer than 500 employees, including employees of affiliates.

''(B) WAIVER OF APPLICATION FEE.—The Secretary shall waive under paragraph (1)(E) the application fee for the first human drug application that a small business or its affiliate submits to the Secretary for review. After a small business or its affiliate is granted such a waiver, the small business or its affiliate shall pay—

''(i) application fees for all subsequent human drug applications submitted to the Secretary for review in the same manner as an entity that does not qualify as a small business; and

''(ii) all supplement fees for all supplements to human drug applications submitted to the Secretary for review in the same manner as an entity that does not qualify as a small business.''.

(5) ASSESSMENT OF FEES.—Section 736(f)(1) (21 U.S.C. 379h(f)(1)) is amended—

(A) by striking ''fiscal year 1993'' and inserting ''fiscal year 1997''; and

(B) by striking ''fiscal year 1992'' and inserting ''fiscal year 1997 (excluding the amount of fees appropriated for such fiscal year)''.

(6) CREDITING AND AVAILABILITY OF FEES.—Section 736(g) (21 U.S.C. 379h(g)) is amended—

(A) in paragraph (1), by adding at the end the following: ''Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for the process for the review of human drug applications within the meaning of section 735(6).'';

(B) in paragraph (2)—

(i) in subparagraph (A), by striking ''Acts'' and inserting ''Acts, or otherwise made available for obligation,''; and

(ii) in subparagraph (B), by striking ''over such costs for fiscal year 1992'' and inserting ''over such costs, excluding costs paid from fees collected under this section, for fiscal year 1997''; and

(C) by striking paragraph (3) and inserting the following:

''(3) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated for fees under this section—

''(A) $106,800,000 for fiscal year 1998;

''(B) $109,200,000 for fiscal year 1999;

''(C) $109,200,000 for fiscal year 2000;

''(D) $114,000,000 for fiscal year 2001; and

''(E) $110,100,000 for fiscal year 2002,

as adjusted to reflect adjustments in the total fee revenues made under this section and changes in the total amounts collected by application, supplement, establishment, and product fees.

''(4) OFFSET.—Any amount of fees collected for a fiscal year which exceeds the amount of fees specified in appropriation Acts for such fiscal year shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under appropriation Acts for a subsequent fiscal year.''.

(7) REQUIREMENT FOR WRITTEN REQUESTS FOR WAIVERS, REDUCTIONS, AND FEES.—Section 736 (21 U.S.C. 379h) is amended—

(A) by redesignating subsection (i) as subsection (j); and

(B) by inserting after subsection (h) the following:

''(i) WRITTEN REQUESTS FOR WAIVERS, REDUCTIONS, AND REFUNDS.—To qualify for consideration for a waiver or reduction under subsection (d), or for a refund of any fee collected in accordance with subsection (a), a person shall submit to the Secretary a written request for such waiver, reduction, or refund not later than 180 days after such fee is due.''.

(8) SPECIAL RULE FOR WAIVER, REFUNDS, AND EXCEPTIONS.—Any requests for waivers, refunds, or exceptions for fees assessed prior to the date of enactment of this Act shall be submitted in writing to the Secretary of Health and Human Services within 1 year after the date of enactment of this Act.

(d) ANNUAL REPORTS.—

(1) PERFORMANCE REPORT.—Beginning with fiscal year 1998, not later than 60 days after the end of each fiscal year during which fees are collected under part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g et seq.), the Secretary of Health and Human Services shall prepare and submit to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letter described in subsection (a)(4) during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals.

(2) FISCAL REPORT.—Beginning with fiscal year 1998, not later than 120 days after the end of each fiscal year during which fees are collected under the part described in subsection (a), the Secretary of Health and Human Services shall prepare and submit to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected during such fiscal year for which the report is made.

(e) EFFECTIVE DATE.—The amendments made by this section shall take effect October 1, 1997.

(f) TERMINATION OF EFFECTIVENESS.—The amendments made by subsections (b) and (c) cease to be effective October 1, 2002, and subsection (d) ceases to be effective 120 days after such date.

SEC. 102. PEDIATRIC STUDIES OF DRUGS.

Chapter V (21 U.S.C. 351 et seq.) is amended by inserting after section 505 the following:

''PEDIATRIC STUDIES OF DRUGS

''SEC. 505A. (a) MARKET EXCLUSIVITY FOR NEW DRUGS.—If, prior to approval of an application that is submitted under section 505(b)(1), the Secretary determines that information relating to the use of a drug in the pediatric population may produce health benefits in that population, the Secretary makes a written request for pediatric studies (which shall include a timeframe for completing such studies), and such studies are completed within any such timeframe and the reports thereof submitted in accordance with subsection (d)(2) or accepted in accordance with subsection (d)(3)—

''(1)(A) the period during which an application may not be submitted under subsections (c)(3)(D)(ii) and (j)(4)(D)(ii) of section 505 shall be five years and six months rather than five years, and the references in subsections (c)(3)(D)(ii) and (j)(4)(D)(ii) of section 505 to four years, to forty-eight months, and to seven and one-half years shall be deemed to be four and one-half years, fifty-four months, and eight years, respectively; or

''(B) the period of market exclusivity under subsections (c)(3)(D)(iii) and (iv) and (j)(4)(D)(iii) and (iv) of section 505 shall be three years and six months rather than three years; and

''(2)(A) if the drug is the subject of—

''(i) a listed patent for which a certification has been submitted under subsections (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of section 505 and for which pediatric studies were submitted prior to the expiration of the patent (including any patent extensions); or

''(ii) a listed patent for which a certification has been submitted under subsections (b)(2)(A)(iii) or (j)(2)(A)(vii)(III) of section 505,

the period during which an application may not be approved under section 505(c)(3) or section 505(j)(4)(B) shall be extended by a period of six months after the date the patent expires (including any patent extensions); or

''(B) if the drug is the subject of a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505, and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed, the period during which an application may not be approved under section 505(c)(3) or section 505(j)(4)(B) shall be extended by a period of six months after the date the patent expires (including any patent extensions).

''(b) SECRETARY TO DEVELOP LIST OF DRUGS FOR WHICH ADDITIONAL PEDIATRIC INFORMATION MAY BE BENEFICIAL.—Not later than 180 days after the date of enactment of this section, the Secretary, after consultation with experts in pediatric research shall develop, prioritize, and publish an initial list of approved drugs for which additional pediatric information may produce health benefits in the pediatric population. The Secretary shall annually update the list.

''(c) MARKET EXCLUSIVITY FOR ALREADY-MARKETED DRUGS.—If the Secretary makes a written request to the holder of an approved application under section 505(b)(1) for pediatric studies (which shall include a timeframe for completing such studies) concerning a drug identified in the list described in subsection (b), the holder agrees to the request, the studies are completed within any such timeframe and the reports thereof are submitted in accordance with subsection (d)(2) or accepted in accordance with subsection (d)(3)—

''(1)(A) the period during which an application may not be submitted under subsection (c)(3)(D)(ii) or (j)(4)(D)(ii) of section 505 shall be five years and six months rather than five years, and the references in subsections (c)(3)(D)(ii) and (j)(4)(D)(ii) of section 505 to four years, to forty-eight months, and to seven and one-half years shall be deemed to be four and one-half years, fifty-four months, and eight years, respectively; or

''(B) the period of market exclusivity under subsections (c)(3)(D)(iii) and (iv) and (j)(4)(D)(iii) and (iv) of section 505 shall be three years and six months rather than three years; and

''(2)(A) if the drug is the subject of—

''(i) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of section 505 and for which pediatric studies were submitted prior to the expiration of the patent (including any patent extensions); or

''(ii) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iii) or (j)(2)(A)(vii)(III) of section 505,

the period during which an application may not be approved under section 505(c)(3) or section 505(j)(4)(B) shall be extended by a period of six months after the date the patent expires (including any patent extensions); or

''(B) if the drug is the subject of a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505, and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed, the period during which an application may not be approved under section 505(c)(3) or section 505(j)(4)(B) shall be extended by a period of six months after the date the patent expires (including any patent extensions).

''(d) CONDUCT OF PEDIATRIC STUDIES.—

''(1) AGREEMENT FOR STUDIES.—The Secretary may, pursuant to a written request for studies, after consultation with—

''(A) the sponsor of an application for an investigational new drug under section 505(i);

''(B) the sponsor of an application for a drug under section 505(b)(1); or

''(C) the holder of an approved application for a drug under section 505(b)(1),

agree with the sponsor or holder for the conduct of pediatric studies for such drug.

''(2) WRITTEN PROTOCOLS TO MEET THE STUDIES REQUIREMENT.—If the sponsor or holder and the Secretary agree upon written protocols for the studies, the studies requirement of subsection (a) or (c) is satisfied upon the completion of the studies and submission of the reports thereof in accordance with the original written request and the written agreement referred to in paragraph (1). Not later than 60 days after the submission of the report of the studies, the Secretary shall determine if such studies were or were not conducted in accordance with the original written request and the written agreement and reported in accordance with the requirements of the Secretary for filing and so notify the sponsor or holder.

''(3) OTHER METHODS TO MEET THE STUDIES REQUIREMENT.—If the sponsor or holder and the Secretary have not agreed in writing on the protocols for the studies, the studies requirement of subsection (a) or (c) is satisfied when such studies have been completed and the reports accepted by the Secretary. Not later than 90 days after the submission of the reports of the studies, the Secretary shall accept or reject such reports and so notify the sponsor or holder. The Secretary's only responsibility in accepting or rejecting the reports shall be to determine, within the 90 days, whether the studies fairly respond to the written request, whether such studies have been conducted in accordance with commonly accepted scientific principles and protocols, and whether such studies have been reported in accordance with the requirements of the Secretary for filing.

''(e) DELAY OF EFFECTIVE DATE FOR CERTAIN APPLICATIONS; PERIOD OF MARKET EXCLUSIVITY.—If the Secretary determines that the acceptance or approval of an application under section 505(b)(2) or 505(j) for a drug may occur after submission of reports of pediatric studies under this section, which were submitted prior to the expiration of the patent (including any patent extension) or market exclusivity protection, but before the Secretary has determined whether the requirements of subsection (d) have been satisfied, the Secretary shall delay the acceptance or approval under section 505(b)(2) or 505(j), respectively, until the determination under subsection (d) is made, but such delay shall not exceed 90 days. In the event that requirements of this section are satisfied, the applicable period of market exclusivity referred to in subsection (a) or (c) shall be deemed to have been running during the period of delay.

''(f) NOTICE OF DETERMINATIONS ON STUDIES REQUIREMENT.—The Secretary shall publish a notice of any determination that the requirements of subsection (d) have been met and that submissions and approvals under section 505(b)(2) or (j) for a drug will be subject to the provisions of this section.

''(g) DEFINITIONS.—As used in this section, the term 'pediatric studies' or 'studies' means at least one clinical investigation (that, at the Secretary's discretion, may include pharmacokinetic studies) in pediatric age groups in which a drug is anticipated to be used.

''(h) LIMITATION.—The holder of an approved application for a new drug that has already received six months of market exclusivity under subsection (a) or (c) may, if otherwise eligible, obtain six months of market exclusivity under subsection (c)(1)(B) for a supplemental application, except that the holder is not eligible for exclusivity under subsection (c)(2).

''(i) RELATIONSHIP TO REGULATIONS.—Notwithstanding any other provision of law, if any pediatric study is required pursuant to regulations promulgated by the Secretary, such study shall be deemed to satisfy the requirement for market exclusivity pursuant to this section.

''(j) SUNSET.—No period of market exclusivity shall be granted under this section based on studies commenced after January 1, 2002. The Secretary shall conduct a study and report to Congress not later than January 1, 2001, based on the experience under the program. The study and report shall examine all relevant issues, including—

''(1) the effectiveness of the program in improving information about important pediatric uses for approved drugs;

''(2) the adequacy of the incentive provided under this section;

''(3) the economic impact of the program on taxpayers and consumers, including the impact of the lack of lower cost generic drugs on lower income patients; and

''(4) any suggestions for modification that the Secretary deems appropriate.''.

SEC. 103. EXPEDITING STUDY AND APPROVAL OF FAST TRACK DRUGS.

(a) IN GENERAL.—Chapter VII is amended by adding at the end the following:

''SUBCHAPTER D—FAST TRACK PRODUCTS

''SEC. 741. FAST TRACK PRODUCTS.

''(a) DESIGNATION OF DRUG AS A FAST TRACK PRODUCT.—

''(1) IN GENERAL.—The Secretary shall facilitate the development and expedite the review of new drugs that are intended for the treatment of serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs for such conditions. In this section, such products shall be known as 'fast track products'.

''(2) REQUEST FOR DESIGNATION.—The sponsor of a drug may request the Secretary to designate the drug as a fast track product. A request for the designation may be made concurrently with, or at any time after, submission of an application for the investigation of the drug under section 505(i) or section 351(a)(3) of the Public Health Service Act.

''(3) DESIGNATION.—Within 30 calendar days after the receipt of a request under paragraph (2), the Secretary shall determine whether the drug that is the subject of the request meets the criteria described in paragraph (1). If the Secretary finds that the drug meets the criteria, the Secretary shall designate the drug as a fast track product and shall take such actions as are appropriate to expedite the development and review of the application for approval of such product.

''(b) APPROVAL OF APPLICATION FOR A FAST TRACK PRODUCT.—

''(1) IN GENERAL.—The Secretary may approve an application for approval of a fast track product under section 505(b) or section 351 of the Public Health Service Act (21 U.S.C. 262) upon a determination that the product has an effect on a clinical endpoint or on a surrogate endpoint that is reasonably likely to predict clinical benefit.

''(2) LIMITATION.—Approval of a fast track product under this subsection may be subject to the requirements—

''(A) that the sponsor conduct appropriate post-approval studies to validate the surrogate endpoint or otherwise confirm the effect on the clinical endpoint; and

''(B) that the sponsor submit copies of all promotional materials related to the fast track product during the preapproval review period and, following approval and for such period thereafter as the Secretary deems appropriate, at least 30 days prior to dissemination of the materials.

''(3) EXPEDITED WITHDRAWAL OF APPROVAL.—The Secretary may withdraw approval of a fast track product using expedited procedures (as prescribed by the Secretary in regulations which shall include an opportunity for an informal hearing), if—

''(A) the sponsor fails to conduct any required post-approval study of the fast track drug with due diligence;

''(B) a post-approval study of the fast track product fails to verify clinical benefit of the product;

''(C) other evidence demonstrates that the fast track product is not safe or effective under the conditions of use; or

''(D) the sponsor disseminates false or misleading promotional materials with respect to the product.

''(c) REVIEW OF INCOMPLETE APPLICATIONS FOR APPROVAL OF A FAST TRACK PRODUCT.—

''(1) IN GENERAL.—If the Secretary determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective the Secretary shall evaluate for filing, and may commence review of portions of, an application for the approval of the product before the sponsor submits a complete application. The Secretary shall commence such review only if the applicant (A) provides a schedule for submission of information necessary to make the application complete, and (B) pays any fee that may be required under section 736.

''(2) EXCEPTION.—Any time period for review of human drug applications that has been agreed to by the Secretary and that has been set forth in goals identified in letters of the Secretary (relating to the use of fees collected under section 736 to expedite the drug development process and the review of human drug applications) shall not apply to an application submitted under paragraph (1) until the date on which the application is complete.

''(d) AWARENESS EFFORTS.—The Secretary shall—

''(1) develop and disseminate to physicians, patient organizations, pharmaceutical and biotechnology companies, and other appropriate persons a description of the provisions applicable to fast track products established under this section; and

''(2) establish a program to encourage the development of surrogate endpoints that are reasonably likely to predict clinical benefit for serious or life-threatening conditions for which there exist significant unmet medical needs.''.

(b) GUIDANCE.—Within 1 year after the date of enactment of this Act, the Secretary shall issue guidance for fast track products (as defined in section 741(a)(1) of the Federal Food, Drug, and Cosmetic Act) that describes the policies and procedures that pertain to section 741 of such Act.

SEC. 104. EXPANDED ACCESS TO INVESTIGATIONAL THERAPIES.

Chapter V (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

''SUBCHAPTER D—UNAPPROVED THERAPIES AND DIAGNOSTICS

''SEC. 551. EXPANDED ACCESS TO UNAPPROVED THERAPIES AND DIAGNOSTICS.

''(a) EMERGENCY SITUATIONS.—The Secretary may, under appropriate conditions determined by the Secretary, authorize the shipment of investigational drugs (as defined in regulations prescribed by the Secretary) for the diagnosis or treatment of a serious disease or condition in emergency situations.

''(b) INDIVIDUAL PATIENT ACCESS TO INVESTIGATIONAL PRODUCTS INTENDED FOR SERIOUS DISEASES.—Any person, acting through a physician licensed in accordance with State law, may request from a manufacturer or distributor, and any manufacturer or distributor may provide to such physician after compliance with the provisions of this subsection, an investigational drug (as defined in regulations prescribed by the Secretary) for the diagnosis or treatment of a serious disease or condition if—

''(1) the licensed physician determines that the person has no comparable or satisfactory alternative therapy available to diagnose or treat the disease or condition involved, and that the risk to the person from the investigational drug is not greater than the risk from the disease or condition;

''(2) the Secretary determines that there is sufficient evidence of safety and effectiveness to support the use of the investigational drug in the case described in paragraph (1);

''(3) the Secretary determines that provision of the investigational drug will not interfere with the initiation, conduct, or completion of clinical investigations to support marketing approval; and

''(4) the sponsor, or clinical investigator, of the investigational drug submits to the Secretary a clinical protocol consistent with the provisions of section 505(i) and any regulations promulgated under section 505(i) describing the use of investigational drugs in a single patient or a small group of patients.

''(c) TREATMENT INDs.—Upon submission by a sponsor or a physician of a protocol intended to provide widespread access to an investigational drug for eligible patients, the Secretary shall permit such investigational drug to be made available for expanded access under a treatment investigational new drug application if the Secretary determines that—

''(1) under the treatment investigational new drug application, the investigational drug is intended for use in the diagnosis or treatment of a serious or immediately life-threatening disease or condition;

''(2) there is no comparable or satisfactory alternative therapy available to diagnose or treat that stage of disease or condition in the population of patients to which the investigational drug is intended to be administered;

''(3)(A) the investigational drug is under investigation in a controlled clinical trial for the use described in paragraph (1) under an effective investigational new drug application; or

''(B) all clinical trials necessary for approval of that use of the investigational drug have been completed;

''(4) the sponsor of the controlled clinical trials is actively pursuing marketing approval of the investigational drug for the use described in paragraph (1) with due diligence;

''(5) the provision of the investigational drug will not interfere with the enrollment of patients in ongoing clinical investigations under section 505(i);

''(6) in the case of serious diseases, there is sufficient evidence of safety and effectiveness to support the use described in paragraph (1); and

''(7) in the case of immediately life-threatening diseases, the available scientific evidence, taken as a whole, provides a reasonable basis to conclude that the product may be effective for its intended use and would not expose patients to an unreasonable and significant risk of illness or injury.

A protocol submitted under this subsection shall be subject to the provisions of section 505(i) and regulations promulgated under section 505(i). The Secretary may inform national, State, and local medical associations and societies, voluntary health associations, and other appropriate persons about the availability of an investigational drug under expanded access protocols submitted under this subsection. The information provided by the Secretary, in accordance with the preceding sentence, shall be of the same type of information that is required by section 402(j)(3) of the Public Health Service Act.

''(d) TERMINATION.—The Secretary may, at any time, with respect to a sponsor, physician, manufacturer, or distributor described in this section, terminate expanded access provided under this section for an investigational drug if the requirements under this section are no longer met.''.

SEC. 105. INFORMATION PROGRAM ON CLINICAL TRIALS FOR SERIOUS OR LIFE-THREATENING DISEASES.

(a) IN GENERAL.—Section 402 of the Public Health Service Act (42 U.S.C. 282) is amended—

(1) by redesignating subsections (j) and (k) as subsections (k) and (l), respectively; and

(2) by inserting after subsection (i), the following:

''(j)(1) The Secretary, acting through the Director of the National Institutes of Health, shall establish, maintain, and operate a program with respect to information on research relating to the treatment, detection, and prevention of serious or life-threatening diseases and conditions. The program shall, with respect to the agencies of the Department of Health and Human Services, be integrated and coordinated, and, to the extent practicable, coordinated with other data banks containing similar information.

''(2)(A) After consultation with the Commissioner of Food and Drugs, the directors of the appropriate agencies of the National Institutes of Health (including the National Library of Medicine), and the Director of the Centers for Disease Control and Prevention, the Secretary shall, in carrying out paragraph (1), establish a data bank of information on clinical trials for drugs for serious or life-threatening diseases and conditions.

''(B) In carrying out subparagraph (A), the Secretary shall collect, catalog, store, and disseminate the information described in such subparagraph. The Secretary shall disseminate such information through information systems, which shall include toll-free telephone communications, available to individuals with serious or life-threatening diseases and conditions, to other members of the public, to health care providers, and to researchers.

''(3) The data bank shall include the following:

''(A) A registry of clinical trials (whether federally or privately funded) of experimental treatments for serious or life-threatening diseases and conditions under regulations promulgated pursuant to sections 505 of the Federal Food, Drug, and Cosmetic Act that provides a description of the purpose of each experimental drug, either with the consent of the protocol sponsor, or when a trial to test effectiveness begins. Information provided shall consist of eligibility criteria, a description of the location of trial sites, and a point of contact for those wanting to enroll in the trial, and shall be in a form that can be readily understood by members of the public. Such information must be forwarded to the data bank by the sponsor of the trial not later than 21 days after trials to test clinical effectiveness have begun.

''(B) Information pertaining to experimental treatments for serious or life-threatening diseases and conditions that may be available—

''(i) under a treatment investigational new drug application that has been submitted to the Food and Drug Administration under section 551(c) of the Federal Food, Drug, and Cosmetic Act; or

''(ii) as a Group C cancer drug (as defined by the National Cancer Institute).

The data bank may also include information pertaining to the results of clinical trials of such treatments, with the consent of the sponsor, including information concerning potential toxicities or adverse effects associated with the use or administration of such experimental treatments.

''(4) The data bank shall not include information relating to an investigation if the sponsor has provided a detailed certification to the Secretary that disclosure of such information would substantially interfere with the timely enrollment of subjects in the investigation, unless the Secretary, after the receipt of the certification, provides the sponsor with a detailed written determination that such disclosure would not substantially interfere with such enrollment.

''(5) For the purpose of carrying out this subsection, there are authorized to be appropriated such sums as may be necessary. Fees collected under section 736 of the Federal Food, Drug, and Cosmetic Act shall not be used in carrying out this subsection.''.

(b) COLLABORATION AND REPORT.—

(1) IN GENERAL.—The Secretary of Health and Human Services, the Director of the National Institutes of Health, and the Commissioner of Food and Drugs shall collaborate to determine the feasibility of including device investigations within the scope of the registry requirements set forth in section 402(j) of the Public Health Service Act.

(2) REPORT.—Not later than 2 years after the date of enactment of this section, the Secretary of Health and Human Services shall prepare and submit to the Committee on Labor and Human Resources of the Senate and the Committee on Commerce of the House of Representatives a report—

(A) of the public health need, if any, for inclusion of device investigations within the scope of the registry requirements set forth in section 402(j) of the Public Health Service Act;

(B) on the adverse impact, if any, on device innovation and research in the United States if information relating to such device investigation is required to be publicly disclosed; and

(C) on such other issues relating to such section 402(j) as the Secretary may deem appropriate.

SEC. 106. DISSEMINATION OF INFORMATION ON NEW USES.

(a) IN GENERAL.—Chapter VII (2 U.S.C. 371 et seq.), as amended by section 103, is amended by adding at the end the following:

''SUBCHAPTER E—DISSEMINATION OF TREATMENT INFORMATION

''SEC. 745. REQUIREMENTS FOR DISSEMINATION OF TREATMENT INFORMATION ON DRUGS.

''(a) IN GENERAL.—Notwithstanding sections 301(d), 502(f), and 505 and section 351 of the Public Health Service Act (42 U.S.C. 262), a manufacturer may disseminate to—

''(1) a health care practitioner,

''(2) a pharmacy benefit manager,

''(3) a health insurance issuer,

''(4) a group health plan, or

''(5) a Federal or State governmental agency,

written information concerning the safety, effectiveness, or benefit of a use not described in the approved labeling of a drug if the manufacturer meets the requirements of subsection (b).

''(b) SPECIFIC REQUIREMENTS.—A manufacturer may disseminate information about a new use of a drug under subsection (a) only if—

''(1) there is in effect for such drug an application filed under section 505(b) or a biologics license issued under section 351 of the Public Health Service Act;

''(2) the information meets the requirements of section 746;

''(3) the information to be disseminated is not derived from clinical research conducted by another manufacturer or if it was derived from research conducted by another manufacturer, the manufacturer disseminating the information has the permission of such other manufacturer to make the dissemination;

''(4) the manufacturer has, 60 days before such dissemination, submitted to the Secretary—

''(A) a copy of the information to be disseminated; and

''(B) any clinical trial information the manufacturer has relating to the safety or effectiveness of the new use, any reports of clinical experience pertinent to the safety of the new use, and a summary of such information;

''(5) the manufacturer has complied with the requirements of section 748 (relating to certification that the manufacturer will submit a supplemental application with respect to such use);

''(6) the manufacturer includes along with the information to be disseminated under this subsection—

''(A) a prominently displayed statement that discloses—

''(i) that the information concerns a use of a drug that has not been approved by the Food and Drug Administration;

''(ii) if applicable, that the information is being disseminated at the expense of the manufacturer;

''(iii) if applicable, the name of any authors of the information who are employees of, consultants to, or have received compensation from, the manufacturer, or who have a significant financial interest in the manufacturer;

''(iv) the official labeling for the drug and all updates with respect to the labeling;

''(v) if applicable, a statement that there are products or treatments that have been approved for the use that is the subject of the information being disseminated pursuant to subsection (a)(1); and

''(vi) the identification of any person that has provided funding for the conduct of a study relating to the new use of a drug for which such information is being disseminated; and

''(B) a bibliography of other articles from a scientific reference publication or scientific or medical journal that have been previously published about the use of the drug covered by the information disseminated (unless the information already includes such bibliography).

''(c) ADDITIONAL INFORMATION.—If the Secretary determines, after providing notice of such determination and an opportunity for a meeting with respect to such determination, that the information submitted by a manufacturer under subsection (b)(3)(B), with respect to the use of a drug for which the manufacturer intends to disseminate information, fails to provide data, analyses, or other written matter that is objective and balanced, the Secretary may require the manufacturer to disseminate—

''(1) additional objective and scientifically sound information that pertains to the safety or effectiveness of the use and is necessary to provide objectivity and balance, including any information that the manufacturer has submitted to the Secretary or, where appropriate, a summary of such information or any other information that the Secretary has authority to make available to the public; and

''(2) an objective statement of the Secretary, based on data or other scientifically sound information available to the Secretary, that bears on the safety or effectiveness of the new use of the drug.

''SEC. 746. INFORMATION AUTHORIZED TO BE DISSEMINATED.

''(a) AUTHORIZED INFORMATION.—A manufacturer may disseminate the information on the new use of a drug under section 745 only if the information—

''(1) is in the form of an unabridged—

''(A) reprint or copy of an article, peer-reviewed by experts qualified by scientific training or experience to evaluate the safety or effectiveness of the drug, which was published in a scientific or medical journal (as defined in section 750(6)), which is about a clinical investigation with respect to the drug, and which would be considered to be scientifically sound by such experts; or

''(B) reference publication, described in subsection (b), that includes information about a clinical investigation with respect to the drug that would be considered to be scientifically sound by experts qualified by scientific training or experience to evaluate the safety or effectiveness of the drug that is the subject of such a clinical investigation; and

''(2) is not false or misleading and would not pose a significant risk to the public health.

''(b) REFERENCE PUBLICATION.—A reference publication referred to in subsection (a)(1)(B) is a publication that—

''(1) has not been written, edited, excerpted, or published specifically for, or at the request of, a manufacturer of a drug;

''(2) has not been edited or significantly influenced by a such a manufacturer;

''(3) is not solely distributed through such a manufacturer but is generally available in bookstores or other distribution channels where medical textbooks are sold;

''(4) does not focus on any particular drug of a manufacturer that disseminates information under section 745 and does not have a primary focus on new uses of drugs that are marketed or under investigation by a manufacturer supporting the dissemination of information; and

''(5) presents materials that are not false or misleading.

''SEC. 747. ESTABLISHMENT OF LIST OF ARTICLES AND PUBLICATIONS DISSEMINATED AND LIST OF PROVIDERS THAT RECEIVED ARTICLES AND REFERENCE PUBLICATIONS.

''(a) IN GENERAL.—A manufacturer may disseminate information under section 745 only if the manufacturer prepares and submits to the Secretary biannually—

''(1) a list containing the titles of the articles and reference publications relating to the new use of drugs that were disseminated by the manufacturer to a person described in section 745(a) for the 6-month period preceding the date on which the manufacturer submits the list to the Secretary; and

''(2) a list that identifies the categories of providers (as described in section 745(a)) that received the articles and reference publications for the 6-month period described in paragraph (1).

''(b) RECORDS.—A manufacturer that disseminates information under section 745 shall keep records that may be used by the manufacturer when, pursuant to section 749, such manufacturer is required to take corrective action and shall be made available to the Secretary, upon request, for purposes of ensuring or taking corrective action pursuant to such section. Such records, at the Secretary's discretion, may identify the recipient of information provided pursuant to section 745 or the categories of such recipients.

''SEC. 748. REQUIREMENT REGARDING SUBMISSION OF SUPPLEMENTAL APPLICATION FOR NEW USE; EXEMPTION FROM REQUIREMENT.

''(a) IN GENERAL.—A manufacturer may disseminate information under section 745 on a new use only if—

''(1) the manufacturer meets the condition described in subsection (b) or in subsection (c); or

''(2) there is in effect for the manufacturer an exemption under subsection (d) from the requirement of paragraph (1).

''(b) SUPPLEMENTAL APPLICATION; CONDITION IN CASE OF COMPLETED STUDIES.—For purposes of subsection (a)(1), a manufacturer may disseminate information on a new use if the manufacturer has submitted to the Secretary an application containing a certification that—

''(1) the studies needed for the submission of a supplemental application for the new use have been completed; and

''(2) the supplemental application will be submitted to the Secretary not later than 6 months after the date of the initial dissemination of information under section 745.

''(c) SUPPLEMENTAL APPLICATION; CONDITION IN CASE OF PLANNED STUDIES.—

''(1) IN GENERAL.—For purposes of subsection (a)(1), a manufacturer may disseminate information on a new use if—

''(A) the manufacturer has submitted to the Secretary an application containing—

''(i) a proposed protocol and schedule for conducting the studies needed for the submission of a supplemental application for the new use; and

''(ii) a certification that the supplemental application will be submitted to the Secretary not later than 36 months after the date of the initial dissemination of information under section 745 (or, as applicable, not later than such date as the Secretary may specify pursuant to an extension under this paragraph or paragraph (3)); and

''(B) the Secretary has determined that the proposed protocol is adequate and that the schedule for completing such studies is reasonable.

The Secretary may grant a longer period of time for a manufacturer to submit a supplemental application if the Secretary determines that the studies needed to submit such an application cannot be completed and submitted within 36 months.

''(2) PROGRESS REPORTS ON STUDIES.—A manufacturer that submits to the Secretary an application under paragraph (1) shall submit to the Secretary periodic reports describing the status of the studies involved.

''(3) EXTENSION OF TIME REGARDING PLANNED STUDIES.—The period of 36 months authorized in paragraph (1)(A)(ii) for the completion of studies may be extended by the Secretary if the manufacturer involved submits to the Secretary a written request for the extension and the Secretary determines that the manufacturer has acted with due diligence to conduct the studies in a timely manner. Such extension may not provide more than 24 additional months.

''(d) EXEMPTION FROM REQUIREMENT OF SUPPLEMENTAL APPLICATION.—

''(1) IN GENERAL.—For purposes of subsection (a)(2), a manufacturer may disseminate information on a new use if—

''(A) the manufacturer has submitted to the Secretary an application for an exemption from meeting the requirement of subsection (a)(1); and

''(B)(i) the Secretary has approved the application in accordance with paragraph (2); or

''(ii) the application is deemed under paragraph (3)(A) to have been approved (unless such approval is terminated pursuant to paragraph (3)(B)).

''(2) CONDITIONS FOR APPROVAL.—The Secretary may approve an application under paragraph (1) for an exemption only if the Secretary determines that—

''(A) it would be economically prohibitive with respect to such drug for the manufacturer to incur the costs necessary for the submission of a supplemental application for reasons, as defined by the Secretary, such as the lack of availability under law of any period during which the manufacturer would have exclusive marketing rights with respect to the new use involved or that the population expected to benefit from approval of the supplemental application is small; or

''(B) it would be unethical to conduct the studies necessary for the supplemental application for a reason such as the new use involved is the standard of medical care for a health condition.

''(3) TIME FOR CONSIDERATION OF APPLICATION; DEEMED APPROVAL.—

''(A) IN GENERAL.—The Secretary shall approve or deny an application under paragraph (1) for an exemption not later than 60 days after the receipt of the application. If the Secretary does not comply with the preceding sentence, the application is deemed to be approved.

''(B) TERMINATION OF DEEMED APPROVAL.—If pursuant to a deemed approval under subparagraph (A) a manufacturer disseminates written information under section 745 on a new use, the Secretary may at any time terminate such approval and under section 749(b)(3) order the manufacturer to cease disseminating the information.

''(e) REQUIREMENTS REGARDING APPLICATIONS.—Applications under this section shall be submitted in the form and manner prescribed by the Secretary.

''(f) TRANSITION RULE.—For purposes of this section, in any case in which a manufacturer has submitted to the Secretary a supplemental application for which action by the Secretary is pending as of the date of the enactment of the Food and Drug Administration Regulatory Modernization Act of 1997, the application is deemed to be a supplemental application submitted under subsection (b).

''SEC. 749. CORRECTIVE ACTIONS; CESSATION OF DISSEMINATION.

''(a) POSTDISSEMINATION DATA REGARDING SAFETY AND EFFECTIVENESS.—

''(1) CORRECTIVE ACTIONS.—With respect to data received by the Secretary after the dissemination of information under section 745 by a manufacturer has begun (whether received pursuant to paragraph (2) or otherwise), if the Secretary determines that the data indicate that the new use involved may not be effective or may present a significant risk to public health, the Secretary shall, after consultation with the manufacturer, take such action regarding the dissemination of the information as the Secretary determines to be appropriate for the protection of the public health, which may include ordering that the manufacturer cease the dissemination of the information.

''(2) RESPONSIBILITIES OF MANUFACTURERS TO SUBMIT DATA.—After a manufacturer disseminates information pursuant to section 745, the manufacturer shall submit to the Secretary a notification of any additional knowledge of the manufacturer on clinical research or other data that relate to the safety or effectiveness of the new use involved. If the manufacturer is in possession of the data, the notification shall include the data. The Secretary shall by regulation establish the scope of the responsibilities of manufacturers under this paragraph, including such limits on the responsibilities as the Secretary determines to be appropriate.

''(b) CESSATION OF DISSEMINATION.—

''(1) FAILURE OF MANUFACTURER TO COMPLY WITH REQUIREMENTS.—The Secretary may order a manufacturer to cease the dissemination of information pursuant to section 745 if the Secretary determines that the information being disseminated does not comply with the requirements established in this subchapter. Such an order may be issued only after the Secretary has provided notice to the manufacturer of the intent of the Secretary to issue the order and has provided an opportunity for a meeting with respect to such intent unless paragraph (2)(B) applies. If the failure of the manufacturer constitutes a minor violation of this subchapter, the Secretary shall delay issuing the order and provide to the manufacturer an opportunity to correct the violation.

''(2) SUPPLEMENTAL APPLICATIONS.—The Secretary may order a manufacturer to cease the dissemination of information pursuant to section 745 if the Secretary determines that—

''(A) in the case of a manufacturer to which section 748(b) applies, the Secretary determines that the supplemental application received under such section does not contain adequate information for approval of the new use with respect to which the application was submitted; or

''(B) in the case of a manufacturer to which section 748(c) applies, the Secretary determines, after an informal hearing, that the manufacturer is not acting with due diligence to complete the studies involved.

''(3) TERMINATION OF DEEMED APPROVAL OF EXEMPTION REGARDING SUPPLEMENTAL APPLICATIONS.—If under section 748(d)(3) the Secretary terminates a deemed approval of an exemption, the Secretary may order the manufacturer involved to cease disseminating the information. A manufacturer shall comply with an order under the preceding sentence not later than 60 days after the receipt of the order.

''(c) CORRECTIVE ACTIONS BY MANUFACTURERS.—

''(1) IN GENERAL.—In any case in which under this section the Secretary orders a manufacturer to cease disseminating information, the Secretary may order the manufacturer to take action to correct the information that has been disseminated, except as provided in paragraph (2).

''(2) TERMINATION OF DEEMED APPROVAL OF EXEMPTION REGARDING SUPPLEMENTAL APPLICATIONS.—In the case of an order under subsection (b)(3) to cease disseminating information, the Secretary may not order the manufacturer involved to take action to correct the information that has been disseminated unless the Secretary determines that the new use described in the information would pose a significant risk to the public health.

''SEC. 750. DEFINITIONS.

''For purposes of this subchapter:

''(1) The term 'health care practitioner' means a physician, or other individual who is a provider of health care, who is licensed under the law of a State to prescribe drugs.

''(2) The terms 'health insurance issuer' and 'group health plan' have the meaning given such terms under section 2791 of the Public Health Service Act.

''(3) The term 'manufacturer' means a person who manufactures a drug, or who is licensed by such person to distribute or market the drug.

''(4) The term 'new use', with respect to a drug, means a use that is not included in the approved labeling of the drug.

''(5) The term 'pharmacy benefit manager' means an organization that—

''(A) manages pharmaceutical costs through—

''(i) pharmacy benefit administration, including claims processing adjudication, pharmacy networks, mail service, and data reporting;

''(ii) formulary management and contracting, including evaluating drugs for formulary status, negotiations of contracts with manufacturers, and disbursement of rebates; and

''(iii) utilization management, including communicating and enforcing therapy guidelines and drug use principles to physicians, pharmacists, and patients; and

''(B) serves 2 principal types of customers which are—

''(i) employers, both private- and public-sector, who use either self-funded health benefits through a third party administrator's insurance carrier or use traditional indemnity coverage, using providers from a preferred provider network or in a fee-for-service capacity; and

''(ii) health maintenance organizations.

''(6) The term 'scientific or medical journal' means a scientific or medical publication—

''(A) that is published by an organization—

''(i) that has an editorial board;

''(ii) that utilizes experts, who have demonstrated expertise in the subject of an article under review by the organization and who are independent of the organization, to review and objectively select, reject, or provide comments about proposed articles; and

''(iii) that has a publicly stated policy, to which the organization adheres, of full disclosure of any conflict of interest or biases for all authors or contributors involved with the journal or organization;

''(B) whose articles are peer-reviewed and published in accordance with the regular peer-review procedures of the organization;

''(C) that is generally recognized to be of national scope and reputation;

''(D) that is indexed in the Index Medicus of the National Library of Medicine of the National Institutes of Health; and

''(E) that is not in the form of a special supplement that has been funded in whole or in part by 1 or more manufacturers.

''SEC. 751. RULES OF CONSTRUCTION.

''(a) UNSOLICITED REQUEST.—Nothing in section 745 shall be construed as prohibiting a manufacturer from disseminating information in response to an unsolicited request from a health care practitioner.

''(b) DISSEMINATION OF INFORMATION ON DRUGS NOT EVIDENCE OF INTENDED USE.—Notwithstanding subsection (a), (f), or (o) of section 502, or any other provision of law, the dissemination of information relating to a new use of a drug, in accordance with section 745, shall not be construed by the Secretary as evidence of a new intended use of the drug that is different from the intended use of the drug set forth in the official labeling of the drug. Such dissemination shall not be considered by the Secretary as labeling, adulteration, or misbranding of the drug.

''(c) PATENT PROTECTION.—Nothing in section 745 shall affect patent rights in any manner.

''(d) AUTHORIZATION FOR DISSEMINATION OF ARTICLES AND FEES FOR REPRINTS OF ARTICLES.—Nothing in section 745 shall be construed as prohibiting an entity that publishes a scientific journal (as defined in section 750(6)) from requiring authorization from the entity to disseminate an article published by such entity or charging fees for the purchase of reprints of published articles from such entity.''.

(b) PROHIBITED ACT.—Section 301 (21 U.S.C. 331) is amended by adding at the end the following:

''(x) The dissemination of information in violation of section 745.''.

(c) REGULATIONS.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall promulgate regulations to implement the amendments made by this section.

(d) EFFECTIVE DATE.—The amendments made by this section shall take effect 1 year after the date of enactment of this Act, or upon the Secretary's issuance of final regulations pursuant to subsection (c), whichever is sooner.

(e) SUNSET.—The amendments made by this section cease to be effective September 30, 2006, or 7 years after the date on which the Secretary promulgates the regulations described in subsection (c), whichever is later.

SEC. 107. STUDIES AND REPORTS.

(a) IN GENERAL.—The Comptroller General of the United States shall conduct a study—

(1) to determine the impact of the amendments made by section 7 on the resources of the Department of Health and Human Services; and

(2) of the scientific issues raised as a result of the amendments made by section 7, including issues relating to—

(A) the effectiveness of such amendments with respect to the provision of useful scientific information to health care practitioners;

(B) the quality of the information being disseminated pursuant to such amendments;

(C) the quality and usefulness of the information provided, in accordance with such amendments, by the Secretary or by a manufacturer at the request of the Secretary; and

(D) the impact of such amendments on research in the area of new uses of drugs, indications for new uses, or dosages of drugs for new uses, particularly the impact on pediatric indications and rare diseases.

(b) REPORT.—Not later than January 1, 2002, the Comptroller General of the United States shall prepare and submit to the Committee on Labor and Human Resources of the Senate and the Committee on Commerce of the House of Representatives a report of the results of the study under subsection (a).

SEC. 108. APPROVAL OF SUPPLEMENTAL APPLICATIONS FOR APPROVED PRODUCTS.

(a) PERFORMANCE STANDARDS.—Not later than 180 days after the date of enactment of this Act, the Secretary shall publish in the Federal Register performance standards for the prompt review of supplemental applications submitted for approved drugs under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.) or section 351 of the Public Health Service Act (42 U.S.C. 262).

(b) GUIDANCE TO INDUSTRY.—Not later than 180 days after the date of enactment of this Act, the Secretary shall issue final guidances to clarify the requirements for, and facilitate the submission of data to support, the approval of supplemental applications for the approved articles described in subsection (a). The guidances shall—

(1) clarify circumstances in which published matter may be the basis for approval of a supplemental application;

(2) specify data requirements that will avoid duplication of previously submitted data by recognizing the availability of data previously submitted in support of an original application; and

(3) define supplemental applications that are eligible for priority review.

(c) RESPONSIBILITIES OF CENTERS.—The Secretary shall designate an individual in each center within the Food and Drug Administration which is responsible for the review of applications for approval of drugs for—

(1) encouraging the prompt review of supplemental applications for approved articles; and

(2) working with sponsors to facilitate the development and submission of data to support supplemental applications.

(d) COLLABORATION.—The Secretary shall implement programs and policies that will foster collaboration between the Food and Drug Administration, the National Institutes of Health, professional medical and scientific societies, and other persons, to identify published and unpublished studies that may support a supplemental application, and to encourage sponsors to make supplemental applications or conduct further research in support of a supplemental application based, in whole or in part, on such studies.

SEC. 109. HEALTH CARE ECONOMIC INFORMATION.

Section 502(a) (21 U.S.C. 352(a)) is amended by adding at the end the following: ''Health care economic information provided to a formulary committee, or other similar entity, in the course of the committee or the entity carrying out its responsibilities for the selection of drugs for managed care or other similar organizations, shall not be considered to be false or misleading if the health care economic information directly relates to an indication approved under section 505 or 507 or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) for such drug and is based on competent and reliable scientific evidence. The requirements set forth in section 505(a), 507, or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) shall not apply to health care economic information provided to such a committee or entity in accordance with this paragraph. Information that is relevant to the substantiation of the health care economic information presented pursuant to this paragraph shall be made available to the Secretary upon request. In this paragraph, the term 'health care economic information' means any analysis that identifies, measures, or compares the economic consequences, including the costs of the represented health outcomes, of the use of a drug to the use of another drug, to another health care intervention, or to no intervention.''.

SEC. 110. CLINICAL INVESTIGATIONS.

(a) CLARIFICATION OF THE NUMBER OF REQUIRED CLINICAL INVESTIGATIONS FOR APPROVAL.—Section 505(d) (21 U.S.C. 355(d)) is amended by adding at the end the following: ''If the Secretary determines, based on relevant science, that data from one adequate and well-controlled clinical investigation and confirmatory evidence (obtained prior to or after such investigation) are sufficient to establish effectiveness, the Secretary may consider such data and evidence to constitute substantial evidence for purposes of the preceding sentence.''.

(b) WOMEN AND MINORITIES.—Section 505(b)(1) (21 U.S.C. 355(b)(1)) is amended by adding at the end the following: ''The Secretary shall, in consultation with the Director of the National Institutes of Health, review and develop guidance, as appropriate, on the inclusion of women and minorities in clinical trials required by clause (A).''.

SEC. 111. MANUFACTURING CHANGES FOR DRUGS.

(a) IN GENERAL.—Chapter VII (21 U.S.C. 371 et seq.), as amended by section 106, is amended by adding at the end the following subchapter:

''SUBCHAPTER F—MANUFACTURING CHANGES

''SEC. 755. MANUFACTURING CHANGES.

''(a) IN GENERAL.—With respect to a drug for which there is in effect an approved application under section 505 or 512 or a license under section 351 of the Public Health Service Act, a change from the manufacturing process approved pursuant to such application or license may be made, and the drug as made with the change may be distributed, if—

''(1) the holder of the approved application or license (referred to in this section as a 'holder') has validated the effects of the change in accordance with subsection (b); and

''(2)(A) in the case of a major manufacturing change, the holder has complied with the requirements of subsection (c); or

''(B) in the case of a change that is not a major manufacturing change, the holder complies with the applicable requirements of subsection (d).

''(b) VALIDATION OF EFFECTS OF CHANGES.—For purposes of subsection (a)(1), a drug made with a manufacturing change (whether a major manufacturing change or otherwise) may be distributed only if, before distribution of the drug as so made, the holder involved validates the effects of the change on the identity, strength, quality, purity, and potency of the drug as the identity, strength, quality, purity, and potency may relate to the safety, bioequivalence, bioavailability, or effectiveness of the drug.

''(c) MAJOR MANUFACTURING CHANGES.—

''(1) REQUIREMENT OF SUPPLEMENTAL APPLICATION.—For purposes of subsection (a)(2)(A), a drug made with a major manufacturing change may be distributed only if, before the distribution of the drug as so made, the holder involved submits to the Secretary a supplemental application for such change and the Secretary approves the application. The application shall contain such information as the Secretary determines to be appropriate, and shall include the information developed under subsection (b) by the holder in validating the effects of the change.

''(2) CHANGES QUALIFYING AS MAJOR CHANGES.—For purposes of subsection (a)(2)(A), a major manufacturing change is a manufacturing change that—

''(A) is determined by the Secretary to have substantial potential to adversely affect the identity, strength, quality, purity, or potency of the drug as they may relate to the safety, bioequivalence, bioavailability, or effectiveness of a drug; and

''(B)(i) is made in the qualitative or quantitative formulation of the drug involved or in the specifications in the approved application or license referred to in subsection (a) for the drug (unless exempted by the Secretary from the requirements of this subsection);

''(ii) is determined by the Secretary by regulation or guidance to require completion of an appropriate clinical study demonstrating equivalence of the drug to the drug as manufactured without the change; or

''(iii) is determined by the Secretary by regulation or guidance to have a substantial potential to adversely affect the safety or effectiveness of the drug.

''(d) OTHER MANUFACTURING CHANGES.—

''(1) IN GENERAL.—For purposes of subsection (a)(2)(B), the Secretary may regulate drugs made with manufacturing changes that are not major manufacturing changes as follows:

''(A) The Secretary may authorize holders to distribute such drugs without prior approval by the Secretary.

''(B) The Secretary may require that, prior to the distribution of such drugs, holders submit to the Secretary supplemental applications for such changes.

''(C) The Secretary may establish categories of such changes and designate categories to which subparagraph (A) applies and categories to which subparagraph (B) applies.

''(2) CHANGES NOT REQUIRING SUPPLEMENTAL APPLICATION.—

''(A) SUBMISSION OF REPORT.—A holder making a manufacturing change to which paragraph (1)(A) applies shall submit to the Secretary a report on the change, which shall contain such information as the Secretary determines to be appropriate, and which shall include the information developed under subsection (b) by the holder in validating the effects of the change. The report shall be submitted by such date as the Secretary may specify.

''(B) AUTHORITY REGARDING ANNUAL REPORTS.—In the case of a holder that during a single year makes more than one manufacturing change to which paragraph (1)(A) applies, the Secretary may in carrying out subparagraph (A) authorize the holder to comply with such subparagraph by submitting a

single report for the year that provides the information required in such subparagraph for all the changes made by the holder during the year.

''(3) CHANGES REQUIRING SUPPLEMENTAL APPLICATION.—

''(A) SUBMISSION OF SUPPLEMENTAL APPLICATION.—The supplemental application required under paragraph (1)(B) for a manufacturing change shall contain such information as the Secretary determines to be appropriate, which shall include the information developed under subsection (b) by the holder in validating the effects of the change.

''(B) AUTHORITY FOR DISTRIBUTION.—In the case of a manufacturing change to which paragraph (1)(B) applies:

''(i) The holder involved may commence distribution of the drug involved 30 days after the Secretary receives the supplemental application under such paragraph, unless the Secretary notifies the holder within such 30-day period that prior approval of the application is required before distribution may be commenced.

''(ii) The Secretary may designate a category of such changes for the purpose of providing that, in the case of a change that is in such category, the holder involved may commence distribution of the drug involved upon the receipt by the Secretary of a supplemental application for the change.

''(iii) If the Secretary disapproves the supplemental application, the Secretary may order the manufacturer to cease the distribution of the drugs that have been made with the manufacturing change.''.

(b) TRANSITION RULE.—The amendment made by subsection (a) takes effect upon the effective date of regulations promulgated by the Secretary of Health and Human Services to implement such amendment, or upon the expiration of the 24-month period beginning on the date of the enactment of this Act, whichever occurs first.

SEC. 112. STREAMLINING CLINICAL RESEARCH ON DRUGS.

Section 505(i) (21 U.S.C. 355(i)) is amended by adding ''(1)'' before ''The Secretary'', by redesignating paragraphs (1), (2), and (3) as subparagraphs (A), (B), and (C), respectively, by striking the last two sentences, and by adding the following new paragraphs:

''(2) Subject to paragraph (3), a clinical investigation of a new drug may begin 30 days after the Secretary has received from the manufacturer or sponsor of the investigation a submission containing such information about the drug and the clinical investigation, including —

''(A) information on design of the investigation and adequate reports of basic information, certified by the applicant to be accurate reports, necessary to assess the safety of the drug for use in clinical investigation; and

''(B) adequate information on the chemistry and manufacturing of the drug, controls available for the drug, and primary data tabulations from animal or human studies.

''(3)(A) At any time, the Secretary may prohibit the sponsor of an investigation from conducting the investigation (referred to in this paragraph as a 'clinical hold') if the Secretary makes a determination described in subparagraph (B). The Secretary shall specify the basis for the clinical hold, including the specific information available to the Secretary which served as the basis for such clinical hold, and confirm such determination in writing.

''(B) For purposes of subparagraph (A), a determination described in this subparagraph with respect to a clinical hold is that—

''(i) the drug involved represents an unreasonable risk to the safety of the persons who are the subject of the clinical investigation, taking into account the qualifications of the clinical investigators, information about the drug, the design of the clinical investigation, the condition for which the drug is to be investigated, and the health status of the subjects involved; or

''(ii) the clinical hold should be issued for such other reasons as the Secretary may by regulation establish (including reasons established by regulation before the date of the enactment of the Food and Drug Administration Regulatory Modernization Act of 1997).

Such regulations shall provide that such exemption shall be conditioned upon the manufacturer, or the sponsor of the investigation, requiring that experts using such drugs for investigational purposes certify to such manufacturer or sponsor that they will inform any human beings to whom such drugs, or any controls used in connection therewith, are being administered, or their representatives, that such drugs are being used for investigational purposes and will obtain the consent of such human beings or their representatives, except where they deem it not feasible or, in their professional judgment, contrary to the best interests of such human beings. Nothing in this subsection shall be construed to require any clinical investigator to submit directly to the Secretary reports on the investigational use of drugs.

''(C) Any request to the Secretary from the sponsor of an investigation that a clinical hold be removed shall receive a decision, in writing and specifying the reasons therefor, within 30 days after receipt of such request. Any such request shall include sufficient information to support the removal of such clinical hold.''.

SEC. 113. DATA REQUIREMENTS FOR DRUGS.

Within 12 months after the date of enactment of this Act, the Secretary of the Health and Human Services, acting through the Commissioner of Food and Drugs, shall issue guidance that describes, for certain types of studies, when abbreviated study reports may be submitted, in lieu of full reports, with a new drug application under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) and with a biologics license application under section 351 of the Public Health Service Act (42 U.S.C. 262). Such guidance shall describe the kinds of studies for which abbreviated reports are appropriate and the appropriate abbreviated report formats.

SEC. 114. CONTENT AND REVIEW OF APPLICATIONS.

(a) SECTION 505(b).—Section 505(b) (21 U.S.C. 355(b)) is amended by adding at the end the following:

''(4)(A) The Secretary shall issue guidance for the review of applications submitted under paragraph (1) relating to promptness, technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards which shall apply equally to all individuals who review such applications.

''(B) The Secretary shall meet with a sponsor of an investigation or an applicant for approval under this section or section 351 of the Public Health Service Act if the sponsor or applicant makes a reasonable request for a meeting, for the purpose of reaching agreement on the design and size of clinical trials. Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant upon request.

''(C) Agreement regarding the parameters of the design and size of clinical trials of a new drug that are reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Such agreement shall not be changed after the testing begins, except—

''(i) with the written agreement of the sponsor or applicant; or

''(ii) pursuant to a decision, made in accordance with subparagraph (D) by the director of the division in which the drug is reviewed, that a substantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the testing has begun.

''(D) A decision under subparagraph (C)(ii) by the director shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant will be present and at which the director documents the scientific issue involved.

''(E) The written decisions of the reviewing division shall be binding upon, and may not directly or indirectly be changed by, the field or compliance division personnel unless such field or compliance division personnel demonstrate to the reviewing division why such decision should be modified. For purposes of this paragraph, the reviewing division is the division responsible for the review of an application for approval of a drug (including all scientific and medical matters, chemistry, manufacturing, and controls).

''(F) No action by the reviewing division may be delayed because of the unavailability of information from or action by field personnel unless the reviewing division determines that a delay is necessary to assure the marketing of a safe and effective drug.''.

(b) SECTION 505(j).—

(1) AMENDMENT.—Section 505(j) (21 U.S.C 355(j)) is amended by redesignating paragraphs (3) through (8) as paragraphs (4) through (9), respectively, and by adding after paragraph (2) the following:

''(3)(A) The Secretary shall issue guidance for the review of applications submitted under paragraph (1) relating to promptness, technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards which shall apply equally to all individuals who review such applications.

''(B) The Secretary shall meet with an applicant for approval of a drug under this subsection if the applicant makes a reasonable request for a meeting for the purpose of reaching agreement on the design and size of studies needed for approval of such application. Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant.

''(C) Agreements regarding the parameters of design and size of bioavailability and bioequivalence trials of a drug under this subsection that are reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Such agreement shall not be changed after the testing begins, except—

''(i) with the written agreement of the sponsor or applicant; or

''(ii) pursuant to a decision, made in accordance with subparagraph (D) by the director of the division in which the drug is reviewed, that a substantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the testing has begun.

''(D) A decision under subparagraph (C)(ii) by the director shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant will be present and at which the director documents the scientific issue involved.

''(E) The written decisions of the reviewing division shall be binding upon, and may not directly or indirectly be changed by, the field or compliance office personnel unless such field or compliance office personnel demonstrate to the reviewing division why

such decision should be modified. For purposes of this paragraph, the reviewing division is the division responsible for the review of an application under this subsection (including scientific matters, chemistry, manufacturing, and controls).

''(F) No action by the reviewing division may at any time be delayed because of the unavailability of information from or action by field personnel unless the reviewing division determines that a delay is necessary to assure the marketing of a safe and effective drug.''.

(2) CONFORMING AMENDMENTS.—Section 505(j) (21 U.S.C. 355(j)), as amended by paragraph (1), is amended—

(A) in paragraph (2)(A)(i), by striking ''(6)'' and inserting ''(7)'';

(B) in paragraph (4), by striking ''(4)'' and inserting ''(5)'';

(C) in paragraph (4)(I), by striking ''(5)'' and inserting ''(6)''; and

(D) in paragraph (7)(C), by striking ''(5)'' each place it occurs and inserting ''(6)''.

SEC. 115. SCIENTIFIC ADVISORY PANELS.

Section 505 (21 U.S.C. 355) is amended by adding at the end the following:

''(n)(1) For the purpose of providing expert scientific advice and recommendations to the Secretary regarding a clinical investigation of a drug or the approval for marketing of a drug under section 505 or section 351 of the Public Health Service Act, the Secretary shall establish panels of experts or use panels of experts established before the date of the enactment of this subsection, or both.

''(2) The Secretary may delegate the appointment and oversight authority granted under section 904 to a director of a center or successor entity within the Food and Drug Administration.

''(3) The Secretary shall make appointments to each panel established under paragraph (1) so that each panel shall consist of—

''(A) members who are qualified by training and experience to evaluate the safety and effectiveness of the drugs to be referred to the panel and who, to the extent feasible, possess skill and experience in the development, manufacture, or utilization of such drugs;

''(B) members with diverse expertise in such fields as clinical and administrative medicine, pharmacy, pharmacology, pharmacoeconomics, biological and physical sciences, and other related professions;

''(C) a representative of consumer interests and a representative of interests of the drug manufacturing industry not directly affected by the matter to be brought before the panel; and

''(D) 2 or more members who are specialists or have other expertise in the particular disease or condition for which the drug under review is proposed to be indicated.

Scientific, trade, and consumer organizations shall be afforded an opportunity to nominate individuals for appointment to the panels. No individual who is in the regular full-time employ of the United States and engaged in the administration of this Act may be a voting member of any panel. The Secretary shall designate one of the members of each panel to serve as chairman thereof.

''(4) Each member of a panel shall publicly disclose all conflicts of interest that member may have with the work to be undertaken by the panel. No member of a panel may vote on any matter where the member or the immediate family of such member could gain financially from the advice given to the Secretary. The Secretary may grant a waiver of any conflict of interest upon public disclosure of such conflict of interest if such waiver is necessary to afford the panel essential expertise, except that the Secretary may not grant a waiver for a member of a panel when the member's own scientific work is involved.

''(5) The Secretary shall provide education and training to each new panel member before such member participates in a panel's activities, including education regarding requirements under this Act and related regulations of the Secretary, and the administrative processes and procedures related to panel meetings.

''(6) Panel members (other than officers or employees of the United States), while attending meetings or conferences of a panel or otherwise engaged in its business, shall be entitled to receive compensation for each day so engaged, including traveltime, at rates to be fixed by the Secretary, but not to exceed the daily equivalent of the rate in effect for positions classified above grade GS–15 of the General Schedule. While serving away from their homes or regular places of business, panel members may be allowed travel expenses (including per diem in lieu of subsistence) as authorized by section 5703 of title 5, United States Code, for persons in the Government service employed intermittently.

''(7) The Secretary shall ensure that scientific advisory panels meet regularly and at appropriate intervals so that any matter to be reviewed by such panel can be presented to the panel not more than 60 days after the matter is ready for such review. Meetings of the panel may be held using electronic communication to convene the meeting.

''(8) Within 60 days after a scientific advisory panel makes recommendations on any matter under its review, the Food and Drug Administration official responsible for the matter shall review the conclusions and recommendations of the panel, and notify the affected persons of the final decision on the matter, or of the reasons that no such decision has been reached. Each such final decision shall be documented including the rationale for the decision.

''(9) A scientific advisory panel under this subsection shall not be subject to the annual chartering and annual report requirements of the Federal Advisory Committee Act.''.

SEC. 116. DISPUTE RESOLUTION.

Chapter V (21 U.S.C. 351 et seq.), as amended by section 102, is amended by inserting after section 505A the following:

''DISPUTE RESOLUTION

''SEC. 506. If, regarding an obligation under this Act, there is a scientific controversy between the Secretary and a person who is a sponsor, applicant, or manufacturer and no specific provision of this Act or regulation promulgated under this Act provides a right of review of the matter in controversy, the Secretary shall, by regulation, establish a procedure under which such sponsor, applicant, or manufacturer may request a review of such controversy by an appropriate scientific advisory panel under section 505(n). Such review shall take place in a timely manner. The Secretary shall promulgate such regulations within 180 days of the date of the enactment of the Food and Drug Administration Regulatory Modernization Act of 1997.''.

SEC. 117. INFORMAL AGENCY STATEMENTS.

Section 701 (21 U.S.C. 371) is amended by adding at the end the following:

''(h)(1)(A) The Secretary shall develop guidance documents with public participation and ensure that the existence of such documents and the documents themselves are made available to the public both in written form and through electronic means. Such documents shall not create or confer any rights for or on any person, although they present the views of the Secretary on matters under the jurisdiction of the Food and Drug Administration.

''(B) Although guidance documents shall not be binding on the Secretary, the Secretary shall ensure that employees of the Food and Drug Administration do not deviate from such guidances without appropriate justification and supervisory concurrence.

''(C) For guidance documents that set forth initial interpretations of statute or regulation, changes in interpretation or policy that are of more than a minor nature, complex scientific issues, or highly controversial issues, the Secretary shall ensure public participation prior to implementation of any guidance documents, unless the Secretary determines that for reasons of the public health need, such prior public participation is not feasible. In such cases, the Secretary shall provide for public comment upon implementation, and take such comment into account.

''(D) For guidance documents that set forth existing practices or minor changes in policy, the Secretary shall provide for public comment upon implementation.

''(2) In developing guidance documents, the Secretary shall ensure uniform nomenclature and uniform internal procedures for approval of such documents. The Secretary shall ensure that guidance documents and revisions of such documents are properly dated and indicate the nonbinding nature of the documents.

''(3) The Secretary, through the Food and Drug Administration, shall maintain electronically and publish periodically in the Federal Register a list of guidance documents. Such list shall be updated quarterly. All such documents shall be made available to the public.

''(4) The Secretary shall report to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate no later than July 1, 2000, on the implementation of these practices.''.

SEC. 118. POSITRON EMISSION TOMOGRAPHY.

(a) REGULATION OF COMPOUNDED POSITRON EMISSION TOMOGRAPHY DRUGS.—

(1) DEFINITION.—Section 201 (21 U.S.C. 321) is amended by adding at the end the following:

''(ii) The term 'compounded positron emission tomography drug'—

''(1) means a drug that—

''(A) exhibits spontaneous disintegration of unstable nuclei by the emission of positrons and is used for the purpose of providing dual photon positron emission tomographic diagnostic images; and

''(B) has been compounded by or on the order of a practitioner who is licensed by a State to compound or order compounding for a drug described in subparagraph (A), and is compounded in accordance with that State's law, for a patient or for research, teaching, or quality control; and

''(2) includes any nonradioactive reagent, reagent kit, ingredient, nuclide generator, accelerator, target material, electronic synthesizer, or other apparatus or computer program to be used in the preparation of such a drug.''.

(b) ADULTERATION.—

(1) IN GENERAL.—Section 501(a)(2) (21 U.S.C. 351(a)(2)) is amended by striking ''; or (3)'' and inserting the following: ''; or (C) if it is a compounded positron emission tomography drug and the methods used in, or the facilities and controls used for, its compounding, processing, packing, or holding do not conform to or are not operated or administered in conformity with the positron emission tomography compounding standards and the official monographs of the United States Pharmacopeia to assure that such drug meets the requirements of this Act as to safety and has the identity and strength, and

meets the quality and purity characteristics, that it purports or is represented to possess; or (3)''.

(2) SUNSET.—Section 501(a)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351(a)(2)(C)) shall not apply 4 years after the date of enactment of this Act or 2 years after the date on which the Secretary of Health and Human Services establishes the requirements described in subsection (c)(1)(B), whichever is later.

(c) REQUIREMENTS FOR REVIEW OF APPROVAL PROCEDURES AND CURRENT GOOD MANUFACTURING PRACTICES FOR POSITRON EMISSION TOMOGRAPHY.—

(1) PROCEDURES AND REQUIREMENTS.—

(A) IN GENERAL.—In order to take account of the special characteristics of compounded positron emission tomography drugs and the special techniques and processes required to produce these drugs, not later than 2 years after the date of enactment of this Act, the Secretary of Health and Human Services shall establish—

(i) appropriate procedures for the approval of compounded positron emission tomography drugs pursuant to section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355); and

(ii) appropriate current good manufacturing practice requirements for such drugs.

(B) CONSIDERATIONS AND CONSULTATION.—In establishing the procedures and requirements required by subparagraph (A), the Secretary of Health and Human Services shall take due account of any relevant differences between not-for-profit institutions that compound the drugs for their patients and commercial manufacturers of the drugs. Prior to establishing the procedures and requirements, the Secretary of Health and Human Services shall consult with patient advocacy groups, professional associations, manufacturers, and physicians and scientists licensed to make or use compounded positron emission tomography drugs.

(2) SUBMISSION OF NEW DRUG APPLICATIONS AND ABBREVIATED NEW DRUG APPLICATIONS.—

(A) IN GENERAL.—Except as provided in subparagraph (B), the Secretary of Health and Human Services shall not require the submission of new drug applications or abbreviated new drug applications under subsection (b) or (j) of section 505 (21 U.S.C. 355), for compounded positron emission tomography drugs that are not adulterated drugs described in section 501(a)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351(a)(2)(C)) (as amended by subsection (b)), for a period of 4 years after the date of enactment of this Act, or for 2 years after the date on which the Secretary establishes procedures and requirements under paragraph (1), whichever is later.

(B) EXCEPTION.—Nothing in this Act shall prohibit the voluntary submission of such applications or the review of such applications by the Secretary of Health and Human Services. Nothing in this Act shall constitute an exemption for a compounded positron emission tomography drug from the requirements of regulations issued under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) for such drugs.

(d) REVOCATION OF CERTAIN INCONSISTENT DOCUMENTS.—Within 30 days after the date of enactment of this Act, the Secretary of Health and Human Services shall publish in the Federal Register a notice terminating the application of the following notices and rule, to the extent the notices and rule relate to compounded positron emission tomography drugs:

(1) A notice entitled ''Regulation of Positron Emission Tomographic Drug Products: Guidance; Public Workshop'', published in the Federal Register on February 27, 1995.

(2) A notice entitled ''Guidance for Industry: Current Good Manufacturing Practices for Positron Emission Tomographic (PET) Drug Products; Availability'', published in the Federal Register on April 22, 1997.

(3) A final rule entitled ''Current Good Manufacturing Practice for Finished Pharmaceuticals; Positron Emission Tomography'', published in the Federal Register on April 22, 1997.

(e) DEFINITION.—As used in this section, the term ''compounded positron emission tomography drug'' has the meaning given the term in section 201 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321).

SEC. 119. REQUIREMENTS FOR RADIOPHARMACEUTICALS.

(a) REQUIREMENTS.—

(1) REGULATIONS.—

(A) PROPOSED REGULATIONS.—Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services, after consultation with patient advocacy groups, associations, physicians licensed to use radiopharmaceuticals, and the regulated industry, shall issue proposed regulations governing the approval of radiopharmaceuticals designed for diagnosis and monitoring of diseases and conditions. The regulations shall provide that the determination of the safety and effectiveness of such a radiopharmaceutical under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or section 351 of the Public Health Service Act (42 U.S.C. 262) shall include consideration of the proposed use of the radiopharmaceutical in the practice of medicine, the pharmacological and toxicological activity of the radiopharmaceutical (including any carrier or ligand component of the radiopharmaceutical), and the estimated absorbed radiation dose of the radiopharmaceutical.

(B) FINAL REGULATIONS.—Not later than 18 months after the date of enactment of this Act, the Secretary shall promulgate final regulations governing the approval of the radiopharmaceuticals.

(2) SPECIAL RULE.—In the case of a radiopharmaceutical intended to be used for diagnostic or monitoring purposes, the indications for which such radiopharmaceutical is approved for marketing may, in appropriate cases, refer to manifestations of disease (such as biochemical, physiological, anatomic, or pathological processes) common to, or present in, one or more disease states.

(b) DEFINITION.—In this section, the term ''radiopharmaceutical'' means—

(1) an article—

(A) that is intended for use in the diagnosis or monitoring of a disease or a manifestation of a disease in humans; and

(B) that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons; or

(2) any nonradioactive reagent kit or nuclide generator that is intended to be used in the preparation of any such article.

SEC. 120. MODERNIZATION OF REGULATION.

(a) LICENSES.—

(1) IN GENERAL.—Section 351(a) of the Public Health Service (42 U.S.C. 262(a)) is amended to read as follows:

''(a)(1) No person shall introduce or deliver for introduction into interstate commerce any biological product unless—

''(A) a biologics license is in effect for the biological product; and

''(B) each package of the biological product is plainly marked with—

''(i) the proper name of the biological product contained in the package;

''(ii) the name, address, and applicable license number of the manufacturer of the biological product; and

''(iii) the expiration date of the biological product.

''(2)(A) The Secretary shall establish, by regulation, requirements for the approval, suspension, and revocation of biologics licenses.

''(B) The Secretary shall approve a biologics license application—

''(i) on the basis of a demonstration that—

''(I) the biological product that is the subject of the application is safe, pure, and potent; and

''(II) the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent; and

''(ii) if the applicant (or other appropriate person) consents to the inspection of the facility that is the subject of the application, in accordance with subsection (c).

''(3) The Secretary shall prescribe requirements under which a biological product undergoing investigation shall be exempt from the requirements of paragraph (1).''.

(2) ELIMINATION OF EXISTING LICENSE REQUIREMENT.—Section 351(d) of the Public Health Service Act (42 U.S.C. 262(d)) is amended—

(A) by striking ''(d)(1)'' and all that follows through ''of this section.'';

(B) in paragraph (2)—

(i) by striking ''(2)(A) Upon'' and inserting ''(d)(1) Upon'' and

(ii) by redesignating subparagraph (B) as paragraph (2); and

(C) in paragraph (2) (as so redesignated by subparagraph (B)(ii))—

(i) by striking ''subparagraph (A)'' and inserting ''paragraph (1)''; and

(ii) by striking ''this subparagraph'' each place it appears and inserting ''this paragraph''.

(b) LABELING.—Section 351(b) of the Public Health Service Act (42 U.S.C. 262(b)) is amended to read as follows:

''(b) No person shall falsely label or mark any package or container of any biological product or alter any label or mark on the package or container of the biological product so as to falsify the label or mark.''.

(c) INSPECTION.—Section 351(c) of the Public Health Service Act (42 U.S.C. 262(c)) is amended by striking ''virus, serum,'' and all that follows and inserting ''biological product.''.

(d) DEFINITION; APPLICATION.—Section 351 of the Public Health Service Act (42 U.S.C. 262) is amended by adding at the end the following:

''(i) In this section, the term 'biological product' means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.''.

(e) CONFORMING AMENDMENT.—Section 503(g)(4) (21 U.S.C. 353(g)(4)) is amended—

(1) in subparagraph (A)—

(A) by striking ''section 351(a)'' and inserting ''section 351(i)''; and

(B) by striking ''262(a)'' and inserting ''262(i)''; and

(2) in subparagraph (B)(iii), by striking ''product or establishment license under subsection (a) or (d)'' and inserting ''biologics license application under subsection (a)''.

(f) SPECIAL RULE.—The Secretary of Health and Human Services shall take measures to minimize differences in the review and approval of products required to have approved biologics license applications under section 351 of the Public Health Service Act (42 U.S.C. 262) and products required to have approved new drug applications under section

505(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(1)).

(g) EXAMINATIONS AND PROCEDURES.—Paragraph (3) of section 353(d) of the Public Health Service Act (42 U.S.C. 263a(d)) is amended to read as follows:

''(3) EXAMINATIONS AND PROCEDURES.—The examinations and procedures identified in paragraph (2) are laboratory examinations and procedures which have been approved by the Food and Drug Administration for home use or which, as determined by the Secretary, are simple laboratory examinations and procedures which have an insignificant risk of an erroneous result, including those which—

''(A) employ methodologies that are so simple and accurate as to render the likelihood of erroneous results by the user negligible, or

''(B) the Secretary has determined pose no unreasonable risk of harm to the patient if performed incorrectly.''.

SEC. 121. PILOT AND SMALL SCALE MANUFACTURE.

(a) HUMAN DRUGS.—Section 505(c) (21 U.S.C. 355(c)) is amended by adding at the end thereof the following:

''(4) A drug manufactured in a pilot or other small facility may be used to demonstrate the safety and effectiveness of the drug and to obtain approval prior to scaling up to a larger facility, unless the Secretary makes a determination that a full scale production facility is necessary to ensure the safety or effectiveness of the drug.''.

(b) ANIMAL DRUGS.—Section 512(c) (21 U.S.C. 360b(c)) is amended by adding at the end the following:

''(4) A drug manufactured in a pilot or other small facility may be used to demonstrate the safety and effectiveness of the drug and to obtain approval prior to scaling up to a larger facility, unless the Secretary makes a determination that a full scale production facility is necessary to ensure the safety or effectiveness of the drug.''.

SEC. 122. INSULIN AND ANTIBIOTICS.

(a) CERTIFICATION OF DRUGS CONTAINING INSULIN.—

(1) AMENDMENT.—Section 506 (21 U.S.C. 356), as in effect before the date of the enactment of this Act, is repealed.

(2) CONFORMING AMENDMENTS.—

(A) Section 301(j) (21 U.S.C. 331(j)) is amended by striking ''506, 507,''.

(B) Subsection (k) of section 502 (21 U.S.C. 352) is repealed.

(C) Sections 301(i)(1), 510(j)(1)(A), and 510(j)(1)(D) (21 U.S.C. 331(i)(1), 360(j)(1)(A), 360(j)(1)(D)) are each amended by striking '', 506, 507,''.

(D) Section 801(d)(1) (21 U.S.C. 381(d)(1)) is amended by inserting after ''503(b)'' the following: ''or composed wholly or partly of insulin''.

(E) Section 8126(h)(2) of title 38, United States Code, is amended by inserting ''or'' at the end of subparagraph (B), by striking ''; or'' at the end of subparagraph (C) and inserting a period, and by striking subparagraph (D).

(b) CERTIFICATION OF ANTIBIOTICS.—

(1) AMENDMENT.—Section 507 (21 U.S.C. 357) is repealed.

(2) CONFORMING AMENDMENTS.—

(A) Section 201(aa) (21 U.S.C. 321(aa)) is amended by striking out ''or 507'', section 201(dd) (21 U.S.C. 321(dd)) is amended by striking ''507,'', and section 201(ff)(3)(A) (21 U.S.C. 321(ff)(3)(A)) is amended by striking '', certified as an antibiotic under section 507,''.

(B) Section 301(e) (21 U.S.C. 331(e)) is amended by striking ''507(d) or (g),''.

(C) Section 306(d)(4)(B)(ii) (21 U.S.C. 335a(d)(4)(B)(ii)) is amended by striking ''or 507''.

(D) Section 502 (21 U.S.C. 352) is amended by striking subsection (l).

(E) Section 520(l) (21 U.S.C. 360j(l)) is amended by striking paragraph (4) and by striking ''or Antibiotic Drugs'' in the subsection heading.

(F) Section 525(a) (21 U.S.C. 360aa(a)) is amended by inserting ''or'' at the end of paragraph (1), by striking paragraph (2), and by redesignating paragraph (3) as paragraph (2).

(G) Section 525(a) (21 U.S.C. 360aa(a)) is amended by striking '', certification of such drug for such disease or condition under section 507,''.

(H) Section 526(a)(1) (21 U.S.C. 360bb) is amended by striking ''the submission of an application for certification of the drug under section 507,'', by inserting ''or'' at the end of subparagraph (A), by striking subparagraph (B), and by redesignating subparagraph (C) as subparagraph (B).

(I) Section 526(b) (21 U.S.C. 360bb(b)) is amended—

(i) in paragraph (1), by striking '', a certificate was issued for the drug under section 507,''; and

(ii) in paragraph (2) by striking '', a certificate has not been issued for the drug under section 507,'' and by striking '', approval of an application for certification under section 507,''.

(J) Section 527(a) (21 U.S.C. 360cc(a)) is amended by inserting ''or'' at the end of paragraph (1), by striking paragraph (2), by redesignating paragraph (3) as paragraph (2), and by striking '', issue another certificate under section 507,''.

(K) Section 527(b) (21 U.S.C. 360cc(b)) is amended by striking '', if a certification is issued under section 507 for such a drug, or'', ''of the issuance of the certification under section 507,'', and ''issue another certification under section 507, or''.

(L) Section 704(a)(1) (21 U.S.C. 374(a)(1)) is amended by striking '', section 507 (d) or (g)''.

(M) Section 735(1) (21 U.S.C. 379g(1)(C)) is amended by inserting ''or'' at the end of subparagraph (B), by striking subparagraph (C), and by redesignating subparagraph (D) as subparagraph (C).

(N) Subparagraphs (A)(ii) and (B) of sections 5(b)(1) of the Orphan Drug Act (21 U.S.C. 360ee(b)(1)(A), 360ee(b)(1)(B)) are each amended by striking ''or 507''.

(O) Section 45C(b)(2)(A)(ii)(II) of the Internal Revenue Code of 1986 is amended by striking ''or 507''.

(P) Section 156(f)(4)(B) of title 35, United States Code, is amended by striking ''507,'' each place it occurs.

(c) EXPORTATION.—Section 802 (21 U.S.C. 382) is amended by adding at the end thereof the following:

''(i) Insulin and antibiotic drugs may be exported without regard to the requirements in this section if the insulin and antibiotic drugs meet the requirements of section 801(e)(1).''.

(d) EFFECT.—The amendments made by subsection (b) shall not apply with respect to any application for a drug that contains an active ingredient (including any ester or salt of the active ingredient) that was an antibiotic drug within the meaning of section 507 of such Act and was the subject of an approved or pending application under such section 507 for certification or exemption from certification before the date of the enactment of this Act.

SEC. 123. FDA MISSION AND ANNUAL REPORT.

(a) MISSION.—Section 903 (21 U.S.C. 393) is amended by redesignating subsections (b) and (c) as subsections (c) and (d), respectively, and by adding after subsection (a) the following:

''(b) MISSION.—The Food and Drug Administration shall promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner, and with respect to such products shall protect the public health by ensuring that—

''(1) foods are safe, wholesome, sanitary, and properly labeled;

''(2) human and veterinary drugs are safe and effective;

''(3) there is reasonable assurance of safety and effectiveness of devices intended for human use;

''(4) cosmetics are safe and properly labeled; and

''(5) public health and safety are protected from electronic product radiation.

The Food and Drug Administration shall participate with other countries to reduce the burden of regulation, harmonize regulatory requirements, and achieve appropriate reciprocal arrangements.''.

(b) ANNUAL REPORT.—Section 903 (21 U.S.C. 393), as amended by subsection (a), is amended by adding at the end the following:

''(e) ANNUAL REPORT.—The Secretary shall, simultaneously with the submission each year of the budget for the Food and Drug Administration, submit to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate an annual report which shall—

''(1) review the performance of the Food and Drug Administration in meeting its mission and the development of Food and Drug Administration policies to implement such mission;

''(2) review the performance of the Food and Drug Administration in meeting its own performance standards, including its own outcome measurements, and statutory deadlines for the approval of products or for other purposes contained in this Act;

''(3) describe the staffing and resources of the Food and Drug Administration;

''(4)(A) list each bilateral and multinational meeting held by the Food and Drug Administration to address methods and approaches to reduce the burden of regulation, to harmonize regulation, and to seek appropriate reciprocal arrangements, (B) describe the goals, activities, and accomplishments of the Food and Drug Administration in such meetings, and (C) list issues that the Food and Drug Administration is considering or has presented for each such meeting.''.

SEC. 124. INFORMATION SYSTEM.

Chapter IX is amended by adding at the end the following section:

''SEC. 906. INFORMATION SYSTEM.

''The Secretary shall establish and maintain an information system to track the status and progress of each application or submission (including a petition, notification, or other similar form of request) submitted to the Food and Drug Administration requesting agency action.''.

SEC. 125. EDUCATION AND TRAINING.

Chapter IX, as amended by section 124, is amended by adding at the end the following sections:

''SEC. 907. EDUCATION.

''The Secretary shall conduct training and education programs for the employees of the Food and Drug Administration relating to the regulatory responsibilities and policies established by this Act, including programs for scientific training and training in administrative process and procedure and integrity issues.''.

SEC. 126. CENTERS FOR EDUCATION AND RESEARCH ON DRUGS.

Chapter IX, as amended by section 125, is amended by adding at the end the following section:

"SEC. 908. DEMONSTRATION PROGRAM REGARDING CENTERS FOR EDUCATION AND RESEARCH ON DRUGS.

"(a) IN GENERAL.—The Secretary, acting through the Commissioner of Food and Drugs, shall establish a demonstration program for the purpose of making one or more grants for the establishment and operation of one or more centers to carry out the activities specified in subsection (b).

"(b) REQUIRED ACTIVITIES.—The activities referred to in subsection (a) are the following:

"(1) The conduct of state-of-the-art clinical and laboratory research for the following purposes:

"(A) To increase awareness of new uses of drugs and the unforeseen risks of new uses of drugs.

"(B) To provide objective clinical information to the following entities:

"(i) Health care practitioners or other providers of health care goods or services.

"(ii) Pharmacy benefit managers.

"(iii) Health maintenance organizations or other managed health care organizations.

"(iv) Health care insurers or governmental agencies.

"(C) To improve the quality of health care while reducing the cost of health care through the prevention of adverse effects of drugs and the consequences of such effects, such as unnecessary hospitalizations.

"(2) The conduct of research on the comparative effectiveness and safety of drugs.

"(3) Such other activities as the Secretary determines to be appropriate, except that the grant may not be expended to assist the Secretary in the review of new drugs.

"(c) APPLICATION FOR GRANT.—A grant under subsection (a) may be made only if an application for the grant is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

"(d) PEER REVIEW.—A grant under subsection (a) may be made only if the application for the grant has undergone appropriate technical and scientific peer review.

"(e) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $2,000,000 for fiscal year 1998, and $3,000,000 for fiscal year 1999.".

SEC. 127. HARMONIZATION.

Section 803 (21 U.S.C. 383) is amended by adding at the end the following:

"(c) The Secretary shall participate in meetings with representatives of other countries to discuss methods and approaches to reduce the burden of regulation and harmonize regulatory requirements if the Secretary determines that such harmonization continues consumer protections consistent with the purposes of this Act. The Secretary shall report to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate at least 60 days before executing any bilateral or multilateral agreement under subsection (b).".

SEC. 128. ENVIRONMENTAL IMPACT REVIEW.

Chapter VII, as amended by section 111, is amended by adding at the end the following:

"SUBCHAPTER G—ENVIRONMENTAL IMPACT REVIEW

"SEC. 761. ENVIRONMENTAL IMPACT REVIEW.

"Notwithstanding any other provision of law, an environmental impact statement prepared in accordance with the regulations published at part 25 of 21 C.F.R. (as in effect on August 31, 1997) in connection with an action carried out under (or a recommendation or report relating to) this Act, shall be considered to meet the requirements for a detailed statement under section 102(2)(C) of the National Environmental Policy Act.".

SEC. 129. NATIONAL UNIFORMITY.

(a) NONPRESCRIPTION DRUGS.—Chapter VII (21 U.S.C. 371 et seq.), as amended by section 128, is amended by adding at the end the following:

"SUBCHAPTER H—NATIONAL UNIFORMITY FOR NONPRESCRIPTION DRUGS FOR HUMAN USE AND PREEMPTION FOR LABELING OR PACKAGING OF COSMETICS

"SEC. 771. NATIONAL UNIFORMITY FOR NONPRESCRIPTION DRUGS FOR HUMAN USE.

"(a) IN GENERAL.—Except as provided in subsection (b), (c)(1), (d), (e), or (f), no State or political subdivision of a State may establish or continue in effect any requirement—

"(1) that relates to the regulation of a drug intended for human use that is not subject to the requirements of section 503(b)(1); and

"(2) that is different from or in addition to, or that is otherwise not identical with, a requirement under this Act, the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.), or the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.).

"(b) EXEMPTION.—Upon application of a State or political subdivision thereof, the Secretary may by regulation, after notice and opportunity for written and oral presentation of views, exempt from subsection (a), under such conditions as may be prescribed in such regulation, a State or political subdivision requirement that—

"(1) protects an important public interest that would otherwise be unprotected;

"(2) would not cause any drug to be in violation of any applicable requirement or prohibition under Federal law; and

"(3) would not unduly burden interstate commerce.

"(c) SCOPE.—

"(1) IN GENERAL.—This section shall not apply to—

"(A) any State or political subdivision requirement that relates to the practice of pharmacy; or

"(B) any State or political subdivision requirement that a drug be dispensed only upon the prescription of a practitioner licensed by law to administer such drug.

"(2) SAFETY OR EFFECTIVENESS.—For purposes of subsection (a), a requirement that relates to the regulation of a drug shall be deemed to include any requirement relating to public information or any other form of public communication relating to a warning of any kind for a drug.

"(d) EXCEPTIONS.—

"(1) IN GENERAL.—In the case of a drug described in subsection (a)(1) that is not the subject of an application approved under section 505 or 507 or a final regulation promulgated by the Secretary establishing conditions under which the drug is generally recognized as safe and effective and not misbranded, subsection (a) shall apply only with respect to a requirement of a State or political subdivision of a State that relates to the same subject as, but is different from or in addition to, or that is otherwise not identical with—

"(A) a regulation in effect with respect to the drug pursuant to a statute described in subsection (a)(2); or

"(B) any other requirement in effect with respect to the drug pursuant to an amendment to such a statute made on or after the date of enactment of this section.

"(2) STATE INITIATIVES.—This section shall not apply to a State public initiative enacted prior to the date of enactment of this section.

"(e) NO EFFECT ON PRODUCT LIABILITY LAW.—Nothing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.

"(f) STATE ENFORCEMENT AUTHORITY.—Nothing in this section shall prevent a State or political subdivision thereof from enforcing, under any relevant civil or other enforcement authority, a requirement that is identical to a requirement of this Act.".

(b) INSPECTIONS.—Section 704(a)(1) (21 U.S.C. 374(a)(1)) is amended by striking "prescription drugs" each place it appears and inserting "prescription drugs, nonprescription drugs intended for human use,".

(c) MISBRANDING.—Paragraph (1) of section 502(e) (21 U.S.C. 352(e)(1)) is amended to read as follows:

"(1)(A) If it is a drug, unless its label bears, to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula)—

"(i) the established name (as defined in subparagraph (3)) of the drug, if there is such a name;

"(ii) the established name and quantity or, if deemed appropriate by the Secretary, the proportion of each active ingredient, including the quantity, kind, and proportion of any alcohol, and also including whether active or not the established name and quantity or if deemed appropriate by the Secretary, the proportion of any bromides, ether, chloroform, acetanilide, acetophenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein, except that the requirement for stating the quantity of the active ingredients, other than the quantity of those specifically named in this subclause, shall not apply to nonprescription drugs not intended for human use; and

"(iii) the established name of each inactive ingredient listed in alphabetical order on the outside container of the retail package and, if deemed appropriate by the Secretary, on the immediate container, as prescribed in regulation promulgated by the Secretary, but nothing in this clause shall be deemed to require that any trade secret be divulged, except that the requirements of this subclause with respect to alphabetical order shall apply only to nonprescription drugs that are not also cosmetics and this subclause shall not apply to nonprescription drugs not intended for human use.

"(B) For any prescription drug the established name of such drug or ingredient, as the case may be, on such label (and on any labeling on which a name for such drug or ingredient is used) shall be printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug or ingredient, except that to the extent that compliance with the requirements of clause (A)(ii) or (iii) or this subparagraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary.".

(d) COSMETICS.—Subchapter H of chapter VII, as amended by subsection (a), is further amended by adding at the end the following:

"SEC. 772. PREEMPTION FOR LABELING OR PACKAGING OF COSMETICS.

"(a) IN GENERAL.—Except as provided in subsection (b), (d), or (e), a State or political subdivision of a State shall not impose or continue in effect any requirement for labeling or packaging of a cosmetic that is different from or in addition to, or that is otherwise not identical with a requirement that is specifically applicable to a particular cosmetic or class of cosmetics under this Act, the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.), or the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.).

"(b) EXEMPTION.—Upon application of a State or political subdivision thereof, the

Secretary may by regulation after notice and opportunity for written and oral presentation of views, exempt from subsection (a), under such conditions as may be prescribed in such regulation, a State or political subdivision requirement for labeling and packaging that—

''(1) protects an important public interest that would otherwise be unprotected;

''(2) would not cause a cosmetic to be in violation of any applicable requirements or prohibition under Federal law; and

''(3) would not unduly burden interstate commerce.

''(c) SCOPE.—For purposes of subsection (a), a reference to a State requirement that relates to the packaging or labeling of a cosmetic means any specific requirement relating to the same aspect of such cosmetic as a requirement specifically applicable to that particular cosmetic or class of cosmetics under this Act for packaging or labeling, including any State requirement relating to public information or any other form of public communication.

''(d) NO EFFECT ON PRODUCT LIABILITY LAW.—Nothing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.

''(e) STATE INITIATIVE.—This section shall not apply to a State requirement adopted by a State public initiative or referendum enacted prior to September 1, 1997.''.

SEC. 130. FDA STUDY OF MERCURY COMPOUNDS IN DRUGS AND FOOD.

(a) LIST AND ANALYSIS.—The Secretary of Health and Human Services shall, through the Food and Drug Administration—

(1) compile a list of drugs and foods that contain intentionally introduced mercury compounds, and

(2) provide a quantitative and qualitative analysis of the mercury compounds in the list under paragraph (1).

The Secretary shall compile the list required by paragraph (1) within 2 years after the date of the enactment of this section and shall provide the analysis required by paragraph (2) within 2 years of such date of enactment.

(b) STUDY.—The Secretary of Health and Human Services, acting through the Food and Drug Administration, shall conduct a study of the effect on humans of the use of mercury compounds in nasal sprays. Such study shall include data from other studies that have been made of such use.

(c) STUDY OF MERCURY SALES.—

(1) STUDY.—The Secretary of Health and Human Services, acting through the Food and Drug Administration and subject to appropriations, shall conduct, or shall contract with the Institute of Medicine of the National Academy of Sciences to conduct, a study of the effect on humans of the use of elemental, organic or inorganic mercury when offered for sale as a drug or dietary supplement. Such study shall, among other things, evaluate—

(A) the scope of mercury use as a drug or dietary supplement; and

(B) the adverse effects on health of children and other sensitive populations resulting from exposure to, or ingestion or inhalation of, mercury when so used.

In conducting such study, the Secretary shall consult with the Administrator of the Environmental Protection Agency, the Chair of the Consumer Product Safety Commission, and the Administrator of the Agency for Toxic Substances and Disease Registry, and, to the extent the Secretary believes necessary or appropriate, with any other Federal or private entity.

(2) REGULATIONS.—If, in the opinion of the Secretary, the use of elemental, organic or inorganic mercury offered for sale as a drug or dietary supplement poses a threat to human health, the Secretary shall promulgate regulations restricting the sale of mercury intended for such use. At a minimum, such regulations shall be designed to protect the health of children and other sensitive populations from adverse effects resulting from exposure to, or ingestion or inhalation of, mercury. Such regulations, to the extent feasible, should not unnecessarily interfere with the availability of mercury for use in religious ceremonies.

SEC. 131. NOTIFICATION OF DISCONTINUANCE OF A LIFE SAVING PRODUCT.

Chapter VII (21 U.S.C. 371 et seq.), as amended by section 129, is further amended by adding at the end the following:

''Subchapter I—Notification of the Discontinuance of a Life Saving Product

''SEC. 781. DISCONTINUANCE OF A LIFE SAVING PRODUCT.

''(a) IN GENERAL.—A manufacturer that is the sole manufacturer of a drug (including a biological product) or device—

''(1) that is—

''(A) life supporting;

''(B) life sustaining; or

''(C) intended for use in the prevention of a debilitating disease or condition; and

''(2) for which an application has been approved under section 505(b), 505(j), or 515(d),

shall notify the Secretary of a discontinuance of the manufacture of the drug or device at least 6 months prior to the date of the discontinuance.

''(b) REDUCTION IN NOTIFICATION PERIOD.—On application of a manufacturer, the Secretary may reduce the notification period required under subsection (a) for the manufacturer if good cause exists for the reduction, such as a situation in which—

''(1) a public health problem may result from continuation of the manufacturing for the 6-month period;

''(2) a biomaterials shortage prevents the continuation of the manufacturing for the 6-month period;

''(3) a liability problem may exist for the manufacturer if the manufacturing is continued for the 6-month period;

''(4) continuation of the manufacturing for the 6-month period may cause substantial economic hardship for the manufacturer; or

''(5) the manufacturer has filed for bankruptcy under chapter 7 or 11 of title 11, United States Code.

''(c) DISTRIBUTION.—To the maximum extent practicable, the Secretary shall distribute information on the discontinuation of the drugs and devices described in subsection (a) to appropriate physician and patient organizations.''.

TITLE II—IMPROVING REGULATION OF DEVICES

SEC. 201. DISPUTE RESOLUTION.

Section 506, as added by section 116, is amended in the first sentence by inserting before the period the following: '', or under section 515(g)(2)(B), as applicable''.

SEC. 202. INVESTIGATIONAL DEVICE EXEMPTIONS; EXPANDED ACCESS.

Section 520(g) (21 U.S.C. 360j(g)) is amended by adding at the end the following:

''(6)(A) Not later than 120 days after the date of the enactment of the Food and Drug Administration Regulatory Modernization Act of 1997, the Secretary shall by regulation establish, with respect to a device for which an exemption under this subsection is in effect, the following:

''(i) Procedures and conditions under which the Secretary will, without requiring an additional approval of an application for an exemption or the approval of a supplement to such an application, permit—

''(I) developmental changes in the device that do not constitute a significant change in design or in basic principles of operation and that are made in response to information gathered during the course of an investigation; and

''(II) changes or modifications to clinical protocols that do not affect the validity of data or information resulting from the completion of an approved protocol and do not alter the relationship of likely patient risk to benefit relied upon to approve a protocol.

''(ii) Procedures and conditions under which the Secretary will, outside of an approved investigational protocol (subject to compliance with regulations for the protection of patients), permit uses of the device in the diagnosis, monitoring, or treatment of diseases or conditions that are life-threatening or could be irreversibly debilitating, when—

''(I) the treating physician determines that the investigational use of the device likely will provide a benefit; that the risk of not using the device exceeds the probable risk of using the device; and that there is no legally marketed device alternative for the satisfactory treatment or diagnosis of such disease or condition;

''(II) the Secretary determines that there is sufficient evidence of safety and effectiveness to support the investigational use of the device in the case described in subclause (I);

''(III) the Secretary determines that the investigational use of the device will not interfere with the initiation, conduct, or completion of clinical investigations to support marketing approval; and

''(IV) the sponsor, or clinical investigator, of the investigational use of the device submits to the Secretary a clinical protocol consistent with the provisions of paragraph (3) and any regulations promulgated under such paragraph describing the investigational use of devices in a single patient or a small group of patients.

''(B) Regulations under subparagraph (A)(i) shall provide that a change or modification described in such subparagraph is not permitted unless, not later than 5 days after making the change or modification, a notice of the change or modification is submitted to the Secretary.

''(C) Regulations under subparagraph (A)(ii) shall provide that, under appropriate conditions described by the Secretary in the regulations, the Secretary will authorize the shipment of investigational devices (as defined in the regulations) for the diagnosis, monitoring, or treatment of a serious disease or condition in emergency situations.

''(7)(A) In the case of a person intending to investigate the safety or effectiveness of a class III device or any implantable device, the Secretary shall ensure that the person has an opportunity, prior to submitting an application to the Secretary or to an institutional review board, to submit to the Secretary, for review, an investigational plan (including a clinical protocol). If the applicant requests a meeting with the Secretary regarding such review, the Secretary shall meet with the applicant not later than 30 days after receiving the request for the meeting.

''(B) Agreements regarding the parameters of an investigational plan (including clinical protocol) that are reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Such agreements shall not be changed, except—

''(i) with the written agreement of the sponsor or applicant; or

''(ii) pursuant to a decision, made in accordance with subparagraph (C) by the director of the office in which the device involved is reviewed, that a substantial scientific issue essential to determining the safety or effectiveness of the device involved has been identified.

''(C) A decision under subparagraph (B)(ii) by the director shall be in writing, and may be made only after the Secretary has provided to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant are present and at which the director documents the scientific issue involved.''.

SEC. 203. SPECIAL REVIEW FOR CERTAIN DEVICES.

Section 515(d) (21 U.S.C. 360e(d)) is amended—

(1) by redesignating paragraphs (2) and (3) as paragraphs (3) and (4), respectively; and

(2) by adding at the end the following:

''(5) In order to provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human diseases or conditions, the Secretary shall provide review priority for devices—

''(A) representing breakthrough technologies,

''(B) for which no approved alternatives exist,

''(C) which offer significant advantages over existing approved alternatives, or

''(D) the availability of which is in the best interest of the patients.''.

SEC. 204. EXPANDING HUMANITARIAN USE OF DEVICES.

(a) SECTION 520(m).—Section 520(m) (21 U.S.C. 360j(m)) is amended—

(1) in paragraph (2), by inserting after and below subparagraph (C) the following:

''The request shall be in the form of an application to the Secretary. Within 60 days of the date of the receipt of an application, the Secretary shall issue an order approving or denying the application, except that if the Secretary convenes a scientific advisory panel, the Secretary shall within 120 days of the receipt of an application issue such order.'';

(2) by amending paragraph (5) to read as follows:

''(5) The Secretary may suspend or withdraw an exemption from the effectiveness requirements of sections 514 and 515 for a humanitarian device, after providing notice and an opportunity for an informal hearing, if any condition for granting such exemption for such device set forth in paragraphs (2) through (4) no longer is met.''; and

(3) by amending paragraph (6) to read as follows:

''(6) The Secretary may require a person granted an exemption under paragraph (2) to demonstrate continued compliance with the requirements of this subsection if the Secretary believes such demonstration to be necessary to protect the public health or if the Secretary has reason to believe that the criteria for the exemption are no longer met.''.

(b) REGULATIONS.—Any provision in a regulation included in title 21 of the Code of Federal Regulations pertaining to humanitarian devices which is inconsistent with the amendments made by subsection (a) shall be deemed rescinded on the date of the enactment of this Act. The Secretary shall amend regulations pertaining to humanitarian devices to conform with the amendments made by subsection (a).

SEC. 205. DEVICE STANDARDS.

(a) ALTERNATIVE PROCEDURE.—Section 514 (21 U.S.C. 360d) is amended by adding at the end thereof the following:

''Listing of Recognized Standards

''(c)(1) The Secretary shall issue notices identifying and adopting applicable nationally or internationally recognized standards (or portions of such standards) to which a person may self-certify compliance for the purpose of demonstrating a reasonable assurance that a device is safe or effective or to determine compliance with any requirement of this Act. Such notices shall be published in the Federal Register, and the Secretary shall provide an opportunity for public comment on the standards involved.

''(2) The Secretary shall accept a certification that a device conforms with each type of standard referenced in subsection (a) and identified in such certification to the extent such standard applies, except that the Secretary may, at any time, require the person who submitted the certification to submit the data and information which such person relied upon in making such certification, and may reject the certification if the Secretary determines that the data and information do not demonstrate compliance with the standards identified in the certification. Such person shall maintain the data and information for a period of 2 years after the submission of the certification, or for the expected design life of the device, whichever is later.

''(3) The Secretary may remove from the list of standards adopted under subsection (a) a standard (or portion of a standard) which the Secretary determines is not reliable for the purpose set out in such subsection.

''(4) In the case of a person who does not self-certify compliance pursuant to paragraph (1) regarding a device, the person may elect to utilize data other than those required by standards under paragraph (1) to demonstrate a reasonable assurance of the safety or effectiveness of the device.''.

(b) PROHIBITED ACTS.—Section 301 (21 U.S.C. 331), as amended by section 106(b), is amended by adding at the end the following:

''(y) The falsification of a certification under section 514(c) or the failure or refusal to provide data or information required by the Secretary under such section.''.

(c) ADULTERATED DEVICES.—Section 501(e) (21 U.S.C. 351(e)) is amended by striking ''subject to a performance standard'' and all that follows and inserting the following: ''subject to a performance standard established under subsection (b) of section 514, unless such device is in all respects in conformity with such standard; or subject to a standard listed under subsection (c) of such section (in the case of a person who has self-certified to such standard), unless such device is in all respects in conformity with such standard.''.

(d) CONFORMING AMENDMENTS.—

(1) DEFINITION OF CLASS II DEVICE.—Section 513(a)(1)(B) (21 U.S.C. 360c(a)(1)(B)) is amended by inserting after ''performance standards,'' the following: ''the listing of standards under section 514(c),'' .

(2) RELATIONSHIP TO PERFORMANCE STANDARDS.—Section 514(a) (21 U.S.C. 360d(a)) is amended—

(A) in paragraph (1), in the second sentence, by striking ''under this section'' and inserting ''under subsection (b)'';

(B) in paragraph (2), in the matter preceding subparagraph (A), by striking ''under this section'' and inserting ''under subsection (b)'';

(C) in paragraph (3), by striking ''under this section'' and inserting ''under subsection (b)''; and

(D) in paragraph (4), in the matter preceding subparagraph (A), by striking ''this section'' and inserting ''this subsection and subsection (b)''.

SEC. 206. SCOPE OF REVIEW.

(a) SECTION 513(a).—Section 513(a)(3) (21 U.S.C. 360c(a)(3)) is amended—

(1) in subparagraph (A) by inserting ''one or more'' before ''clinical investigation''; and

(2) by adding at the end the following:

''(C) In making a determination of a reasonable assurance of the effectiveness of a device for which an application under section 515 has been submitted, the Secretary shall consider whether the extent of data that otherwise would be required for approval of the application with respect to effectiveness can be reduced through reliance on postmarket controls.

''(D)(i) Upon the request of any person intending to submit an application under section 515, the Secretary shall, not later than 30 days after receiving such request, meet with the person to determine the type of valid scientific evidence within the meaning of subparagraphs (A) and (B) that will be necessary to demonstrate the effectiveness of a device for the proposed conditions of use. Within 30 days of such meeting, the Secretary shall identify, and confirm in writing, the type of valid scientific evidence that will provide a reasonable assurance that a device is effective under the proposed conditions of use.

''(ii) Agreements under section 515 regarding the parameters of valid scientific evidence for a device that are reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Such agreements shall not be changed, except—

''(I) with the written agreement of the sponsor or applicant; or

''(II) pursuant to a decision, made in accordance with clause (iii) by the director of the office in which the device involved is reviewed, that a substantial scientific issue essential to determining the safety or effectiveness of the device has been identified.

''(iii) A decision under clause (ii) by the director shall be in writing, and may be made only after the Secretary has provided to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant are present and at which the director documents the scientific issue involved.''.

(b) SECTION 513(i).—Section 513(i)(1) (21 U.S.C. 360c(i)(1)) is amended by adding at the end the following:

''(C) To facilitate reviews of reports submitted to the Secretary under section 510(k), the Secretary shall consider the extent to which reliance on postmarket controls may expedite the classification of devices under subsection (f)(1) of this section.

''(D) Whenever the Secretary requests information to demonstrate that devices with differing technological characteristics are substantially equivalent, the Secretary shall only request information that is necessary to making substantial equivalence determinations. In making such request, the Secretary shall consider the least burdensome means of demonstrating substantial equivalence and request information accordingly.

''(E)(i) Any determination by the Secretary of the intended use of a device shall be based upon the proposed labeling submitted in a report for the device under section 510(k), unless the director of the organizational unit responsible for regulating devices (in this subparagraph referred to as the 'Director'), after providing an opportunity for consultation with the person who submitted such report, determines and states in writing (I) that there is a reasonable likelihood that the device will be used for an intended use not identified in the proposed labeling for the device, and (II) on the basis of data or the absence of data, that such use could cause harm.

''(ii) Such determination shall—

''(I) be provided to the person who submitted the report within 10 days from the date of the notification of the Director's concerns regarding the proposed labeling;

''(II) specify limitations on the device's labeling which proscribe the use not included in proposed labeling; and

''(III) find the device substantially equivalent when the labeled intended use and the technological characteristics of the device relative to a legally marketed device conform with the requirements of subparagraph (A).

''(iii) The responsibilities of the Director under this subparagraph may not be delegated.

''(iv) This subparagraph has no legal effect after the expiration of the five-year period beginning on the date of the enactment of the Food and Drug Administration Regulatory Modernization Act of 1997.''.

(c) SECTION 515(d).—Section 515(d) (21 U.S.C. 360e(d)) is amended—

(1) in paragraph (1)(A), by adding after and below clause (ii) the following:

''In making the determination whether to approve or deny the application, the Secretary shall rely on the conditions of use included in the proposed labeling as the basis for determining whether or not there is a reasonable assurance of safety and effectiveness, if the proposed labeling is neither false nor misleading. In determining whether or not such labeling is false or misleading, the Secretary shall fairly evaluate all material facts pertinent to the proposed labeling.''; and

(2) by adding after paragraph (5) (as added by section 5(2)) the following:

''(6)(A)(i) A supplemental application shall be required for any change to a device subject to an approved application under this subsection that affects safety or effectiveness, unless such change is a modification in a manufacturing procedure or method of manufacturing and the holder of the approved application submits a written notice to the Secretary that describes in detail the change, summarizes the data or information supporting the change, and informs the Secretary that the change has been made under the requirements of section 520(f).

''(ii) The holder of an approved application who submits a notice under clause (i) with respect to a manufacturing change of a device may distribute the device 30 days after the date on which the Secretary receives the notice, unless the Secretary within such 30-day period notifies the holder that the notice is not adequate and describes such further information or action that is required for acceptance of such change. If the Secretary notifies the holder that a premarket approval supplement is required, the Secretary shall review the supplement within 135 days after the receipt of the supplement. The time used by the Secretary to review the notice of the manufacturing change shall be deducted from the 135-day review period if the notice meets appropriate content requirements for premarket approval supplements.

''(B)(i) Subject to clause (ii), in reviewing a supplement to an approved application, for an incremental change to the design of a device that affects safety or effectiveness, the Secretary shall approve such supplement if—

''(I) nonclinical data demonstrate that the design modification creates the intended additional capacity, function, or performance of the device; and

''(II) clinical data from the approved application and any supplement to the approved application provide a reasonable assurance of safety and effectiveness for the changed device.

''(ii) The Secretary may require, when necessary, additional clinical data to evaluate the design modification of the device to provide a reasonable assurance of safety and effectiveness.''.

SEC. 207. PREMARKET NOTIFICATION.

(a) SECTION 510.—Section 510 (21 U.S.C. 360) is amended—

(1) in subsection (k)—

(A) in the matter preceding paragraph (1), by adding after ''report to the Secretary'' the following: ''or person who is accredited under section 712(a)''; and

(B) by adding after and below paragraph (2) the following:

''Such a report is not required for a device intended for human use that is exempted from the requirements of this subsection under subsection (l) or is classified into class I under section 513. The exception established in the preceding sentence does not apply to any class I device that is intended to be life supporting or life sustaining or is intended for a use which is of substantial importance in preventing impairment of human health, or to any class I device that presents a potential unreasonable risk of illness or injury. With respect to a person who is accredited under section 712(a), such accredited person shall review a report under this subsection that is received by such person and shall submit, not later than 60 days after receiving the report, to the Secretary such person's recommendation for action to be taken by the Secretary on the report.''; and

(2) by adding after subsection (k) the following subsection:

''(l) Not later than 30 days after the date of the enactment of the Food and Drug Administration Regulatory Modernization Act of 1997, the Secretary shall publish in the Federal Register a list of each type of class II device that does not require a report under subsection (k) to provide reasonable assurance of safety and effectiveness. Each type of class II device listed by the Secretary shall be exempt from the requirement to file a report under subsection (k) as of the date of the publication of the list in the Federal Register. Beginning on the date that is 1 day after the date of the publication of the list, any person may petition the Secretary to exempt a type of class II device from the reporting requirement of subsection (k). The Secretary shall publish in the Federal Register notice of the intent of the Secretary to exempt the device, or of the petition, and provide a 30-day period for public comment. If the Secretary fails to respond to a petition within 120 days of receiving it, the petition shall be deemed to be granted.''.

(b) INITIAL CLASSIFICATION.—Section 513(f) (21 U.S.C. 360c(f)) is amended—

(1) in the second sentence of paragraph (1) by striking the period at the end and inserting the following: ''unless within 30 days of receiving an order classifying the device into class III the person who submits a report under section 510(k) for such device requests review with respect to the classification of the device and a final order of classification from the Secretary. Such person shall submit to the Secretary data and information supporting the classification of the device into class I or II. After the request, a device classified into class III under this paragraph remains in class III, but shall not be deemed to be finally classified until the Secretary has determined the classification of the device based on the classification criteria set forth in subparagraphs (A) through (C) of subsection (a)(1), within 60 days of receiving the request to review and classify a device. Any device found under this paragraph not to be substantially equivalent to a device described in subparagraph (A)(i) and which is classified by the Secretary into class III may not be commercially distributed in commerce before it is approved under section 515.''; and

(2) by adding at the end the following:

''(4) The Secretary may not withhold a determination of the initial classification of a device under paragraph (1) because of a failure to comply with any provision of this Act unrelated to a substantial equivalence decision, including a finding that the facility in which the device is manufactured is not in compliance with good manufacturing requirements as set forth in regulations of the Secretary under section 520(f) (other than a finding that the failure to comply with such regulations is directly related to the safety or effectiveness of the device).''.

(c) SECTION 513.—Section 513(i)(1) (21 U.S.C. 360c(i)), as amended by section 206(b), is amended—

(1) in subparagraph (A)(ii)(I), by striking ''clinical data'' and inserting ''appropriate clinical or scientific data'' and by inserting ''or a person accredited under section 712'' after ''Secretary'';

(2) in subparagraph (A)(ii)(II), by striking ''efficacy'' and inserting ''effectiveness''; and

(3) by adding at the end of paragraph (1) the following:

''(F) For purposes of subparagraph (A), the term 'legally marketed device' includes any device introduced into interstate commerce for commercial distribution before May 28, 1976, and any device determined to be substantially equivalent to such device which has not been removed from the market by an order of the Secretary or a judicial order because it is not safe or not effective.

''(G) Not later than 270 days after the date of the enactment of the Food and Drug Administration Regulatory Modernization Act of 1997, the Secretary shall issue guidance specifying the general principles that the Secretary will consider in determining when a specific intended use of a device is not reasonably included within a general use of such device for purposes of a determination of substantial equivalence under subsection (f) or section 520(l).''.

(d) SUNSET.—The amendments made by subsections (a)(1)(A) and (c)(1), to the extent that they relate to an accredited person under section 712 of the Federal Food, Drug, and Cosmetic Act, shall be of no force or effect upon the expiration of 7 years from the date of the enactment of this Act.

SEC. 208. CLASSIFICATION PANELS.

Section 513(b) (21 U.S.C. 360c(b)) is amended by adding at the end the following:

''(5) Classification panels covering each type of device shall be scheduled to meet at such times as may be appropriate for the Secretary to meet applicable statutory deadlines.

''(6)(A) Any person whose device is specifically the subject of review by a classification panel shall have the same rights as the Secretary regarding—

''(i) access to data and information submitted to a classification panel (except for data and information that are not available for public disclosure under section 552 of title 5, United States Code);

''(ii) the submission, for review by a classification panel, of information that is based on the data or information provided in the application submitted under section 515 by the person, which information shall be submitted to the Secretary for prompt transmittal to the classification panel; and

''(iii) the participation of the persons at meetings of the panel.

''(B) Any meetings of a classification panel shall provide adequate time for initial presentations and for response to any differing views by persons whose devices are specifically the subject of a classification panel review, and shall encourage free and open participation by all interested persons.

''(7) After receiving from a classification panel the conclusions and recommendations of the panel on a matter that the panel has reviewed, the Secretary shall review the conclusions and recommendations, shall make a final decision on the matter in accordance with section 515(d)(2), and shall notify the affected persons of the decision in writing and,

if the decision differs from the conclusions and recommendations of the panel, shall include the reasons for the difference.

''(8) A scientific advisory panel under this subsection shall not be subject to the annual chartering and annual report requirements of the Federal Advisory Committee Act.''.

SEC. 209. PREMARKET APPROVAL.

Section 515(d) (21 U.S.C. 360e(d)), as amended by section 203(1), is amended by inserting after paragraph (1) the following:

''(2) Each application received under subsection (c) shall be reviewed in a manner to achieve final action on such application within 180 days of its receipt. At the request of the applicant, the Secretary shall meet with an applicant under such an application within 90 days of the date of the application's submission.''.

SEC. 210. ACCREDITATION FOR ACCREDITED PERSONS.

(a) AMENDMENT.—Subchapter A of chapter VII is amended by adding at the end the following:

''ACCREDITED PERSONS

''SEC. 712. (a) IN GENERAL.—The Secretary shall, not later than 1 year after the date of the enactment of the Food and Drug Administration Regulatory Modernization Act of 1997, accredit persons for the purpose of reviewing and initially classifying devices under section 513(f)(1) that are subject to a report under section 510(k). An accredited person may not be used to perform a review of a class III device, or a class II device which is intended to be permanently implantable or life sustaining or life supporting.

''(b) ACCREDITATION.—

''(1) PROGRAMS.—The Secretary shall provide for such accreditation through programs administered by the Food and Drug Administration, other government agencies, or by other qualified nongovernment organizations.

''(2) ACCREDITATION.—

''(A) GENERAL RULE.—Not later than 180 days after the date of the enactment of the Food and Drug Administration Regulatory Modernization Act of 1997, the Secretary shall establish and publish in the Federal Register requirements to accredit or deny accreditation to persons who request to perform the duties specified in subsection (a). The Secretary shall respond to a request for accreditation within 60 days of the receipt of the request. The accreditation of such person shall specify the particular activities under subsection (a) for which such person is accredited.

''(B) WITHDRAWAL OF ACCREDITATION.—The Secretary may withdraw accreditation of any person accredited under this paragraph, after providing notice and an opportunity for an informal hearing, when such person acts in a manner that is inconsistent with the purposes of this section or poses a threat to public health or fails to act in a manner that is consistent with the purposes of this section.

''(C) PERFORMANCE AUDITING.—To ensure that persons accredited under this section will continue to meet the standards of accreditation, the Secretary shall—

''(i) make onsite visits on a periodic basis to each accredited person to audit the performance of such person; and

''(ii) take such additional measures as the Secretary determines to be appropriate.

''(D) ANNUAL REPORT.—The Secretary shall include in the annual report required under section 903(e)(2) the names of all accredited persons and the particular activities under subsection (a) for which each such person is accredited and the name of each accredited person whose accreditation has been withdrawn during the year.

''(3) QUALIFICATIONS.—An accredited person shall, at a minimum, meet the following requirements:

''(A) Such person shall be an independent organization which is not owned or controlled by a manufacturer, supplier, or vendor of devices and which has no organizational, material, or financial affiliation with such a manufacturer, supplier, or vendor.

''(B) Such person shall be a legally constituted entity permitted to conduct the activities for which it seeks accreditation.

''(C) Such person shall not engage in the design, manufacture, promotion, or sale of devices.

''(D) Such person shall be operated in accordance with generally accepted professional and ethical business practices and shall agree in writing that as a minimum it will—

''(i) certify that reported information accurately reflects data reviewed;

''(ii) limit work to that for which competence and capacity are available;

''(iii) treat information received, records, reports, and recommendations as proprietary information;

''(iv) promptly respond and attempt to resolve complaints regarding its activities for which it is accredited; and

''(v) protect against the use, in carrying out subsection (a) with respect to a device, of any officer or employee of the person who has a financial conflict of interest regarding the device, and annually make available to the public disclosures of the extent to which the person, and the officers and employees of the person, have maintained compliance with requirements under this clause relating to financial conflicts of interest.

''(4) SELECTION OF ACCREDITED PERSONS.—The Secretary shall provide each person who chooses to use an accredited person to receive a section 510(k) report a panel of at least 2 or more accredited persons from which the regulated person may select 1 for a specific regulatory function.''.

(b) CONFORMING AMENDMENT.—Section 301 (21 U.S.C. 331), as amended by section 205(b), is amended by adding at the end the following:

''(z) In the case of a drug, device, or food—

''(1) the submission of a report or recommendation by a person accredited under section 712 that is false or misleading in any material respect;

''(2) the disclosure by a person accredited under section 712 of confidential commercial information or any trade secret without the express written consent of the person who submitted such information or secret to such person; or

''(3) the receipt by a person accredited under section 712 of a bribe in any form or the doing of any corrupt act by such person associated with a responsibility delegated to such person under this Act.''.

(c) SUNSET.—The amendments made by subsections (a) and (b) to the extent they relate to an accredited person under section 712 of the Federal Food, Drug, and Cosmetic Act shall be of no force or effect upon the expiration of 7 years from the date of the enactment of this Act.

(d) REPORT.—Not later than 5 years after the date of the enactment of this Act, the Comptroller General of the United States shall report to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate on the use of accredited persons under section 712 of the Federal Food, Drug, and Cosmetic Act, the extent to which such use was helpful in the implementation of such Act, and the extent to which such use promoted actions which were contrary to the purposes of such Act.

SEC. 211. PREAMENDMENT DEVICES.

Section 515(i) (21 U.S.C. 360e(i)) is amended to read as follows:

''Revision

''(i) Not later than 180 days after the date of the enactment of the Food and Drug Administration Regulatory Modernization Act of 1997, the Secretary shall publish in the Federal Register a list of the types of devices classified into class III under section 513(d), which are not subject to a regulation under subsection (b), and for which the Secretary has determined after classification of such devices that premarket approval is unnecessary to protect the public health. Each such type of device listed in the Federal Register publication shall be reclassified into class II or class I, as appropriate.''.

SEC. 212. DEVICE TRACKING.

Subsection (e) of section 519 (21 U.S.C. 360i) is amended to read as follows:

''Device Tracking

''(e) The Secretary may by order require a manufacturer to adopt a method of tracking a class II or class III device—

''(1) the failure of which would be reasonably likely to have serious adverse health consequences; or

''(2) which is—

''(A) intended to be an implantable device, or

''(B) a life sustaining or life supporting device used outside a device user facility.''.

SEC. 213. POSTMARKET SURVEILLANCE.

Section 522 (21 U.S.C. 360l) is amended to read as follows:

''POSTMARKET SURVEILLANCE

''SEC. 522. (a) IN GENERAL.—The Secretary may by order require a manufacturer to conduct postmarket surveillance for any device of the manufacturer which is a class II or class III device the failure of which would be reasonably likely to have serious adverse health consequences or which is intended to be—

''(1) an implantable device, or

''(2) a life-sustaining or life-supporting device used outside a device user facility.

''(b) SURVEILLANCE APPROVAL.—Each manufacturer required to conduct a surveillance of a device shall, within 30 days of receiving an order from the Secretary prescribing that the manufacturer is required under this section to conduct such surveillance, submit, for the approval of the Secretary, a plan for the required surveillance. The Secretary, within 60 days of the receipt of such plan, shall determine if the person designated to conduct the surveillance has appropriate qualifications and experience to undertake such surveillance and if such plan will result in information necessary to determine the occurrence of unforeseen events. The Secretary, in consultation with the manufacturer, may by order require a prospective surveillance period of up to 36 months. Any determination by the Secretary that a longer period is necessary shall be made by mutual agreement between the Secretary and the manufacturer or, if no agreement can be reached, after the completion of a dispute resolution process as described in section 506A.''.

SEC. 214. HARMONIZATION.

(a) SECTION 520(f).—Section 520(f)(1)(B) (21 U.S.C. 360j(f)(1)(B)) is amended by striking ''and'' at the end of clause (i), by striking the period at the end of clause (ii) and inserting ''; and'' and by adding after clause (ii) the following:

''(iii) ensure that such regulation conforms, to the extent practicable, with internationally recognized standards defining quality systems, or parts thereof, for medical devices.''.

(b) SECTION 803.—Section 803 (21 U.S.C. 383), as amended by section 127, is amended in subsection (c)—

(1) by adding at the end the following sentence: ''The Secretary shall, not later than 180 days after the date of enactment of the Food and Drug Administration Regulatory Modernization Act of 1997, make public a plan that establishes a framework for achieving mutual recognition of good manufacturing practices inspections.'';

(2) by inserting ''(1)'' after ''(c)''; and

(3) by adding at the end the following:

''(2) The Secretary shall report to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate at least 60 days before executing any bilateral or multilateral agreement under paragraph (1).''.

SEC. 215. REPORTS.

(a) REPORTS.—Section 519 (21 U.S.C. 360i) is amended—

(1) in subsection (a)—

(A) in the matter preceding paragraph (1), by striking ''manufacturer, importer, or distributor'' and inserting ''manufacturer or importer''; and

(B) by striking paragraph (9) and inserting the following:

''(9) shall require distributors to keep records and make such records available to the Secretary upon request.'';

(2) by striking subsection (d); and

(3) in subsection (f), by striking '', importer, or distributor'' each place it appears and inserting ''or importer''.

(b) REGISTRATION.—Section 510(g) (21 U.S.C. 360(g)) is amended—

(1) by redesignating paragraph (4) as paragraph (5);

(2) by inserting after paragraph (3) the following:

''(4) any distributor who acts as a wholesale distributor of devices, and who does not manufacture, repackage, process, or relabel a device; or''; and

(3) by adding at the end the following flush sentence:

''In this subsection, the term 'wholesale distributor' means any person who distributes a device from the original place of manufacture to the person who makes the final delivery or sale of the device to the ultimate consumer or user.''.

(c) DEVICE USER FACILITIES.—

(1) IN GENERAL.—Section 519(b) (21 U.S.C. 360i(b)) is amended—

(A) in paragraph (1)(C)—

(i) in the first sentence, by striking ''a semi-annual basis'' and inserting ''an annual basis'';

(ii) in the second sentence, by striking ''and July 1''; and

(iii) by striking the matter after and below clause (iv); and

(B) in paragraph (2)—

(i) in subparagraph (A), by inserting ''or'' after the comma at the end;

(ii) in subparagraph (B), by striking '', or'' at the end and inserting a period; and

(iii) by striking subparagraph (C).

(2) SENTINEL SYSTEM.—Section 519(b) (21 U.S.C. 360i(b)) is amended—

(A) by redesignating paragraph (5) as paragraph (6); and

(B) by inserting after paragraph (4) the following paragraph:

''(5) With respect to device user facilities that are hospitals or nursing homes:

''(A) The Secretary shall by regulation plan and implement a program under which the Secretary limits user reporting under paragraphs (1) through (4) to a subset of hospitals and nursing homes that constitutes a representative profile of user reports for device deaths and serious illnesses or serious injuries.

''(B) During the period of planning the program under subparagraph (A), paragraphs (1) through (4) continue to apply to such device user facilities.

''(C) During the period in which the Secretary is providing for a transition to the full implementation of the program, paragraphs (1) through (4) apply to such facilities except to the extent that the Secretary determines otherwise.

''(D) On and after the date on which the program is fully implemented, paragraphs (1) through (4) do not apply to such a facility unless the facility is included in the subset referred to in subparagraph (A).

''(E) Not later than one year after the date of the enactment of the Food and Drug Administration Regulatory Modernization Act of 1997, the Secretary shall submit to the Committee on Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report describing the plan developed by the Secretary under subparagraph (A) and the progress that has been made toward the implementation of the plan.''.

SEC. 216. PRACTICE OF MEDICINE.

Chapter IX, as amended by section 126, is amended by adding at the end the following:

''SEC. 909. PRACTICE OF MEDICINE.

''Nothing in this Act shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship. This section shall not limit any existing authority of the Secretary to establish and enforce restrictions on the sale or distribution, or in the labeling, of a device that are part of a determination of substantial equivalence, established as a condition of approval, or promulgated through regulations. Further, this section shall not change any existing prohibition on the promotion of unapproved uses of legally marketed devices.''.

SEC. 217. CLARIFICATION OF DEFINITION.

Section 201(h) (21 U.S.C. 321) is amended by adding at the end the following: ''A computer software product shall not be considered a device under this paragraph solely on the basis that the primary use of such product is related to the provision of health care.''.

SEC. 218. LABELING AND ADVERTISING REGARDING COMPLIANCE WITH STATUTORY REQUIREMENTS.

Section 301 (21 U.S.C. 331) is amended by striking paragraph (l).

SEC. 219. FDA ANNUAL REPORT.

Section 903 (21 U.S.C. 393), as amended by section 123(b), is amended in subsection (e)—

(1) by striking the period at the end of paragraph (4) and inserting ''; and''; and

(2) by adding at the end the following:

''(5) summarize and explain each instance in the previous fiscal year in which an application received under section 515(c) was not reviewed in a manner to achieve final action on such application within 180 days of its receipt.''.

SEC. 220. INFORMATION SYSTEM.

Section 906, as added by section 124, is amended by adding at the end the following: ''With respect to devices, the system shall permit access by the applicant under conditions specified by the Secretary.''.

SEC. 221. NONINVASIVE BLOOD GLUCOSE METER.

(a) FINDINGS.—The Congress finds that—

(1) diabetes and its complications are a leading cause of death by disease in America;

(2) diabetes affects approximately 16,000,000 Americans and another 650,000 will be diagnosed in 1997;

(3) the total health care-related costs of diabetes total nearly $100,000,000,000 per year;

(4) diabetes is a disease that is managed and controlled on a daily basis by the patient;

(5) the failure to properly control and manage diabetes results in costly and often fatal complications including but not limited to blindness, coronary artery disease, and kidney failure;

(6) blood testing devices are a critical tool for the control and management of diabetes, and existing blood testing devices require repeated piercing of the skin;

(7) the pain associated with existing blood testing devices creates a disincentive for people with diabetes to test blood glucose levels, particularly children;

(8) a safe and effective noninvasive blood glucose meter would likely improve control and management of diabetes by increasing the number of tests conducted by people with diabetes, particularly children; and

(9) the Food and Drug Administration is responsible for reviewing all applications for new medical devices in the United States.

(b) SENSE OF CONGRESS.—It is the sense of the Congress that the availability of a safe, effective, noninvasive blood glucose meter would greatly enhance the health and well-being of all people with diabetes across America and the world.

SEC. 222. RULE OF CONSTRUCTION.

Nothing in this title or the amendments made by this title shall be construed to affect the question of whether the Secretary of Health and Human Services has any authority to regulate any tobacco product, tobacco ingredient, or tobacco additive. Such authority, if any, shall be exercised under the Federal Food, Drug, and Cosmetic Act as in effect on the day before the date of the enactment of this Act.

TITLE III—IMPROVING REGULATION OF FOOD

SEC. 301. FLEXIBILITY FOR REGULATIONS REGARDING CLAIMS.

Section 403(r)(4) (21 U.S.C. 343(r)(4)) is amended by adding at the end the following:

''(D) Subject to the time period in the last sentence of clause (A)(i), proposed regulations under this paragraph may be made effective upon publication at the discretion of the Secretary, notwithstanding the provisions of section 553 of title 5, United States Code, pending consideration of public comment and publication of a final regulation. Such regulations shall be deemed final agency action for purposes of judicial review.''.

SEC. 302. PETITIONS FOR CLAIMS.

Section 403(r)(4)(A)(i) (21 U.S.C. 343(r)(4)(A)(i)) is amended—

(1) by adding after the second sentence the following: ''If the Secretary does not act within such 100 days, the petition shall be deemed to be denied unless an extension is mutually agreed upon by the Secretary and the petitioner.'';

(2) in the fourth sentence (as amended by paragraph (1)) by inserting immediately before the comma the following: ''or the petition is deemed to be denied''; and

(3) by adding at the end the following: ''If the Secretary does not act within such 90 days, the petition shall be deemed to be denied unless an extension is mutually agreed upon by the Secretary and the petitioner. If the Secretary issues a proposed regulation, the rulemaking shall be completed within 540 days of the date the petition is received by the Secretary. If the Secretary does not issue such a proposed regulation within such 540 days, the Secretary shall provide the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate the reasons action on the proposed regulation did not occur within such 540 days.''.

SEC. 303. HEALTH CLAIMS FOR FOOD PRODUCTS.

Section 403(r)(3) (21 U.S.C. 343(r)(3)) is amended by adding at the end thereof the following:

''(C) Notwithstanding the provisions of clauses (A)(i) and (B), a claim of the type described in subparagraph (1)(B) which is not authorized by the Secretary in a regulation promulgated in accordance with clause (B) shall be authorized and may be made with respect to a food if—

''(i) a scientific body of the United States Government with official responsibility for public health protection or research directly relating to human nutrition (such as the National Institutes of Health or the Centers for Disease Control and Prevention) or the National Academy of Sciences or any of its subdivisions has published an authoritative statement, which is currently in effect, about the relationship between a nutrient and a disease or health-related condition to which the claim refers;

''(ii) a person has submitted to the Secretary, at least 150 days (during which the Secretary may issue a regulation described in subparagraph (4)(D) and may notify any person who is making a claim as authorized by clause (C) that such person has not submitted all the information required by such clause) before the first introduction into interstate commerce of the food with a label containing the claim, (I) a notice of the claim, which shall include the exact words used in the claim and shall include a concise description of the basis upon which such person relied for determining that the requirements of subclause (i) have been satisfied, (II) a copy of the statement referred to in subclause (i) upon which such person relied in making the claim, and (III) a balanced representation of the scientific literature, including a bibliography of such literature, relating to the relationship between a nutrient and a disease or health-related condition to which the claim refers;

''(iii) the claim and the food for which the claim is made are in compliance with clause (A)(ii) and are otherwise in compliance with paragraph (a) and section 201(n); and

''(iv) the claim is stated in a manner so that the claim is an accurate representation of the authoritative statement referred to in subclause (i) and so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet.

For purposes of this clause, a statement shall be regarded as an authoritative statement of a scientific body described in subclause (i) only if the statement is published by the scientific body and shall not include a statement of an employee of the scientific body made in the individual capacity of the employee.

''(D) A claim submitted under the requirements of clause (C) may be made until—

''(i) such time as the Secretary issues a regulation (including a regulation described in subparagraph (4)(D)) under the standard in clause (B)(i)—

''(I) prohibiting or modifying the claim and the regulation has become effective, or

''(II) finding that the requirements of clause (C) have not been met, including finding that the petitioner has not submitted all the information required by such clause; or

''(ii) a district court of the United States in an enforcement proceeding under chapter III has determined that the requirements of clause (C) have not been met.''.

SEC. 304. NUTRIENT CONTENT CLAIMS.

Section 403(r)(2) (21 U.S.C. 343(r)(2)) is amended by adding at the end the following:

''(G) A claim of the type described in subparagraph (1)(A) for a nutrient, for which the Secretary has not promulgated a regulation under clause (A)(i), shall be authorized and may be made with respect to a food if—

''(i) a scientific body of the United States Government with official responsibility for public health protection or research directly relating to human nutrition (such as the National Institutes of Health or the Centers for Disease Control and Prevention) or the National Academy of Sciences or any of its subdivisions has published an authoritative statement, which is currently in effect, which identifies the nutrient level to which the claim refers;

''(ii) a person has submitted to the Secretary, at least 150 days (during which the Secretary may issue a regulation described in subparagraph (4)(D) and may notify any person who is making a claim as authorized by clause (C) that such person has not submitted all the information required by such clause) before the first introduction into interstate commerce of the food with a label containing the claim, (I) a notice of the claim, which shall include the exact words used in the claim and shall include a concise description of the basis upon which such person relied for determining that the requirements of subclause (i) have been satisfied, (II) a copy of the statement referred to in subclause (i) upon which such person relied in making the claim, and (III) a balanced representation of the scientific literature, including a bibliography of such literature, relating to the nutrient level to which the claim refers;

''(iii) the claim and the food for which the claim is made are in compliance with clauses (A) and (B), and are otherwise in compliance with paragraph (a) and section 201(n); and

''(iv) the claim is stated in a manner so that the claim is an accurate representation of the authoritative statement referred to in subclause (i) and so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet.

For purposes of this clause, a statement shall be regarded as an authoritative statement of a scientific body described in subclause (i) only if the statement is published by the scientific body and shall not include a statement of an employee of the scientific body made in the individual capacity of the employee.

''(H) A claim submitted under the requirements of clause (G) may be made until—

''(i) such time as the Secretary issues a regulation (including a regulation described in subparagraph (4)(D))—

''(I) prohibiting or modifying the claim and the regulation has become effective, or

''(II) finding that the requirements of clause (G) have not been met, including finding that the petitioner had not submitted all the information required by such clause; or

''(ii) a district court of the United States in an enforcement proceeding under chapter III has determined that the requirements of clause (G) have not been met.''.

SEC. 305. REFERRAL STATEMENTS.

Section 403(r)(2)(B) (21 U.S.C. 343(r)(2)(B)) is amended to read as follows:

''(B) If a claim described in subparagraph (1)(A) is made with respect to a nutrient in a food, and the Secretary makes a determination that the food contains a nutrient at a level that increases to persons in the general population the risk of a disease or health-related condition that is diet related, then the label or labeling of such food shall contain, prominently and in immediate proximity to such claim, the following statement: 'See nutrition information for ____ content.' The blank shall identify the nutrient associated with the increased disease or health-related condition risk. In making the determination described in this clause, the Secretary shall take into account the significance of the food in the total daily diet.''.

SEC. 306. DISCLOSURE OF IRRADIATION.

Chapter IV (21 U.S.C. 341 et seq.) is amended by inserting after section 403B the following:

''DISCLOSURE

''SEC. 403C. (a) No provision of section 201(n), 403(a), or 409 shall be construed to require on the label or labeling of a food a separate radiation disclosure statement that is more prominent than the declaration of ingredients required by section 403(i)(2).

''(b) In this section, the term 'radiation disclosure statement' means a written statement or symbol that discloses that a food has been intentionally subject to radiation.''.

SEC. 307. IRRADIATION PETITION.

Not later than 60 days following the date of the enactment of this Act, the Secretary of Health and Human Services shall—

(1) make a final determination on any petition pending with the Food and Drug Administration that would permit the irradiation of red meat under section 409(b)(1) of the Federal Food, Drug, and Cosmetic Act; or

(2) provide the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate an explanation of the process followed by the Food and Drug Administration in reviewing the petition referred to in paragraph (1) and the reasons action on the petition was delayed.

SEC. 308. GLASS AND CERAMIC WARE.

(a) IN GENERAL.—The Secretary may not implement any requirement which would ban, as an unapproved food additive, lead and cadmium based paints in the lip and rim area of glass and ceramic ware before the expiration of one year after the date such requirement is published.

(b) LEAD AND CADMIUM BASED PAINT.—Lead and cadmium based paint may not be banned as an unapproved food additive if it is on glass and ceramic ware—

(1) which has less than 60 millimeters of decorating area below the external rim; and

(2) which is not, by design, representation, or custom of usage intended for use by children.

SEC. 309. FOOD CONTACT SUBSTANCES.

(a) FOOD CONTACT SUBSTANCES.—Section 409(a) (21 U.S.C. 348(a)) is amended—

(1) in paragraph (1)—

(A) by striking ''subsection (i)'' and inserting ''subsection (j)''; and

(B) by striking at the end ''or'';

(2) by striking the period at the end of paragraph (2) and inserting ''; or'';

(3) by inserting after paragraph (2) the following:

''(3) in the case of a food additive that is a food contact substance, there is—

''(A) in effect for such substance a regulation issued under this section prescribing the conditions under which such substance may be safely used and such substance and the use of such substance are in conformity with such regulation; or

''(B) a notification submitted under subsection (h) that is in effect.''; and

(4) in the flush matter following paragraph (3) (as added by paragraph (3)), by inserting ''or notification'' after ''regulation'' each place it appears.

(b) NOTIFICATION FOR FOOD CONTACT SUBSTANCES.—Section 409 (21 U.S.C. 348), as amended by subsection (a), is further amended—

(1) by redesignating subsections (h) and (i), as subsections (i) and (j), respectively;

(2) by inserting after subsection (g) the following:

''Notification Relating to a Food Contact Substance

''(h)(1) Subject to such regulations as may be promulgated under paragraph (3), a person manufacturing or supplying a food contact substance may, at least 120 days prior to the introduction or delivery for introduction into interstate commerce of the food contact substance, notify the Secretary of the—

''(A) name of the person;

''(B) identity and intended use of the food contact substance; and

''(C) determination of the person that the intended use of such food contact substance is safe under the standard described in subsection (c)(3)(A).

The notification shall contain the information that forms the basis of the determination and all information required to be submitted by regulations promulgated by the Secretary.

''(2)(A) A notification submitted under paragraph (1) shall become effective 120 days after the date of receipt by the Secretary and the food contact substance may be introduced or delivered for introduction into interstate commerce, unless, within the 120-day period, the Secretary—

''(i) makes a determination that, based on the data and information before the Secretary, such use of the food contact substance has not been shown to be safe under the standard described in subsection (c)(3)(A), or

''(ii) makes a determination under paragraph (3) with respect to the need for a petition under subsection (b) for such food contact substance,

and informs the person of such determination.

''(B) A determination by the Secretary under subparagraph (A)(i) shall constitute final agency action subject to judicial review.

''(C) A notification under this subsection shall be effective only with respect to the person identified in the notification.

''(3)(A) The notification process in this subsection shall be utilized for authorizing the marketing of a food contact substance except where the Secretary determines that submission and review of a petition under subsection (b) is necessary to provide adequate assurance of safety, or where the Secretary and the person manufacturing or supplying the food contact substance agree that such person should submit a petition under subsection (b).

''(B) The Secretary may promulgate regulations to identify the circumstances in which a petition shall be filed under subsection (b) and shall consider criteria such as the probable consumption of a food contact substance and potential toxicity of the food contact substance in determining the circumstances in which a petition shall be filed under subsection (b) with respect to the food contact substance.

''(4) The Secretary shall keep confidential any information provided in a notification under paragraph (1) for 120 days after receipt by the Secretary of the notification. After the expiration of such 120 days, the information shall be available to any interested party except for any matter in the notification that is a trade secret or confidential commercial information.

''(5) In this section, the term 'food contact substance' means any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food.'';

(3) in subsection (i), as so redesignated by paragraph (1), by adding at the end the following: ''The Secretary shall by regulation prescribe the procedure by which the Secretary may deem a notification under subsection (h) to be no longer in effect.''; and

(4) in subsection (j), as so redesignated by paragraph (1), by striking ''subsections (b) to (h)'' and inserting ''subsections (b) to (i)''.

(c) EFFECTIVE DATE.—Notifications under section 409(h) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (b), may be submitted beginning 18 months after the date of enactment of this Act.

SEC. 310. MARGARINE.

(a) SECTION 301(m).—Paragraph (m) of section 301 (21 U.S.C. 331) is amended by striking ''section 407(b) or 407(c)'' and inserting ''section 407''.

(b) SECTION 407.—Section 407 (21 U.S.C. 347) is amended to read as follows:

''OLEOMARGARINE AND MARGARINE

''SEC. 407. No person shall sell, or offer for sale, oleomargarine or colored margarine unless the principal display panel of such oleomargarine or margarine bears as one of its principal features the word 'oleomargarine' or 'margarine' which is in—

''(1) bold type on such panel;

''(2) a size reasonably related to the most prominent printed matter; and

''(3) lines generally parallel to the base on which the package rests as it is designed to be displayed.''.

(c) ACT OF MARCH 16, 1950.—Sections 3(a) and 6 of the Act of March 16, 1950 (21 U.S.C. 347a, 347b) are repealed.

SEC. 311. EFFECTIVE DATE.

The amendments made by this title shall take effect on the date of the enactment of this Act.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Virginia [Mr. BLILEY] and the gentleman from Michigan [Mr. DINGELL] each will control 20 minutes.

The Chair recognizes the gentleman from Virginia [Mr. BLILEY].

GENERAL LEAVE

Mr. BLILEY. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days within which to revise and extend their remarks on this legislation and to insert extraneous material on the bill.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Virginia?

There was no objection.

Mr. BLILEY. Mr. Speaker, I yield myself 4 minutes.

Mr. Speaker, if my colleagues had told me 3 years ago that FDA modernization would come before the House on the suspension calendar, well, I would have asked them to see their doctor. Yet, here we are.

Today brings to an end almost 3 years of work by the Committee on Commerce. When the committee first discussed the need to modernize the FDA in 1995, we knew that outdated rules were slowing down the vital work of the FDA and that patients were the ones who were suffering.

Vital new medicines and medical devices were not getting to the patients who needed them as quickly as they should. As I said back then, it breaks my heart to see American patients having to go overseas to get medicines and medical devices they need to stay alive.

Congress had to act. But it had to act wisely, with prudence and with balance, because the work of the FDA is just too important to do otherwise. That is why our committee launched what I believe was an unprecedented outreach effort. Literally thousands of hours were devoted to reaching out to all corners of the country on this issue.

Our FDA reform team spoke to patients, to medical specialists, to researchers, and to consumer groups. We held 17 hearings over the last 3 years. We compiled more than 2,000 pages of testimony. Our goal then and our goal now was balanced, well-reasoned legislation, legislation that the President would be eager to sign, legislation that honored the medical oath, ''First do no harm.''

We have fulfilled our objectives. Last year we produced a package of legislative proposals that have been hailed from all quarters as balanced and reasonable in their approach. Two of the three bills were unanimously reported by the committee. The third was approved by a voice vote.

These are the bills that have been consolidated into the measure before us today: H.R. 1411, the Prescription Drug User Fee Reauthorization and Drug Regulatory Modernization Act of 1997, which is contained as title I of this bill; H.R. 1710, the Medical Device Regulatory Modernization Act of 1997, which is title II; and H.R. 2469, the Food and Nutrition Information Reform of 1997, which is title III.

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All three of these measures prove, once again, that men and women of goodwill working together can bridge differences. When we put the interests of the American people first, there is nothing that can keep us apart. We have done our homework, we have reached our objectives. We have built a stronger, better, more efficient FDA. We have enhanced the safety of the medicines we take, the food we feed our children, and we are going to help a lot of people.

Medicines will be approved faster and medical devices will get to people sooner, and those with serious and life-threatening diseases will get access to the best experimental new drugs that modern medicine can provide. That is important, Mr. Speaker, because when we are sick, when we are suffering, every minute counts.

Some of my colleagues deserve special praise and thanks. Their work on this issue has been tireless, and the credit for this legislation belongs to them, the members of our FDA reform team: the gentleman from Florida [Mr. BILIRAKIS], chairman of our Subcommittee on Health and Environment, along with the gentleman from Pennsylvania [Mr. GREENWOOD], the gentleman from North Carolina [Mr. BURR], the gentleman from Texas [Mr. BARTON], the gentleman from Wisconsin [Mr. KLUG], and the gentleman from Kentucky [Mr. WHITFIELD].

I want to reach across the aisle, too, to thank our friends the gentlewoman

from California [Ms. ESHOO], the gentleman from New York [Mr. TOWNS] and the gentleman from Texas [Mr. HALL], and I would like to thank our ranking members, the gentleman from Michigan [Mr. DINGELL] and the gentleman from Ohio [Mr. BROWN], for their invaluable contributions to this effort. My colleagues should all be proud of a job very well done. The American people thank them, and I do too.

Mr. Speaker, I reserve the balance of my time.

(Mr. DINGELL asked and was given permission to revise and extend his remarks.)

Mr. DINGELL. Mr. Speaker, I yield myself 3 minutes.

Mr. Speaker, this is an excellent piece of legislation. I strongly urge my colleagues on both sides of the aisle to support it. I believe it should be adopted and should be signed. It represents some remarkable work in terms of bipartisanship by my good friend, the gentleman from Virginia [Mr. BLILEY], by the ranking member of the subcommittee, by the distinguished chairman of the subcommittee, and by a lot of other Members who have worked very hard on this.

The legislation would extend the Prescription Drug User Fee Act, which has resulted in some enormous advances in terms of the functioning of FDA user fees, which have been wise and right. That is a program which has worked well. Today, virtually all drugs and biological products are reviewed in a year or less. Priority drugs for serious illnesses, drugs that represent true clinical breakthroughs, can be reviewed in 6 months or less.

The entire pharmaceutical industry joins with FDA in supporting this program, and when that happens, we know that we have a winner. This program is indeed a winner, because we have witnessed the continued quality of drugs coming from FDA review, both in terms of safety and consumer protections, and they are a monument to the speedy and careful work now possible to be done by an adequately staffed FDA in this area.

The bill contains reforms in medical device regulation. I am especially pleased that a number of these concerns represent actions suggested by the Committee on Commerce's Subcommittee on Oversight and Investigation's 1993 report, ''Less Than the Sum of Its Parts.''

One of the important things accomplished during the negotiations on the medical device portions of the legislation was development of provisions that allow improvements in efficiency and reduce regulatory requirements while maintaining strong public health protection. The bill's sponsors responsibly and carefully negotiated a number of difficult compromises to assure patient safety would not be jeopardized in a careless attempt to speed up market clearance and approval of products. I believe that these provisions strike a difficult but important balance.

Finally, Mr. Speaker, the bill includes provisions for modifications in food labeling requirements that will help consumers to get access to good information more easily and more quickly.

In total and on balance, we have a good piece of legislation before us today. Members of the committee have worked closely together, and I want to thank the gentleman from Virginia [Mr. BLILEY], the chairman of the committee, and the gentleman from Florida [Mr. BILIRAKIS], the chairman of the subcommittee, for their courtesies to me and other Democratic members of the committee.

The staffs of the committee have worked closely together: Howard Cohen, Rodger Currie, Eric Berger, and Kay Holcombe, who will be, I regret to inform the House, leaving the committee staff at the conclusion of this Congress. They deserve particular thanks for bringing us to this point; also, the gentlewoman from California [Ms. ESHOO] and others who have worked so hard to make this possible deserve the appreciation of the committee and of the Congress.

I strongly urge my colleagues on both sides of the aisle to support this legislation. It is good legislation, it serves the public interests, it moves forward the regulatory process, and it serves the interests of the consuming public.

Mr. Speaker, I reserve the balance of my time.

Mr. BLILEY. Mr. Speaker, I yield 4 minutes to the gentleman from Florida [Mr. BILIRAKIS], the chairman of the subcommittee.

(Mr. BILIRAKIS asked and was given permission to revise and extend his remarks.)

Mr. BILIRAKIS. Mr. Speaker, I thank the gentleman for yielding me this time.

Mr. Speaker, today the House is considering landmark legislation which will streamline the drug approval process, provide safer foods to our citizens, and address critical problems in the approval of medical devices.

On September 17, the Subcommittee on Health and Environment approved all three FDA bills by voice vote. On September 25, the full Committee on Commerce approved the drug and food bills by a vote of 43 to zero, and the device bill by voice vote the following day.

In the ensuing days, a small number of outstanding issues were diligently and successfully resolved following bipartisan discussion between Chairman BLILEY and myself, other interested members of the majority, the distinguished ranking member, the gentleman from Michigan, Mr. DINGELL, the gentleman from California, Mr. WAXMAN, and other concerned members of the minority.

As Members may be aware, at the end of last week Chairman BLILEY and the gentleman from Michigan, Mr. DINGELL, coauthored a memo to all members of the Committee on Commerce informing them that these issues had been successfully resolved and that the legislation would be placed on the Suspension Calendar. Since that time, the three reported FDA reform bills, H.R. 1411, H.R. 1710 and H.R. 2469, were consolidated into the substitute version of H.R. 1411. This morning in a bipartisan ''Dear Colleague'' letter, Chairman BLILEY and the gentleman from Michigan, Mr. DINGELL, urged all Members to support the consolidated bill that is now before the House.

In short, the drafting, negotiations and markup of this legislation have been a shining example of what can be accomplished in the spirit of bipartisanship and cooperation among Members.

The foundation of these bills was developed during the last Congress. For those of my colleagues who may not remember, both Republican and Democrat members of the Committee on Commerce sat shoulder-to-shoulder with the FDA on the legislative package to modernize the agency, and while our committee never actually marked up this legislation, these discussions laid the groundwork for the bill we are considering today.

This has been an open process, one which has been open to anyone who is interested in FDA reform. Since the beginning of the 104th Congress, the Committee on Commerce conducted 17 separate formal hearings on FDA reform and FDA-related issues, which represented 72 hours and 44 minutes and 2,094 pages of testimony.

In addition, members of the committee and their staffs have met with patient and consumer groups, medical consumer groups, manufacturers, the FDA and others who are interested in FDA reform. We have had an open door policy throughout the process, and the fact that this bill was placed on the Suspension Calendar with the full support of the gentleman from Michigan [Mr. DINGELL] is a reflection of our success.

There are many, Mr. Speaker, who deserve credit for bringing this legislation before the House. First I want to thank the gentleman from Pennsylvania [Mr. GREENWOOD], who took the time to educate himself and other Members on complex FDA issues. He played a key role in developing this bill. I want to thank the gentleman from North Carolina [Mr. BURR] for his willingness to sponsor the drug reform legislation. His bill will accomplish an important goal: Improving the drug approval process.

The gentleman from Wisconsin [Mr. KLUG], along with the gentleman from Kentucky [Mr. WHITFIELD], the gentleman from Texas [Mr. HALL], and the gentleman from New York [Mr. TOWNS] have been leaders in reforming food laws.

The gentleman from Texas [Mr. BARTON] and the gentlewoman from California [Ms. ESHOO] have dedicated time and energy to writing a bipartisan

medical device bill. Both have been successful in crafting a bill which is considered reasonable and responsible by both Members of Congress and industry.

Finally, I want to thank our full committee chairman, the gentleman from Virginia [Mr. BLILEY], the subcommittee ranking member, the gentleman from Ohio [Mr. BROWN], and the full committee ranking member, the gentleman from Michigan [Mr. DINGELL]. We are considering FDA reform today due to their willingness to work out the details of this legislation with the administration and the FDA.

And of course I also appreciate the support this process has received from both HHS Secretary Donna Shalala and the acting FDA Commissioner, Dr. Michael Friedman. Their leadership and cooperation helped us achieve our ultimate goal of considering practical and thoughtful FDA reform legislation.

Mr. DINGELL. Mr. Speaker, I yield 3 minutes to the gentleman from Ohio [Mr. BROWN].

Mr. BROWN of Ohio. Mr. Speaker, I thank the gentleman for yielding me this time.

Our first goal must be to ensure that patients have access to safe and effective new products as quickly as humanly and scientifically possible. While this bill continues to include some provisions that give me pause, I also believe it includes provisions that are workable, positive and contribute to the goal of ensuring an FDA operation that works in the best interests of its most important customers: Patients.

Nevertheless, as we proceed with this discussion I think it is important to put a few facts in perspective. Many have argued that FDA reform is essential because new and improved drugs and medical devices are not reaching American patients quickly enough. The facts simply do not bear this out.

For example, through FDA's own management initiatives and without any change in legislation, FDA's Center for Devices has overhauled its operations and dramatically improved its review times for new products. Further, I think the majority of medical device manufacturers will agree that the center is more user-friendly and efficient than ever before. I hope as we proceed to conference with this legislation we will look carefully at provisions relating to medical devices to ensure that we are not increasing requirements for FDA in a way that will set back the progress that has been made.

One of the most important provisions included in this legislation is the reauthorization of the Prescription Drug User Fee program. PDUFA has provided the agency with the resources it clearly needed to allow it to continue to be the world leader in the review and the approval of new drugs. If there were one single reason for the House to pass this bill, drug user fees is that reason.

I am pleased the legislation includes some process improvements related to FDA's regulation of generic drugs. While these products are not the breakthrough miracle drugs we read about in headlines, generic drugs are small miracles to millions of elderly patients, especially those living on fixed incomes, who depend on these alternatives which many times are vastly less expensive than brand name products. Generic products generally save billions of dollars in health care costs.

I was disappointed that the bill did not go further in addressing what I believe are several difficult problems related to the review of generic drugs: Frivolous citizen petitions filed by lawyers representing the large drug companies which divert resources and slow the approval of generic alternatives. I hope we can continue to work on these matters, perhaps in the context of future legislation.

I remain concerned about provisions in the bill that allow manufacturers to distribute information about off-label uses of their products. I am not convinced by the arguments that this kind of system is necessary for physicians to have the information they need to treat patients, especially given the companies' financial interest in promoting their products. I will closely monitor this program to determine whether it, in fact, is in the best interests of patients, or simply serves to enrich drug and device companies.

Mr. Speaker, FDA is a remarkably effective agency. I have never been persuaded that massive changes in laws were needed to correct any dreadful problem lurking under the surface, but working with the gentleman from Virginia [Mr. BLILEY], the gentleman from Florida [Mr. BILIRAKIS], the gentleman from Michigan [Mr. DINGELL], and the gentlewoman from California [Ms. ESHOO], I am pleased that this legislation focuses more on modernizing than completely overhauling this very good public agency.

Mr. BLILEY. Mr. Speaker, I yield myself such time as I may consume to point out that not with us this morning is the gentleman from Pennsylvania [Mr. GREENWOOD], whose father underwent bypass surgery yesterday, and I know all of us will want to have him in our prayers.

With that, I yield 3 minutes to the gentleman from North Carolina [Mr. BURR].

(Mr. BURR of North Carolina asked and was given permission to revise and extend his remarks.)

Mr. BURR of North Carolina. Mr. Speaker, I thank the gentleman from Virginia [Mr. BLILEY], and I thank the gentleman from Florida [Mr. BILIRAKIS], the gentleman from Michigan [Mr. DINGELL], the ranking member, and the gentleman from Ohio [Mr. BROWN]. Without their leadership we would not be here today talking about reform of this crucial agency.

I was fortunate in the 104th Congress to be with a group of individuals committed and focused on FDA reform: The gentleman from Pennsylvania [Mr. GREENWOOD], the gentleman from Wisconsin [Mr. KLUG], and the gentleman from Texas [Mr. BARTON], and I truly believe that that was the real impetus behind our success that we are here to put into law today. Without their focus, and the addition of the gentlewoman from California [Ms. ESHOO] and the gentleman from Kentucky [Mr. WHITFIELD], we might not have completed this task, and I am grateful for their commitment.

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I also realize that this has been a taxing process, one that we could not have completed without Howard Cohen, Eric Berger, Rodger Currie, and Kay Holcombe, staff members who devoted countless hours to the changes that Members sought in this very crucial piece of legislation.

This is extraordinary to have H.R. 1411 on the floor, because today is about one thing and one thing only. It is about patients. It is about patients' access to safe, technologically superior, and affordable medical treatment.

Mr. Speaker, throughout the past 2 years I have compiled countless stories of patients and their experience with the Food and Drug Administration. I remember Lissy Mahler from Lansing, NC, who, after trying everything available at the time, sought an investigational treatment therapy for her cancer. The investigational therapy improved the quality of her life and may have prolonged her life.

And there was Frances Swaim, who wrote me as an elderly mother of a child with multiple sclerosis and said, ''Congressman, the only thing I ask is that you change the Food and Drug Administration so that drugs I know are available other places might be approved so my daughter, and others, can in fact benefit with their quality of life.''

Countless patients across this country have visited my office. I remember the day that Steve Seigel came in to talk about Mary Jo's cancer and about the struggle that she went through and the belief that the FDA, to her, had no human face. What have we done over the past 2½ years? We have placed a human face on the FDA and a human face on patients, and for Mary Jo, her dream has become reality.

Mr. Speaker, I also realize that many of the people who visited my office this year will not be back next year because we have not done it quick enough. But it is important that we understand that now is the time for Congress and the Food and Drug Administration to work together to make the changes, to make sure that as the American people cross that ''Bridge to the 21st Century,'' that we do not look back at the FDA, that in fact they go across with us.

FDA modernization is not radical, it is responsible. It is not senseless, it is safe. I urge my colleagues today to remember that in fact passage of this

legislation is about patients and their quality of life.

Mr. DINGELL. Mr. Speaker, I yield 4 minutes to the distinguished gentlewoman from California [Ms. ESHOO].

Ms. ESHOO. Mr. Speaker, title II of the legislation we are going to vote on today was known as H.R. 1710, the Medical Device Regulatory Modernization Act, sponsored by the gentleman from Texas [Mr. BARTON] and myself.

My colleague from Texas and I have worked very, very hard to craft a bill that can and should be broadly supported by the full House today. I salute the gentleman from Texas for his work on the bill and his commitment to making it a bipartisan effort.

Mr. Speaker, I also want to salute the gentleman from Virginia [Mr. BLILEY], the distinguished chairman of the Committee on Commerce; the gentleman from Florida [Mr. BILIRAKIS], the distinguished chairman of the Subcommittee on Health and Environment; the gentleman from Michigan [Mr. DINGELL], our very distinguished ranking member; and the gentleman from Ohio [Mr. BROWN]. Together I think that we have produced something that we can all be proud of.

Mr. Speaker, H.R. 1710 passed the Subcommittee on Health and Environment and the full Committee on Commerce by a voice vote, and the bill enjoyed almost 150 bipartisan cosponsors.

This bill provides the FDA with new authority to recognize performance standards and initially classify devices according to risk. Patients will get greater access. And I want to underscore that, it is so important to the American people. They have greater access to investigational devices and access to devices that will benefit small numbers of people, much like the successful Orphan Drug Program.

The bill provides companies with the opportunity to meet with the FDA to resolve their differences and focus their research early in the review process. In short, Mr. Speaker, this legislation will help move the FDA into the next century.

Mr. Speaker, the bill improves current law by focusing FDA's review process for 510(k) applications, which is the process by which lower risk devices get cleared by the FDA for marketing.

To address concerns raised by the Agency that the bill was too restrictive on their ability to look at the intended use of the device not listed on the proposed label, the bill allows for very narrow circumstances under which the Agency could seek information beyond the label. Decisions to look beyond the label will be made by senior Agency officials, not individual reviewers, and are clearly intended to be the exception rather than the rule. FDA supported this.

Mr. Speaker, the bill amends the FDA's current process for postmarket surveillance and replaces it with authority requiring surveillance of high-risk devices for 3 years, allowing for surveillance periods of even longer periods of time if agreed to by the FDA and the manufacturer. This provision, too, was fully supported by the FDA.

I also want to point out a section of the bill dealing with outside reviewers, so my colleagues are clear on what the bill proposes. We have exempted all class III devices from outside review. We have exempted any class II device that is implantable, life-supporting, or life-sustaining from outside review. If there is a device for which FDA believes no qualified third party review exists, then the Agency will not have to accredit such an entity.

In closing, Mr. Speaker, I want to thank some very key people from our respective staffs that have worked so hard to make sure that this legislation would move forward. In particular, I want to salute Kay Holcombe, Howard Cohen, Rodger Currie, and Eric Berger of the committee staff, Beth Hall of the staff of the gentleman from Texas [Mr. BARTON], and Bill Bates of my own. He has aged considerably from being a very young man at the beginning of this process to this moment.

Mr. Speaker, all of these individuals brought forward their commitment to us to bring forward a bill that we could be proud of, that would deserve and enjoy bipartisan support, and, most of all, benefit the American people by the benefit of what the industry can bring forward in this country.

Mr. BLILEY. Mr. Speaker, I yield 2 minutes to the gentleman from Kentucky [Mr. WHITFIELD].

Mr. WHITFIELD. Mr. Speaker, I thank the gentleman from Virginia [Mr. BLILEY] very much for the leadership that he has provided in this effort today, and I certainly want to commend both sides of the aisle as they worked very hard together. I also want to emphasize the importance of the staff and all of the long hours that they put in on this legislation.

H.R. 2469 passed the Committee on Commerce by a vote of 43 to 0. It is a bill that is going to help us streamline the processing of petitions at FDA. This is a modest first step in our efforts to streamline the Nutrition Labeling and Education Act of 1990. But the changes will provide FDA with additional flexibility as it processes petitions filed at the Agency, provide alternative petition methods for health and nutrient claims, if claims meet the significant scientific standard, and I want to emphasize that that standard is maintained.

This legislation will place a statutory deadline for FDA to complete action on petitions and will address the first amendment problem raised in the Federal court case of The Nutritional Health Alliance versus Shalala. FDA will be required to complete its actions on petitions within 540 days. This is a more liberal standard for FDA than the nonbinding 270-day limitation it placed on itself in response to the Nutritional Health Alliance case I just mentioned.

Of course, many Members wanted to do more, particularly in the area of national uniformity for labeling standards. But as I stated earlier, this is an important first step, and I want to commend all of those who were involved in this legislation.

Mr. DINGELL. Mr. Speaker, I yield 2 minutes to the distinguished gentleman from California [Mr. WAXMAN].

Mr. WAXMAN. Mr. Speaker, the bill we have before us today is the product of a long and intense period of negotiation between people with very different views of the FDA, how it works today, and how it should do its job in the future.

It is a compromise and one that probably makes no one completely happy, but it is a good faith effort to find a common ground so that we could move legislation forward in a timely way to reauthorize what has been one of the most successful programs we have to help the FDA do its job and do it better and faster. That is known as the Prescription Drug User Fee Program, also PDUFA.

It is a program with broad support by industry and the Agency and one that has been widely acknowledged as working and working extremely well. It has led to faster approval of drugs with no diminution of the thoroughness or scope of the review. Throughout the process, it has been the primary goal of every party of this debate to find legislation that could be broadly supported and achieve this reauthorization.

If I were writing the legislation, it would be a very different product than we have before us today. I would not authorize off-label use of drugs or third party review of devices, for example. I would not weaken the FDA authority to fully review devices for all likely uses, and I firmly believe that over the long run, we will regret that we have changed FDA law in this way.

But, Mr. Speaker, I recognize the broad interest in this body and in the Senate in trying out these changes, and I recognize that the FDA negotiated many protections in the way the off-label provisions would work and that the demonstration of third party review of devices is now considerably more limited than when this debate started.

Most particularly, I recognize that we have provided for a sunset of each of these experimental provisions so that all of us will have an opportunity to understand how they have worked and reconsider them, if necessary. To me, that is a critical aspect of these bills.

Mr. Speaker, I am particularly pleased to see provisions in the bill which expand the clinical trial data base which I think can be helpful to many people around the country dealing with many serious and life-threatening diseases.

I join in supporting this legislation, and will have a further statement in the RECORD.

Mr. BLILEY. Mr. Speaker, I yield 3 minutes to the gentleman from Texas [Mr. BARTON].

(Mr. BARTON of Texas asked and was given permission to revise and extend his remarks and to include extraneous matter therein.)

Mr. BARTON of Texas. Mr. Speaker, at the start of the last Congress, consumers were unhappy with the FDA, the medical community was unhappy with the FDA, patient groups were unhappy with the FDA. I would think if we took a poll within the FDA, many of the FDA employees were unhappy with the FDA. It was so bad that at my first hearing on the FDA, I said that FDA stood for ''Foot Dragging and Alibis.''

Mr. Speaker, because of the hearings we had in this Congress and in the last Congress, we have before us today a bipartisan piece of legislation that is a giant step in the right direction toward bringing the FDA into the 20th and 21st century.

I want to thank Speaker GINGRICH for making this a priority. I want to thank the gentleman from Virginia [Mr. BLILEY], chairman of the full committee; the gentleman from Michigan [Mr. DINGELL], the ranking member; the gentleman from Pennsylvania [Mr. KLINK], my colleague and ranking member; the gentleman from Florida [Mr. BILIRAKIS]; Donna Shalala; and President Clinton for making this day a possibility.

On the medical device section of the bill, that is the section of the bill that the gentlewoman from California [Ms. ESHOO] and I have worked so long and hard on, we have a number of improvements. We have a system of third party review for class I and most class II medical devices. We have a system for expedited approval and reporting requirements for devices that have already been approved overseas. We have a strong provision to protect the practice of medicine for the medical community. We have a requirement that they will establish a workable appeals process for arbitrating scientific disputes in the statute, and we reclassify all existing devices so that they are not automatically classified as class III when they come into the Agency.

Mr. Speaker, we allow the manufacturers to announce in the promotional materials that their products have actually been FDA approved.

There is one section of the bill that deals with the scope of review that I want to go into further detail on. This is the process that would allow a product to come to market as long as it is substantially equivalent to a product already on the market.

In the original bill, there was a provision that would require the FDA to make a determination solely on the intend use of the label. Some members of the committee and the FDA felt that this would prohibit them from adequately reviewing the product. So in this package, we have a compromise that is a very carefully constructed provision that would allow the FDA to go beyond the label under certain conditions. They have to be exceptional, they have to be carefully controlled circumstances, and the FDA has admitted that this authority will be rarely used, and only in the most exceptional cases.

We have a good bipartisan agreement between us. The FDA no longer stands for ''Foot Dragging and Alibis,'' it stands for ''Fair Deals for All.''

Mr. Speaker, I hope that we will unanimously support this, and I want to thank my staff member Beth Hall and Bill Bates from the staff of the gentlewoman from California [Ms. ESHOO]. They have done exceptional work, along with the committee staffs on both sides of the aisle.

Mr. DINGELL. Mr. Speaker, I yield 3 minutes to the gentleman from New Jersey [Mr. PALLONE].

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Mr. PALLONE. Mr. Speaker, the legislation before us has been the product of hard work, tough negotiations and true bipartisanship, and the result is a well crafted bill that will reauthorize the Prescription Drug User Fee Act and enact common sense Food and Drug Administration reform.

I want to take the opportunity to congratulate the chairmen and the ranking members of both the full committee and the subcommittee, as well as the professional staff of the Committee on Commerce on both sides of the aisle, particularly Kay Holcombe, whom I work with the most, for a job well done.

Mr. Speaker, this legislation will take the FDA into the 21st century by giving the FDA the tools to continue to do its job effectively while keeping pace with the new technological innovations and medical breakthroughs.

I just wanted to mention, concerning the drug provisions, I am pleased with the inclusion of a bipartisan amendment which would provide for the notification of discontinuance when a company terminates a product the absence of which would cause severe harm to a patient. To allay industry concerns. We have included a ''good cause'' waiver that allows the FDA to waive the time requirement under certain circumstances.

In addition, there are two amendments concerning mercury that were incorporated into the bill. One of the provisions requires the FDA to study the impact of a form of organic mercury in nasal sprays on the brain. It has already been banned for use on agricultural crops since 1969 and has been considered a neurotoxin. And the second provision would examine the sale of mercury as a drug or for other home use.

Mr. Speaker, with regard to medical devices, I want to congratulate the gentlewoman from California [Ms. ESHOO] and the gentleman from Texas [Mr. BARTON] for their ability to find common ground with the FDA and industry on these issues. I believe that the third party review process has been worked out well. It will free up the FDA's limited resources to review and approve high-risk devices.

Finally, Mr. Speaker, I am pleased that language was included to ensure that this legislation does not hinder the FDA's authority to reduce teen smoking. We already know that 3,000 kids start smoking each day, and that in my State of New Jersey alone over 130,000 children currently under 18 will die prematurely from tobacco-related diseases.

Mr. Speaker, it is my expectation that this bill will pass with overwhelming support today, but along with its passing today we must work quickly in conference to report out a good bill that the President can sign into law. The longer we delay, the more risk we take in slowing the drug approval process.

I have to say certainly that the suspension process today, which I never thought would happen, is a very good indication that every one involved is seeking to move quickly and that any differences with the Senate can be quickly overcome. I certainly urge all of my colleagues, not only Members of the committee but all of our colleagues, to register a strong statement of support by voting overwhelmingly for this legislation today.

Mr. BLILEY. Mr. Speaker, I yield 1 minute to the gentleman from Michigan [Mr. UPTON].

Mr. UPTON. Mr. Speaker, I rise in strong support of H.R. 1411, the Food and Drug Administration Regulatory Modernization Act.

Much has been said about the able leadership of our chairman, the gentleman from Virginia [Mr. BLILEY], the gentleman from Texas [Mr. BARTON], the gentleman from Florida [Mr. BILIRAKIS], and our friends on the other side of the aisle, the gentleman from Michigan [Mr. DINGELL], the gentlewoman from California [Ms. ESHOO], and the gentleman from Ohio [Mr. BROWN].

I would also like to comment on our terrific staff on both sides of the aisle. Howard Cohen, Eric Berger and Jane Williams on my staff spent countless hours walking Members through the myriad of different amendments and travails. It was terrific to see us come together in a great moment of bipartisan harmony and pass this legislation out of our full committee 43 to nothing.

This legislation embodies several basic goals that I believe all of us, patients and consumers, health professionals and drug device and food industries, and the Congress, all share. We want to ensure that patients and consumers continue to enjoy the benefits of innovations in treatments and technologies that bring us lifesaving and enhancing drugs and medical devices, with a safe, abundant healthful, affordable food supply.

Mr. DINGELL. Mr. Speaker, I yield 1 minute to the gentleman from Texas [Mr. GREEN].

(Mr. GREEN asked and was given permission to revise and extend his remarks.)

Mr. GREEN. Mr. Speaker, this morning we are considering a bill that I never believed would be debated under suspension rules. In fact, I thought my chances of winning the lottery in Texas were much better than the FDA reform bill being on the suspension calendar.

This bill has had a long and contentious history on the Committee on Commerce. It was not always clear that a compromise bill could be reached. This bill is a step forward for reform. I believe both sides of the aisle should support it, and we have heard this morning they do.

One of the areas that caused the most concern for me was the approval process for medical devices, particularly third party review. I am pleased that the gentlewoman from California [Ms. ESHOO] and the gentleman from Texas [Mr. BARTON] have come together and worked out a compromise that would utilize the expertise of outside reviewers, prevent conflicts of interest, and involve the FDA in the certification of reviewers. Even with the use of outside reviewers, the bill still gives the FDA discretion to accept or deny the recommendations of outside reviewers.

This reform, combined with other portions of the bill, will help medical device companies know what is required of them during the FDA review, and gives them a sense of certainty that their application will be handled within a certain period of time. At the same time, it recognizes the FDA's role at the center of the medical device and drug review process and reassures the American people they will be accountable for the safety and efficacy of drugs and devices.

Mr. BLILEY. Mr. Speaker, I yield such time as he may consume to the gentleman from Florida [Mr. FOLEY].

(Mr. FOLEY asked and was given permission to revise and extend his remarks.)

Mr. FOLEY. Mr. Speaker, I rise in support of the bill, and will include concerns which were not addressed in the bill which would allow the FDA and EPA to ban products used by asthmatics that are medically necessary.

Mr. BLILEY. Mr. Speaker, I yield 1 minute to a member of the committee, the gentleman from Iowa [Mr. GANSKE].

Mr. GANSKE. Mr. Speaker, I rise in strong support of H.R. 1411.

E. coli bacteria results in between 10,000 and 20,000 illnesses a year. While proper cooking can kill *E. coli*, it deprives us of something that many of us really like, a nice juicy rare hamburger. Pasteurizing red meat with low-dose irradiation kills bacteria without harming the food. The process has already been approved by FDA for spices, poultry, pork. Why not hamburger?

For more than 3 years the Food and Drug Administration has been sitting on a petition to allow the use of low-dose irradiation for red meat. It is time that they passed. H.R. 1411 includes an amendment I offered to make the FDA complete its review within 60 days. Mr. Speaker, we need to have safer meat. Low-dose irradiation would provide that. A vote for this bill will make all of us a hamburger helper.

Mr. DINGELL. Mr. Speaker, I yield myself 1 minute for the purposes of a colloquy, and I yield to the distinguished gentleman from Rhode Island [Mr. KENNEDY].

Mr. KENNEDY of Rhode Island. Mr. Speaker, I would like to thank my colleague from Michigan for yielding to me.

Thirty million Americans rely on CFC propelled metered-dose inhalers. These are the inhalers for asthmatics. Over 30 million Americans rely on them. Yet in March 1997, the FDA proposed a policy that would ban these metered-dose inhalers for asthmatics all across the country, while the FDA did not take into account what alternatives would be available to millions of children in this country.

I want to thank the ranking member of the committee and the chairman for recognizing the need to modify this FDA policy, and look forward to working with them to see that appropriate amendments are made to the FDA law so that metered-dose inhalers are not banned for children in this country.

Mr. DINGELL. Mr. Speaker, the committee considered this matter. We regard it as important and we will pursue it further.

Mr. BLILEY. Mr. Speaker, I reserve the balance of my time to close.

Mr. DINGELL. Mr. Speaker, I yield 2 minutes to the gentleman from Florida [Mr. DEUTSCH].

Mr. DEUTSCH. Mr. Speaker, this is what this process is supposed to be about, making legislation to make the people's lives in the United States a little bit better. I believe very strongly that that is what this legislation will do.

I think just for a second though we should remind ourselves that this was not an easy process and it was a long process. I think the work in particular of the gentleman from Michigan [Mr. DINGELL] and other leadership on the Democratic side and the Democratic Members really have brought us toward this point in time. Just 12 months ago, 24 months ago, the FDA legislation that was in front of us was a much more radical, in fact, a radical and really threatening piece of legislation to the American people.

In terms of the prescription drug area, we have made some dramatic strides. I believe there is still one area in the conference committee, I know that the Members, the gentleman from North Carolina [Mr. BURR] in particular, as well as the gentleman from Florida [Mr. BILIRAKIS], will be working on. That is the issue of exclusivity for new antibiotic drugs. The bill limits exclusivity to new antibiotics and that exclusivity would not apply to any drug for which an NDA is already pending. I am also pleased that we have a commitment to continue working on eliminating exclusivity to antibiotics in which there is not a pending I&D, which is the final stage of clinical investigation.

This Congress has made very significant strides in promoting the use of generic drugs in the United States of America as a cost containment and a health issue for all Americans. In an attempt to both balance the need for innovation in terms of resistant strain antibiotics, while at the same time balancing the need for generics and the purpose for generics that this Congress has stated very strongly on many occasions over the last years, I think it is important that any additional exclusivity that we grant in terms of antibiotics, which would be the first time that there would be exclusivity for antibiotic drugs, that it be limited in scope very narrowly to the challenge that we face in terms of resistant strains. I know we have made some moves in that direction, and hopefully as we enter the conference report we can continue that as much as possible within the specifics.

Mr. DINGELL. Mr. Speaker, I yield myself 1 minute for purposes of closure.

I simply want to read the language of the administration on this. It says:

> The administration applauds the House for its efforts to produce a bipartisan FDA reform bill and appreciates the responsiveness to concerns that have been raised. Because of the importance of obtaining a 5-year extension of the Prescription Drug User Fee Act, [PDUFA], the administration has no objection to the House passage of H.R. 1411.

I urge my colleagues to recognize that this is a compromise. This is a good compromise. It represents a bill which makes progress, which serves the public interest, which helps the manufacturers but which also protects the consumer with exquisite care. It is an excellent bill. I urge my colleagues to vote for it.

Mr. BLILEY. Mr. Speaker, I would like to say, it has been said before in the debate but I want to thank the staff, particularly Howard Cohen, Eric Berger, Roger Carey, and Alan Hill and Kay Holcombe.

With that, Mr. Speaker, I yield the balance of my time to the gentleman from Wisconsin [Mr. KLUG].

Mr. KLUG. Mr. Speaker, I thank the gentleman. I have watched a number of young friends in my district grow a head taller as we have worked on this bill for the past 3 years. And while they have outgrown last year's school clothes, unfortunately they cannot outgrow their diseases. Amber still has juvenile diabetes. Cody still has epilepsy. And Kristin still has asthma. Today's bill will go a long way toward easing their suffering by setting up special testing for new drugs aimed at children and expediting new uses for drugs also aimed at treating children's diseases.

This bill is going to go a long way towards easing the suffering of millions

of Americans across this country and obviously not just children. But most importantly, I think that this legislation will go a long way toward changing the culture at the Food and Drug Administration. It is a move away from scare tactics and toward sounds science on food policy, away from redtape and toward sound science and speedy approval on new medical devices. Perhaps most importantly, it is a move away from bureaucracy, and finally toward compassion.

Congratulations to my colleagues who have worked on this bill for so long and so hard for the past 3 years, the gentleman from Virginia [Mr. BLILEY] and the gentleman from Michigan [Mr. DINGELL], the gentleman from Florida [Mr. BILIRAKIS] and the gentleman from California [Mr. WAXMAN], the gentleman from Texas [Mr. BARTON], the gentleman from North Carolina [Mr. BURR], and the gentleman from Pennsylvania [Mr. GREENWOOD]. Our fight has gone back a long way, back to the early days of 1994.

And thanks to the professional staff on both sides who have worked so hard for the last 3 years as well. But most of all, congratulations to my three young friends. For Cody and Amber and Kristin and millions of Americans suffering from diseases across the country, this bill is for them.

Mr. SMITH of New Jersey. Mr. Speaker, I am pleased that today the House has finally taken long-overdue action to reauthorize the Prescription Drug User Fee Act (H.R. 1411).

In 1992, Congress enacted the Prescription Drug User Fee Act (P.L. 102–571) to authorize the Food and Drug Administration [FDA] to collect user fees from pharmaceutical companies to pay for more timely reviews of new, breakthrough drugs. It has been estimated that over $300 million in user fees have been collected under Public Law 102–571 to help finance safety and efficacy trials at the FDA. All of these user fees have been returned directly to the FDA, which used the money to expand its staff and cut review times for new drugs, thereby ensuring that patients ultimately benefit from the program.

H.R. 1411 also institutes a number of important reforms to the FDA to reduce drug review times and provide more information to patients and physicians in a timely manner. The net effect of this legislation will be to save and improve the lives of sick and injured persons across our nation.

But despite these much needed reforms to the FDA, there is much work that remains to be done. Specifically, I am concerned, like many Americans, about the FDA's plans to accelerate the elimination of metered dose inhalers [MDI's] that contain chlorofluorocarbons [CFC's].

As many of you know, on March 6, 1997, the FDA proposed a plan to phase-out the use of CFC's and MDI's, which are used by asthma and cystic fibrosis patients to breathe.

While I agree it is important to institute a transition strategy that will eventually eliminate CFC use, the advance notice of proposed rulemaking [ANPR] published by FDA on March 6 is deeply flawed and should be scrapped in favor of a plan that put patients—not international bureaucrats—first.

And it is Congress which must ensure that the interests of patients are in fact upheld throughout the formation of our country's MDI transition strategy. To that end, my colleague and friend from Florida, Mr. CLIFF STEARNS, and I have introduced legislation, H.R. 2221, that will temporarily suspend the FDA's ANPR until a new proposal can be crafted. It is our intention to offer our legislation as an amendment to H.R. 1411 had we been afforded an opportunity to do so.

Mr. Speaker, our legislation is necessary because the FDA's plan has numerous problems, including the fact that under the plan patients will have significantly fewer choices in asthma medications, which will leave some patients deprived of the medicines that need to breathe.

Specifically, FDA has classified most MDI-delivered respiratory medications into two therapeutic classes. One therapeutic class has five moieties, or drug types which are delivered to the lungs by the MDI, and other has seven moieties. A moiety refers to the drug's active ingredient, and for each moiety there are usually multiple generic versions produced and marketed.

According to the FDA proposal once two moieties are available in a non-CFC MDI form, all other drugs, including generics, in that therapeutic class will be banned. Thus, if you are a patient that relies on a moiety that is banned by the FDA policy, and the two non-CFC MDI's that remain on the market are unsatisfactory or unusable, your very life could be placed at risk.

As Congress continues to assess and debate the best way to craft a CFC transition strategy for metered dose inhalers, I would like to highlight the case of Tommy Farese, a 9-year-old boy from Spring Lake, NJ, who wrote to the FDA in April to oppose their plan. Tommy told the FDA that as someone who depends on Intal, Vanceril, and Provental every day to breathe, he does not want these medications taken away from him.

Under the FDA plan, the entire therapeutic class of drugs Tommy—and other like him—use to survive could be banned when two different non-CFC MDI moieties are marketed. However, if the first two non-CFC MDIs approved by FDA in a therapeutic class do not include the moieties for Intal and Vanceril, Tommy would lose access to the drugs he needs to physically breathe. Mr. Speaker, as the father of two daughters with asthma, I find any plan that could lead to such an outcome completely unacceptable.

Not surprisingly, the FDA's plan has generated a firestorm of opposition from patients, respiratory therapists, and physicians: nearly 10,000 letters in opposition have been received to date by the FDA. Those expressing their concerns about the FDA plan include: Dr. C. Everett Koop, Mothers of Asthmatics, the Joint Council of Allergy, Asthma and Immunology [JCAAI], the Cystic Fibrosis Foundation, the American Medical Association, and the American Association of Respiratory Therapists.

In my view, any plan to remove safe and effective medications from the marketplace needs to place the interests of children like Tommy Farese first and foremost. Sadly, the FDA plans fails in this regard. Indeed, the FDA plan presumes that CFC-free inhalers serve all patient subpopulations—such as children and the elderly—equally well, despite the fact that children have special needs. Therefore, I call upon all Members to support H.R. 2221 and stop the FDA from implementing this terribly flawed and environmentally marginal proposal.

Mr. PAUL. Mr. Speaker, today, out of nowhere, comes the stealth Prescription Drug User Fee Re-authorization and Drug Regulatory Modernization Act of 1997. Regrettably, but unlike certain militarily procured aircraft, a little rain will not make this bill disintegrate.

According to its proponents, this FDA-strengthening bill was more than 3 years in the making—a so-called compromise between industry and the administration, we are told. Yet, despite the 177 pages attempting to reform an administrative agency and its rulemaking direction, the leadership did not see fit to announce floor consideration of this bill in the Weekly Whip Notice, yesterday's Shipping Post's ''Tuesday's Forecast'' section or any other commonly accepted medium as near as I can discern. More curiously, in my attempts to draw some attention to the broadsweeping nature of the bill on the House floor and the process by which it had come up for consideration, I am told by the bill's proponents that ''there is no time available to speak regarding the bill.'' Instead, C–SPAN viewers will be treated to a love-in during which each of the bill's drafters and advocates commend one another for the fine job of corporatism and internationalism they are about to bestow upon the American citizenry and in such a critical aspect of their lives; that is, their health.

When a 177-page bill comes to the floor under suspension with practically nothing more than an hours notice, one must always question what freedom-depriving regulation is about to be forced upon the citizens. Below is a sneak preview of the latest regulatory loss of individual liberty and State sovereignty.

So-called harmonization language contained in the bill requires the Secretary, through bilateral and multilateral agreements, to ''harmonize regulation * * * and seek appropriate reciprocal arrangements'' with foreign regulatory agencies. Vocal opponents of this harmonization language convincingly argue this internationalizing of what is already an unconstitutional usurpation of States rights, is very likely to greatly limit the availability of food supplements by requiring prescriptions for dispensation as is the case in certain parts of Europe. Perhaps with such harmonization, we will not only have a Federal war on drugs, but a Federal war on riboflavin, folic acid, and bee pollen. At last, an American alfalfa czar.

Food supplement availability may be the least of concerns amongst those who still revere states' rights and acknowledge the continued existence of the tenth amendment. Section 28 of H.R. 1411, as available on the Internet, entitled ''National Uniformity,'' ''prohibits states and subdivisions from regulating food, drugs, or cosmetics * * *'' The bill permits the FDA to set national standards for cosmetics but permits States to issue warning labels and take defective products off the shelves.

To the dismay of medical privacy advocates, the bill authorizes the FDA to mandate the tracking of medical patients who use certain medical devices for up to 36 months as well as conduct post-market surveillance of these patients.

The bill limits the speech of manufacturers who would claim health benefits on their product labels without the approval of a scientific

agency of the Federal Government. The bill responsibly makes provisions for such Scientific Advisory Panels in section 6. According to the bill, these panels are to be made up of ''persons who are qualified by training and experience * * * and who, to the extent feasible, possess skill in the use of, or experience in, the development, manufacture, or utilization of * * * drugs or biological products.'' Here we have yet another chapter in the book of corporatism detailing the means by which one politically connected private concern gains a competitive advantage or Government privilege at the expense of some less-politically-connected entity or the consumer via some Federal Government, regulatory framework.

A bill effecting a major reformation of the Food and Drug Administration with such serious implications for individual liberties and for States' ability to effectuate their constitutionally-ordained police powers, warrants something more than the ''stealth'' procedure by which this regulatory ''bomb'' has been brought to the house floor. This bill apparently will be passed without a real opportunity for responsible debate or even a recorded vote. At a minimum, an opportunity to speak or inquire regarding the bill's provisions on the house floor and/or the opportunity to amend the bill to improve or remove offensive language, should have been provided within the legislative process. Unfortunately, this was not the case. For these reasons, I oppose H.R. 1411.

Mr. TOWNS. Mr. Speaker, I join my colleagues in applauding the scheduling of this measure today. H.R. 1411, the Prescription Drug User Fee Reauthorization and Drug Regulatory Modernization Act of 1997 is the culmination of 2 years of hard work by the Commerce Committee to modernize procedures that the Food and Drug Administration uses to approve drugs, devices, and food products.

Without the modernizing steps that have been incorporated in this legislation today, the FDA would continue to be seen as a barrier to new innovative therapies and products. The bill before us today represents a careful balance between a new, streamlined process and consumer protections against harmful products. These innovations in the way the FDA will do business from now on makes the approval of drugs and devices a more predictable process. This legislation will also provide patients with greater access to information about new investigational treatments. Additionally, we established reasonable national uniformity standards for OTC drugs and cosmetics. These standards offer a excellent beginning for future discussions about national uniformity for food products, discussions which I hope will begin next year with hearings on this issue.

Finally, Mr. Chairman, I am most pleased about the provisions in this bill which relate to food products. I had the wonderful experience of working closely on these issues in a bipartisan fashion with the gentleman from Kentucky [Mr. WHITFIELD], the gentleman from Wisconsin [Mr. KLUG], and the gentleman, from Texas [Mr. HALL]. While some argued that food reforms were too controversial to include in this bill, my colleagues and I never stopped believing that we could craft reasonable and meaningful food reforms that would be acceptable to the industry, FDA, and consumers alike. With the able assistance of our committee counsels on both sides of the aisle, Eric Berger and Kay Holcomb, the measures you see before today accomplished this goal. The food issues in this bill build on the success of the Nutrition Labeling and Education Act and they represent a modest downpayment on more significant food law reforms. The bill promises to provide important public health benefits to consumers by enabling FDA to act quickly on petitions for new health and nutrient content claims and by removing impediments to critical food technologies like irradiation.

I join my colleagues from the Commerce Committee in urging the immediate passage of this legislation.

Mr. FRELINGHUYSEN. Mr. Speaker, I rise today in support of H.R. 1411, a package of three bills reforming the Food and Drug Administration.

Clearly, the modernization and streamlining of the FDA are important goals which have commanded considerable thought, time, and energy from Members of Congress, the Agency, and other interested parties. I am pleased that we are acting today on this important legislation, and I look forward to swift passage and enactment.

Mr. Speaker, I come from New Jersey. And I am proud to say that my home State is considered the Nation's medicine chest. New Jersey is home to some of the world's most innovative pharmaceutical companies, including Johnson & Johnson, Merck, American Home Products, Schering Plough, Warner-Lambert, Novartis, Hoffman-La Roche, and Bristol-Myers Squibb, just to name some of them. More than 40,000 pharmaceutical company employees are working in my State, leading the way in discovering, researching, developing, and marketing life-saving new drugs. I am proud to represent these individuals and businesses.

While the bill will benefit these individuals, by reauthorizing the Prescription Drug User Fee Act [PDUFA] and streamlining and modernizing the Agency, I am supporting H.R. 1411 today because it benefits a larger group: America's patients. All Americans who are in desperate need of new therapies for Alzheimer's, Parkinson's disease, cancer, AIDS, and all other maladies for which no adequate drug treatment exists today. Furthermore, our work benefits the world in every country where there is sickness and suffering.

There is so much in this bipartisan bill that is designed to help patients. There is the reauthorization of PDUFA, the enactment of which has meant more to expediting approval of life-saving new therapies than anything else. Last year, the FDA approved 53 new drugs and 9 new biologics. Since enactment of PDUFA, FDA has approved more than 125 new molecular entities—totally new medicines—all of which have brought relief and benefit to patients.

H.R. 1411 also provides for expedited approval of life-saving new medicines and access to unapproved therapies for the most critically ill among us. The bill allows manufacturers to disseminate information about unapproved uses of approved drugs, while ensuring that the information is balanced and encourages additional research on already-approved products.

The package also facilitates the development, clearance, and use of devices to maintain and improve public health and quality of life.

Finally, H.R. 1411 maintains the Agency's high standards of efficacy and consumer safety.

Mr. Speaker, when we enact this legislation, we will be giving the hope of better health and longer lives to millions of Americans and people around the world. That is good news for New Jersey and good news for America. I urge support of this legislation.

Mr. STEARNS. Mr. Speaker, I rise in support of H.R. 1411. First, I would like to thank Chairman BLILEY and Chairman BILIRAKIS and the staff for getting us to this point. It has been a long and at times very difficult process and you are to be commended for your leadership.

I would also like to give special thanks to my colleagues, Representatives RICHARD BURR, JOE BARTON, and ED WHITFIELD for all their hard work on these three bills.

Legislative proposals to reform the FDA to speed up the approval process for new drugs and medical devices and to improve the regulation and labeling of food is long overdue. Today's vote is historic and I am pleased to see that we have finally gotten to this point.

The problems associated with FDA's regulation of products and related issues are already known in the biomedical industry. Several key issues are: how regulation affects patient access to new drugs, how it impedes new drugs and biotechnology products from being brought to market, and how regulatory delays are forcing drug and medical device companies overseas.

If we are to continue to compete in this global economy, we must streamline the current FDA approval process. Because European review of new medical technologies is more efficient and timely than the FDA, these companies are increasingly moving out of the United States. Start-up biotech companies, also unable to meet the capital demands due to the lengthy and uncertain FDA process, have lost thousands of jobs through both direct exports and opportunity costs.

While our position has slipped in recent years, the United States is still the world's leader in the development and production of medical technology. However, the sad fact is that the United States is beginning to lose ground in health technology to foreign competitors. Unless we provide relief for this industry and curb FDA's burdensome over regulation and countless delays in the approval process, we will continue to see a steady erosion in an industry in which we have always been recognized as a world leader.

It is very gratifying to be a part of this process and I want to applaud the Commerce Committee's desire to make these necessary changes contained in the legislation before us today. We have an opportunity to reverse the trends which have our companies going outside the United States to conduct initial development of new products. When this occurs, not only do we lose jobs, but we also lose U.S.-produced technologies.

One question that we might ask is: What are we doing in comparison to the rest of the world. For instance, it might be useful to have a list of these products and whether they have been approved in tier one countries and for how long. Perhaps there should be some type of annual report that provides us with that type of data. If the FDA objects to this, I think it might be advisable to ask what we can do to make sure that the FDA makes such information available in the future.

While I wholeheartedly support H.R. 1411, I want to call my colleagues attention to an issue I believe is of tremendous importance and that needs to be addressed.

On March 6, 1997, the FDA issued an advance notice of proposed rulemaking [ANPR] that set forth its plan to ban CFC-containing metered-dose inhalers once certain criteria are met. The plan was developed in collaboration with the Environmental Protection Agency [EPA] and is intended to eliminate the minuscule amount of CFC's currently allowed to be used for medications delivered by metered-dose inhalers.

We need to protect the health and well-being of the millions of Americans that use chlorofluorocarbon-containing metered-dose inhalers to treat their respiratory conditions. My colleague, CHRISTOPHER SMITH, and I introduced H.R. 2221. This bill will require the Secretary of Health and Human Services to take no further action on FDA's proposed ban on chlorofluorocarbon [CFC]-containing metered-dose inhalers.

During the full committee markup of PDUFA, I offered an amendment to rectify a serious issue that has arisen due to actions taken by the FDA. Because I did not want to impede the process, I withdrew my amendment. However, I do intend to pursue this issue until I am satisfied that all patients who rely on such life saving drugs will not be denied their rights to such medications.

Again, I want to reiterate my support for H.R. 1411 and look forward to its final passage.

Mr. RAMSTAD. Mr. Speaker, I rise in support of the package of Food and Drug Administration [FDA] reform bills before us today.

I support this entire package, but I would like to specifically talk about title II of this bill, which addresses medical devices.

Reforming FDA's approval process for medical devices is something I have worked on since I first come to Congress in 1991. I have long argued we can save lives, health care dollars, and jobs by creating a more hospitable climate for our biotechnology, pharmaceutical, food, and medical device industries.

That's why, in November 1993, former Rep. Tim Valentine—D–NC—and I founded the bipartisan House Medical Technology Caucus to educate our colleagues on the issues facing the medical technology sector, including the FDA approval process.

As a cosponsor of H.R. 1710, the base language for title II, I know the legislation to expedite review of medical devices will go a long way toward bringing medical devices to market faster, thereby saving lives and creating jobs in this country. With intelligent coordination of regulatory strategies consistent with good science and good manufacturing practices, we can move needed drugs and medical devices to consumers in less time without increasing risk.

The FDA must review products and procedures promptly and effectively, since one of the most important ways to help individuals in need of lifesaving products and procedures is to make sure these products are made accessible as soon as possible without compromising safety.

It now takes 15 years and $350 million to get the average new drug from the laboratory to the patient. The average time for the FDA to approve a medical device has increased from 415 days in 1990 to 773 in 1995—even through the FDA is currently required by law to taken no longer than 180 days to approve new devices. In addition, the majority of all new drugs approved by the FDA in the last 5 years were already in use overseas.

The package of FDA reform legislation will improve the approval process for medical devices, drugs, and biological products without reducing the level of protection for safety or effectiveness.

I urge my colleagues to support this bill today. The patients in our country who have been denied access to lifesaving drugs and devices deserve nothing less.

Mr. SHAYS. Mr. Speaker, I rise in support of H.R. 1411, the Food and Drug Administration Regulatory Modernization Act of 1997. I commend the committee for bringing this bipartisan bill to the full House for consideration.

Since I became chairman of the Government Reform and Oversight Committee's Subcommittee on Human Resources, we have held 14 oversight hearings on the Food and Drug Administration [FDA]. In the course of oversight hearings on medical device regulatory standards, food safety, the food additive petition review process, and the safety of the Nation's blood supply, we found the agency needs to be modernized and streamlined. This bill makes progress toward these goals, while protecting the public health.

I am particularly pleased the compromise struck by the committee provides greater clarity to the medical device approval process by ensuring that FDA's review will be based on the intended use cited on the proposed label submitted by the manufacturer. As an added safeguard, FDA will have procedures to require the manufacturer to place a warning on the label if the agency believes the device will be used for conditions other tan those listed on the label.

Enactment of this legislation will result in lifesaving therapies reaching patients in a more timely fashion. I commend the Commerce Committee for its fair and deliberate approach to meaningful FDA reform.

Mr. FRELINGHUYSEN. Mr. Speaker, I rise to day in support of H.R. 1411, legislation which includes three important reforms and commend Chairman BLILEY and his Commerce Committee for all their hard work on this bill.

First, the bill will reauthorize the Prescription Drug User Fee Act, a user fee that has been tremendously effective in expediting the FDA drug approval process. That reauthorization is absolutely critical.

Second, H.R. 1411 streamlines and vastly improves the FDA drug approval process, clearing the way for lifesaving new drugs to reach individuals in need of them.

Finally, the package facilitates the development, clearance, and use of devices to maintain public health and improve the quality of life for many Americans and so many people around the world that are sick and suffering.

This legislation is certainly a priority for the State of New Jersey, which is home to many of the most innovative pharmaceutical companies and more than 40,000 employees, that have led the way in research, development, and marketing of lifesaving new drugs throughout the world.

However, New Jersey is also home to even more individuals that are in desperate need of new therapies for Alzheimer's, Parkinson's disease, cancer, AIDS and other diseases, for which no adequate drug treatment exists today.

I am pleased that the legislation also maintains and strengthens protection for consumers under the Food and Drug Administration Director.

I would like to commend the Commerce Committee for their hard work on this bill and urge support for H.R. 1411.

The SPEAKER pro tempore (Mr. QUINN). The question is on the motion offered by the gentleman from Virginia [Mr. BLILEY] that the House suspend the rules and pass the bill, H.R. 1411, as amended.

The question was taken; and (two-thirds having voted in favor thereof) the rules were suspended and the bill, as amended, was passed.

□ 1130

The title of the bill was amended so as to read: ''A bill to amend the Federal Food, Drug, and Cosmetic Act to improve the regulation of food, drugs, cosmetics, and devices, and for other purposes.''.

A motion to reconsider was laid on the table.

Mr. BLILEY. Mr. Speaker, I ask unanimous consent to take from the Speaker's table the Senate bill (S. 830) to amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to improve the regulation of food, drugs, devices, and biological products, and for other purposes, and ask for its immediate consideration in the House.

The Clerk read the title of the Senate bill.

The SPEAKER pro tempore (Mr. QUINN). Is there objection to the request of the gentleman from Virginia?

There was no objection.

The Clerk read the Senate bill as follows:

S. 830

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Food and Drug Administration Modernization and Accountability Act of 1997''.

SEC. 2. TABLE OF CONTENTS.

The table of contents for this Act is as follows:

SEC. 3. REFERENCES.

Except as otherwise expressly provided, wherever in this Act an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.).

TITLE I—IMPROVING PATIENT ACCESS

SEC. 101. MISSION OF THE FOOD AND DRUG ADMINISTRATION.

Section 903 (21 U.S.C. 393) is amended—

(1) by redesignating subsections (b) and (c) as subsections (c) and (d), respectively; and

(2) by inserting after subsection (a) the following:

''(b) MISSION.—

''(1) IN GENERAL.—The Secretary, acting through the Commissioner, and in consultation, as determined appropriate by the Secretary, with experts in science, medicine, and public health, and in cooperation with consumers, users, manufacturers, importers, packers, distributors, and retailers of regulated products, shall protect the public health by taking actions that help ensure that—

''(A) foods are safe, wholesome, sanitary, and properly labeled;

''(B) human and veterinary drugs, including biologics, are safe and effective;

''(C) there is reasonable assurance of safety and effectiveness of devices intended for human use;

''(D) cosmetics are safe; and

''(E) public health and safety are protected from electronic product radiation.

''(2) SPECIAL RULES.—The Secretary, acting through the Commissioner, shall promptly and efficiently review clinical research and take appropriate action on the marketing of regulated products in a manner that does not unduly impede innovation or product availability. The Secretary, acting through the Commissioner, shall participate with other countries to reduce the burden of regulation, to harmonize regulatory requirements, and to achieve appropriate reciprocal arrangements with other countries.''.

SEC. 102. EXPANDED ACCESS TO INVESTIGATIONAL THERAPIES.

Chapter V (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

''Subchapter D—Unapproved Therapies and Diagnostics

''SEC. 551. EXPANDED ACCESS TO UNAPPROVED THERAPIES AND DIAGNOSTICS.

''(a) EMERGENCY SITUATIONS.—The Secretary may, under appropriate conditions determined by the Secretary, authorize the shipment of investigational drugs (including investigational biological products), or investigational devices, (as defined in regulations prescribed by the Secretary) for the diagnosis, monitoring, or treatment of a serious disease or condition in emergency situations.

''(b) INDIVIDUAL PATIENT ACCESS TO INVESTIGATIONAL PRODUCTS INTENDED FOR SERIOUS DISEASES.—Any person, acting through a physician licensed in accordance with State law, may request from a manufacturer or distributor, and any manufacturer or distributor may provide to such physician after compliance with the provisions of this subsection, an investigational drug (including an investigational biological product), or investigational device, (as defined in regulations prescribed by the Secretary) for the diagnosis, monitoring, or treatment of a serious disease or condition if—

''(1) the licensed physician determines that the person has no comparable or satisfactory alternative therapy available to diagnose, monitor, or treat the disease or condition involved, and that the risk to the person from the investigational drug or investigational device is not greater than the risk from the disease or condition;

''(2) the Secretary determines that there is sufficient evidence of safety and effectiveness to support the use of the investigational drug or investigational device in the case described in paragraph (1);

''(3) the Secretary determines that provision of the investigational drug or investigational device will not interfere with the initiation, conduct, or completion of clinical investigations to support marketing approval; and

''(4) the product sponsor, or clinical investigator, of the investigational drug or investigational device submits to the Secretary a clinical protocol consistent with the provisions of section 505(i) or 520(g) and any regulations promulgated under section 505(i) or 520(g) describing the use of investigational drugs or investigational devices in a single patient or a small group of patients.

''(c) TREATMENT INDS/IDES.—Upon submission by a product sponsor or a physician of a protocol intended to provide widespread access to an investigational product for eligible patients, the Secretary shall permit an investigational drug (including an investigational biological product) or investigational device to be made available for expanded access under a treatment investigational new drug application or investigational device exemption (as the terms are described in regulations prescribed by the Secretary) if the Secretary determines that—

''(1) under the treatment investigational new drug application or investigational device exemption, the investigational drug or investigational device is intended for use in the diagnosis, monitoring, or treatment of a serious or immediately life-threatening disease or condition;

''(2) there is no comparable or satisfactory alternative therapy available to diagnose, monitor, or treat that stage of disease or condition in the population of patients to which the investigational drug or investigational device is intended to be administered;

''(3)(A) the investigational drug or investigational device is under investigation in a controlled clinical trial for the use described in paragraph (1) under an effective investigational new drug application or investigational device exemption; and

''(B) all clinical trials necessary for approval of that use of the investigational drug or investigational device have been completed;

''(4) the sponsor of the controlled clinical trials is actively pursuing marketing approval of the investigational drug or investigational device for the use described in paragraph (1) with due diligence;

''(5) the provision of the investigational drug or investigational device will not interfere with the enrollment of patients in ongoing clinical investigations under section 505(i) or 520(g);

''(6) in the case of serious diseases, there is sufficient evidence of safety and effectiveness to support the use described in paragraph (1); and

''(7) in the case of immediately life-threatening diseases, the available scientific evidence, taken as a whole, provides a reasonable basis to conclude that the product may be effective for its intended use and would not expose patients to an unreasonable and significant risk of illness or injury.

A protocol submitted under this subsection shall be subject to the provisions of section 505(i) or 520(g) and regulations promulgated under section 505(i) or 520(g). The Secretary may inform national, State, and local medical associations and societies, voluntary health associations, and other appropriate persons about the availability of an investigational drug or investigational device under expanded access protocols submitted under this subsection. The information provided by the Secretary, in accordance with the preceding sentence, shall be of the same type of information that is required by section 402(j)(3).

''(d) TERMINATION.—The Secretary may, at any time, with respect to a person, manufacturer, or distributor described in this section, terminate expanded access provided under this section for an investigational drug (including an investigational biological product) or investigational device if the requirements under this section are no longer met.''.

SEC. 103. EXPANDED HUMANITARIAN USE OF DEVICES.

Section 520(m) (21 U.S.C. 360j(m)) is amended—

(1) in paragraph (2), by adding at the end the following flush sentences:

''The request shall be in the form of an application submitted to the Secretary. Not later than 75 days after the date of the receipt of the application, the Secretary shall issue an order approving or denying the application.'';

(2) in paragraph (4)—

(A) in subparagraph (B), by inserting after ''(2)(A)'' the following: '', unless a physician determines that waiting for such an approval from an institutional review committee will cause harm or death to a patient, and makes a good faith effort to obtain the approval, and does not receive a timely response from an institutional review committee on the request of the physician for approval to use the device for such treatment or diagnosis''; and

(B) by adding at the end the following flush sentences:

''In a case in which a physician described in subparagraph (B) uses a device without an approval from an institutional review committee, the physician shall, after the use of the device, notify the chairperson of the institutional review committee of such use. Such notification shall include the identification of the patient involved, the date on which the device was used, and the reason for the use.''; and

(3) by striking paragraph (5) and inserting the following:

''(5) The Secretary may require a person granted an exemption under paragraph (2) to demonstrate continued compliance with the requirements of this subsection if the Secretary believes such demonstration to be necessary to protect the public health or if the Secretary has reason to believe that the criteria for the exemption are no longer met.''.

TITLE II—INCREASING ACCESS TO EXPERTISE AND RESOURCES

SEC. 201. INTERAGENCY COLLABORATION.

Section 903(b) (21 U.S.C. 393(b)), as added by section 101(2), is amended by adding at the end the following:

''(3) INTERAGENCY COLLABORATION.—The Secretary shall implement programs and policies that will foster collaboration between the Administration, the National Institutes of Health, and other science-based Federal agencies, to enhance the scientific and technical expertise available to the Secretary in the conduct of the duties of the Secretary with respect to the development, clinical investigation, evaluation, and postmarket monitoring of emerging medical therapies, including complementary therapies, and advances in nutrition and food science.''.

SEC. 202. SENSE OF THE COMMITTEE REGARDING MUTUAL RECOGNITION AGREEMENTS AND GLOBAL HARMONIZATION EFFORTS.

It is the sense of the Committee on Labor and Human Resources of the Senate that—

(1) the Secretary of Health and Human Services should support the Office of the United States Trade Representative, in consultation with the Secretary of Commerce, in efforts to move toward the acceptance of mutual recognition agreements relating to the regulation of drugs, biological products, devices, foods, food additives, and color additives, and the regulation of good manufacturing practices, between the European Union and the United States;

(2) the Secretary of Health and Human Services should regularly participate in meetings with representatives of other foreign governments to discuss and reach agreement on methods and approaches to harmonize regulatory requirements; and

(3) the Office of International Relations of the Department of Health and Human Services (as established under section 803 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 383)) should have the responsibility of ensuring that the process of harmonizing international regulatory requirements is continuous.

SEC. 203. CONTRACTS FOR EXPERT REVIEW.

Chapter IX (21 U.S.C. 391 et seq.) is amended by adding at the end the following:

''SEC. 906. CONTRACTS FOR EXPERT REVIEW.

''(a) IN GENERAL.—

''(1) AUTHORITY.—The Secretary may enter into a contract with any organization or any individual (who is not an employee of the Department) with expertise in a relevant discipline, to review, evaluate, and make recommendations to the Secretary on part or all of any application or submission (including a petition, notification, and any other similar form of request) made under this Act for the approval or classification of an article or made under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) with respect to a biological product. Any such contract shall be subject to the requirements of section 708 relating to the confidentiality of information.

''(2) INCREASED EFFICIENCY AND EXPERTISE THROUGH CONTRACTS.—The Secretary shall use the authority granted in paragraph (1) whenever the Secretary determines that a contract described in paragraph (1) will improve the timeliness or quality of the review of an application or submission described in paragraph (1), unless using such authority would reduce the quality, or unduly increase the cost, of such review. Such improvement may include providing the Secretary increased scientific or technical expertise that is necessary to review or evaluate new therapies and technologies.

''(b) REVIEW OF EXPERT REVIEW.—

''(1) IN GENERAL.—Subject to paragraph (2), the official of the Food and Drug Administration responsible for any matter for which expert review is used pursuant to subsection (a) shall review the recommendations of the organization or individual who conducted the expert review and shall make a final decision regarding the matter within 60 days after receiving the recommendations.

''(2) LIMITATION.—A final decision under paragraph (1) shall be made within the applicable prescribed time period for review of the matter as set forth in this Act or in the Public Health Service Act (42 U.S.C. 201 et seq.).

''(3) AUTHORITY OF SECRETARY.—Notwithstanding subsection (a), the Secretary shall retain full authority to make determinations with respect to the approval or disapproval of an article under this Act, the approval or disapproval of a biologics license with respect to a biological product under section 351(a) of the Public Health Service Act, or the classification of an article as a device under section 513(f)(1).''.

SEC. 204. ACCREDITED-PARTY REVIEWS.

(a) IN GENERAL.—Subchapter A of chapter V (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

''SEC. 523. ACCREDITED-PARTY PARTICIPATION.

''(a) ACCREDITATION.—Not later than 1 year after the date of enactment of this section, the Secretary shall accredit entities or individuals who are not employees of the Federal Government to review reports made to the Secretary under section 510(k) for devices and make recommendations to the Secretary regarding the initial classification of such devices under section 513(f)(1), except that this paragraph shall not apply to a report made to the Secretary under section 510(k) for a device that is—

''(1) for a use in supporting or sustaining human life;

''(2) for implantation in the human body for more than 1 year; or

''(3) for a use that is of substantial importance in preventing the impairment of human health.

''(b) ACCREDITATION.—Within 180 days after the date of enactment of this section, the Secretary shall adopt methods of accreditation that ensure that entities or individuals who conduct reviews and make recommendations under this section are qualified, properly trained, knowledgeable about handling confidential documents and information, and free of conflicts of interest. The Secretary shall publish the methods of accreditation in the Federal Register on the adoption of the methods.

''(c) WITHDRAWAL OF ACCREDITATION.—The Secretary may suspend or withdraw the accreditation of any entity or individual accredited under this section, after providing notice and an opportunity for an informal hearing, if such entity or individual acts in a manner that is substantially not in compliance with the requirements established by the Secretary under subsection (b), including the failure to avoid conflicts of interest, the failure to protect confidentiality of information, or the failure to competently review premarket submissions for devices.

''(d) SELECTION AND COMPENSATION.—A person who intends to make a report described in subsection (a) to the Secretary shall have the option to select an accredited entity or individual to review such report. Upon the request by a person to have a report reviewed by an accredited entity or individual, the Secretary shall identify for the person no less than 2 accredited entities or individuals from whom the selection may be made. Compensation for an accredited entity or individual shall be determined by agreement between the accredited entity or individual and the person who engages the services of the accredited entity or individual and shall be paid by the person who engages such services.

''(e) REVIEW BY SECRETARY.—

''(1) IN GENERAL.—The Secretary shall require an accredited entity or individual, upon making a recommendation under this section with respect to an initial classification of a device, to notify the Secretary in writing of the reasons for such recommendation.

''(2) TIME PERIOD FOR REVIEW.—Not later than 30 days after the date on which the Secretary is notified under paragraph (1) by an accredited entity or individual with respect to a recommendation of an initial classification of a device, the Secretary shall make a

determination with respect to the initial classification.

''(3) SPECIAL RULE.—The Secretary may change the initial classification under section 513(f)(1) that is recommended by the accredited entity or individual under this section, and in such case shall notify in writing the person making the report described in subsection (a) of the detailed reasons for the change.

''(f) DURATION.—The authority provided by this section terminates—

''(1) 5 years after the date on which the Secretary notifies Congress that at least 2 persons accredited under subsection (b) are available to review at least 60 percent of the submissions under section 510(k); or

''(2) 4 years after the date on which the Secretary notifies Congress that at least 35 percent of the devices that are subject to review under subsection (a), and that were the subject of final action by the Secretary in the fiscal year preceding the date of such notification, were reviewed by the Secretary under subsection (e),

whichever occurs first.

''(g) REPORT.—

''(1) IN GENERAL.—Not later than 1 year after the date of enactment of this section, the Secretary shall contract with an independent research organization to prepare and submit to the Secretary a written report examining the use of accredited entities and individuals to conduct reviews under this section. The Secretary shall submit the report to Congress not later than 6 months prior to the conclusion of the applicable period described in subsection (f).

''(2) CONTENTS.—The report by the independent research organization described in paragraph (1) shall identify the benefits or detriments to public and patient health of using accredited entities and individuals to conduct such reviews, and shall summarize all relevant data, including data on the review of accredited entities and individuals (including data on the review times, recommendations, and compensation of the entities and individuals), and data on the review of the Secretary (including data on the review times, changes, and reasons for changes of the Secretary).''.

(b) RECORDKEEPING.—Section 704 (21 U.S.C. 374) is amended by adding at the end the following:

''(f)(1) A person accredited under section 523 to review reports made under section 510(k) and make recommendations of initial classifications of devices to the Secretary shall maintain records documenting the training qualifications of the person and the employees of the person, the procedures used by the person for handling confidential information, the compensation arrangements made by the person in accordance with section 523(d), and the procedures used by the person to identify and avoid conflicts of interest. Upon the request of an officer or employee designated by the Secretary, the person shall permit the officer or employee, at all reasonable times, to have access to, to copy, and to verify, the records.

''(2) Within 15 days after the receipt of a written request from the Secretary to a person accredited under section 523 for copies of records described in paragraph (1), the person shall produce the copies of the records at the place designated by the Secretary.''.

SEC. 205. DEVICE PERFORMANCE STANDARDS.

(a) ALTERNATIVE PROCEDURE.—Section 514 (21 U.S.C. 360d) is amended by adding at the end the following:

''Recognition of a Standard

''(c)(1)(A) In addition to establishing performance standards under this section, the Secretary may, by publication in the Federal Register, recognize all or part of a performance standard established by a nationally or internationally recognized standard development organization for which a person may submit a declaration of conformity in order to meet premarket submission requirements or other requirements under this Act to which such standards are applicable.

''(B) If a person elects to use a performance standard recognized by the Secretary under subparagraph (A) to meet the requirements described in subparagraph (A), the person shall provide a declaration of conformity to the Secretary that certifies that the device is in conformity with such standard. A person may elect to use data, or information, other than data required by a standard recognized under subparagraph (A) to fulfill or satisfy any requirement under this Act.

''(2) The Secretary may withdraw such recognition of a performance standard through publication of a notice in the Federal Register that the Secretary will no longer recognize the standard, if the Secretary determines that the standard is no longer appropriate for meeting the requirements under this Act.

''(3)(A) Subject to subparagraph (B), the Secretary shall accept a declaration of conformity that a device is in conformity with a standard recognized under paragraph (1) unless the Secretary finds—

''(i) that the data or information submitted to support such declaration does not demonstrate that the device is in conformity with the standard identified in the declaration of conformity; or

''(ii) that the standard identified in the declaration of conformity is not applicable to the particular device under review.

''(B) The Secretary may request, at any time, the data or information relied on by the person to make a declaration of conformity with respect to a standard recognized under paragraph (1).

''(C) A person relying on a declaration of conformity with respect to a standard recognized under paragraph (1) shall maintain the data and information demonstrating conformity of the device to the standard for a period of 2 years after the date of the classification or approval of the device by the Secretary or a period equal to the expected design life of the device, whichever is longer.''.

(b) SECTION 301.—Section 301 (21 U.S.C. 331) is amended by adding at the end the following:

''(x) The falsification of a declaration of conformity submitted under subsection (c) of section 514 or the failure or refusal to provide data or information requested by the Secretary under section 514(c)(3).''.

(c) SECTION 501.—Section 501(e) (21 U.S.C. 351(e)) is amended—

(1) by striking ''(e)'' and inserting ''(e)(1)''; and

(2) by inserting at the end the following:

''(2) If it is declared to be, purports to be, or is represented as, a device that is in conformity with any performance standard recognized under section 514(c) unless such device is in all respects in conformity with such standard.''.

TITLE III—IMPROVING COLLABORATION AND COMMUNICATION

SEC. 301. COLLABORATIVE DETERMINATIONS OF DEVICE DATA REQUIREMENTS.

Section 513(a)(3) (21 U.S.C. 360c(a)(3)) is amended by adding at the end the following:

''(C)(i)(I) The Secretary, upon the written request of any person intending to submit an application under section 515, shall meet with such person to determine the type of valid scientific evidence (within the meaning of subparagraphs (A) and (B)) that will be necessary to demonstrate the effectiveness of a device for the conditions of use proposed by such person, to support an approval of an application. The written request shall include a detailed description of the device, a detailed description of the proposed conditions of use of the device, a proposed plan for determining whether there is a reasonable assurance of effectiveness, and, if available, information regarding the expected performance from the device. Within 30 days after such meeting, the Secretary shall specify in writing the type of valid scientific evidence that will provide a reasonable assurance that a device is effective under the conditions of use proposed by such person.

''(II) Any clinical data, including 1 or more well-controlled investigations, specified in writing by the Secretary for demonstrating a reasonable assurance of device effectiveness shall be specified as a result of a determination by the Secretary—

''(aa) that such data are necessary to establish device effectiveness; and

''(bb) that no other less burdensome means of evaluating device effectiveness is available that would have a reasonable likelihood of resulting in an approval.

''(ii) The determination of the Secretary with respect to the specification of valid scientific evidence under clause (i) shall be binding upon the Secretary, unless such determination by the Secretary could be contrary to the public health.''.

SEC. 302. COLLABORATIVE REVIEW PROCESS.

Section 515(d) (21 U.S.C. 360e(d)) is amended—

(1) in paragraph (1)(A), by striking ''paragraph (2) of this subsection'' each place it appears and inserting ''paragraph (4)'';

(2) by redesignating paragraphs (2) and (3) as paragraphs (4) and (5), respectively; and

(3) by inserting after paragraph (1) the following:

''(2)(A)(i) The Secretary shall, upon the written request of an applicant, meet with the applicant, not later than 100 days after the receipt of an application from the applicant that has been filed as complete under subsection (c), to discuss the review status of the application.

''(ii) If the application does not appear in a form that would require an approval under this subsection, the Secretary shall in writing, and prior to the meeting, provide to the applicant a description of any deficiencies in the application identified by the Secretary based on an interim review of the entire application and identify the information that is required to correct those deficiencies.

''(iii) The Secretary and the applicant may, by mutual consent, establish a different schedule for a meeting required under this paragraph.

''(B) The Secretary shall notify the applicant immediately of any deficiency identified in the application that was not described as a deficiency in the written description provided by the Secretary under subparagraph (A).''.

TITLE IV—IMPROVING CERTAINTY AND CLARITY OF RULES

SEC. 401. POLICY STATEMENTS.

Section 701(a) (21 U.S.C. 371(a)) is amended—

(1) by striking ''(a) The'' and inserting ''(a)(1) The''; and

(2) by adding at the end the following:

''(2) Not later than February 27, 1999, the Secretary, after evaluating the effectiveness of the Good Guidance Practices document published in the Federal Register at 62 Fed. Reg. 8961, shall promulgate a regulation specifying the policies and procedures of the Food and Drug Administration for the development, issuance, and use of guidance documents.''.

SEC. 402. PRODUCT CLASSIFICATION.

Chapter VII (21 U.S.C. 371 et seq.) is amended by adding at the end the following:

"Subchapter D—Classification of Products and Environmental Impact Reviews

"SEC. 741. CLASSIFICATION OF PRODUCTS.

''(a) REQUEST.—A person who submits an application or submission (including a petition, notification, and any other similar form of request) under this Act, may submit a request to the Secretary respecting the classification of an article as a drug, biological product, device, or a combination product subject to section 503(g) or respecting the component of the Food and Drug Administration that will regulate the article. In submitting the request, the person shall recommend a classification for the article, or a component to regulate the article, as appropriate.

''(b) STATEMENT.—Not later than 60 days after the receipt of the request described in subsection (a), the Secretary shall determine the classification of the article or the component of the Food and Drug Administration that will regulate the article and shall provide to the person a written statement that identifies the classification of the article or the component of the Food and Drug Administration that will regulate the article and the reasons for such determination. The Secretary may not modify such statement except with the written consent of the person or for public health reasons.

''(c) INACTION OF SECRETARY.—If the Secretary does not provide the statement within the 60-day period described in subsection (b), the recommendation made by the person under subsection (a) shall be considered to be a final determination by the Secretary of the classification of the article or the component of the Food and Drug Administration that will regulate the article and may not be modified by the Secretary except with the written consent of the person or for public health reasons.''.

SEC. 403. USE OF DATA RELATING TO PREMARKET APPROVAL.

(a) IN GENERAL.—Section 520(h)(4) (21 U.S.C. 360j(h)(4)) is amended to read as follows:

''(4)(A) Any information contained in an application for premarket approval filed with the Secretary pursuant to section 515(c) (including information from clinical and preclinical tests or studies that demonstrate the safety and effectiveness of a device, but excluding descriptions of methods of manufacture and product composition) shall be available, 6 years after the application has been approved by the Secretary, for use by the Secretary in—

''(i) approving another device;

''(ii) determining whether a product development protocol has been completed, under section 515 for another device;

''(iii) establishing a performance standard or special control under this Act; or

''(iv) classifying or reclassifying another device under section 513 and subsection (l)(2).

''(B) The publicly available detailed summaries of information respecting the safety and effectiveness of devices required by paragraph (1)(A) shall be available for use by the Secretary as the evidentiary basis for the agency actions described in subparagraph (A).''.

(b) CONFORMING AMENDMENT.—Section 517(a) (21 U.S.C. 360g(a)) is amended—

(1) in paragraph (8), by adding ''or'' at the end;

(2) in paragraph (9), by striking '', or'' and inserting a comma; and

(3) by striking paragraph (10).

SEC. 404. CONSIDERATION OF LABELING CLAIMS FOR PRODUCT REVIEW.

(a) PREMARKET APPROVAL.—Section 515(d)(1)(A) (21 U.S.C. 360e(d)(1)(A)) is amended by adding at the end the following flush sentences:

''In making the determination whether to approve or deny the application, the Secretary shall rely on the conditions of use included in the proposed labeling as the basis for determining whether or not there is a reasonable assurance of safety and effectiveness, if the proposed labeling is neither false nor misleading. In determining whether or not such labeling is false or misleading, the Secretary shall fairly evaluate all material facts pertinent to the proposed labeling.''.

(b) PREMARKET NOTIFICATION.—Section 513(i)(1) (21 U.S.C. 360c(i)(1)) is amended by adding at the end the following:

''(C) Whenever the Secretary requests information to demonstrate that the devices with differing technological characteristics are substantially equivalent, the Secretary shall only request information that is necessary to make a substantial equivalence determination. In making such a request, the Secretary shall consider the least burdensome means of demonstrating substantial equivalence and shall request information accordingly.

''(D) The determination of the Secretary under this subsection and section 513(f)(1) with respect to the intended use of a device shall be based on the intended use included in the proposed labeling of the device submitted in a report under section 510(k).''.

(c) RULE OF CONSTRUCTION.—Nothing in the amendments made by subsections (a) and (b) shall be construed to alter any authority of the Secretary of Health and Human Services to regulate any tobacco product, or any additive or ingredient of a tobacco product.

SEC. 405. CERTAINTY OF REVIEW TIMEFRAMES.

(a) CLARIFICATION ON THE 90-DAY TIMEFRAME FOR PREMARKET NOTIFICATION REVIEWS.—Section 510(k) (21 U.S.C. 360) is amended by adding at the end the following flush sentence:

''The Secretary shall review the report required by this subsection and make a determination under section 513(f)(1) not later than 90 days after receiving the report.''.

(b) ONE-CYCLE REVIEW.—Section 515(d) (21 U.S.C. 360e(d)), as amended by section 302, is amended by inserting after paragraph (2) the following:

''(3) Except as provided in paragraph (1), the period for the review of an application by the Secretary under this subsection shall be not more than 180 days. Such period may not be restarted or extended even if the application is amended. The Secretary is not required to review a major amendment to an application, unless the amendment is made in response to a request by the Secretary for information.''.

SEC. 406. LIMITATIONS ON INITIAL CLASSIFICATION DETERMINATIONS.

Section 510 (21 U.S.C. 360) is amended by adding at the end the following:

''(m) The Secretary may not withhold a determination of the initial classification of a device under section 513(f)(1) because of a failure to comply with any provision of this Act that is unrelated to a substantial equivalence decision, including a failure to comply with the requirements relating to good manufacturing practices under section 520(f).''.

SEC. 407. CLARIFICATION WITH RESPECT TO A GENERAL USE AND SPECIFIC USE OF A DEVICE.

Not later than 270 days after the date of enactment of this section, the Secretary of Health and Human Services shall promulgate a final regulation specifying the general principles that the Secretary of Health and Human Services will consider in determining when a specific intended use of a device is not reasonably included within a general use of such device for purposes of a determination of substantial equivalence under section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(1)).

SEC. 408. CLARIFICATION OF THE NUMBER OF REQUIRED CLINICAL INVESTIGATIONS FOR APPROVAL.

(a) DEVICE CLASSES.—Section 513(a)(3)(A) (21 U.S.C. 360c(a)(3)(A)) is amended by striking ''clinical investigations'' and inserting ''1 or more clinical investigations''.

(b) NEW DRUGS.—Section 505(d) (21 U.S.C. 355(d)) is amended by adding at the end the following: ''Substantial evidence may, as appropriate, consist of data from 1 adequate and well-controlled clinical investigation and confirmatory evidence (obtained prior to or after such investigation), if the Secretary determines, based on relevant science, that such data and evidence are sufficient to establish effectiveness.''.

SEC. 409. PROHIBITED ACTS.

Section 301(l) (21 U.S.C. 331(l)) is repealed.

TITLE V—IMPROVING ACCOUNTABILITY

SEC. 501. AGENCY PLAN FOR STATUTORY COMPLIANCE AND ANNUAL REPORT.

Section 903(b) (21 U.S.C. 393(b)), as amended by section 201, is further amended by adding at the end the following:

''(4) AGENCY PLAN FOR STATUTORY COMPLIANCE.—

''(A) IN GENERAL.—Not later than 180 days after the date of enactment of this paragraph, the Secretary, after consultation with relevant experts, health care professionals, representatives of patient and consumer advocacy groups, and the regulated industry, shall develop and publish in the Federal Register a plan bringing the Secretary into compliance with each of the obligations of the Secretary under this Act and other relevant statutes. The Secretary shall biannually review the plan and shall revise the plan as necessary, in consultation with such persons.

''(B) OBJECTIVES OF AGENCY PLAN.—The plan required by subparagraph (A) shall establish objectives, and mechanisms to be used by the Secretary, acting through the Commissioner, including objectives and mechanisms that—

''(i) minimize deaths of, and harm to, persons who use or may use an article regulated under this Act;

''(ii) maximize the clarity of, and the availability of information about, the process for review of applications and submissions (including petitions, notifications, and any other similar forms of request) made under this Act, including information for potential consumers and patients concerning new products;

''(iii) implement all inspection and postmarket monitoring provisions of this Act by July 1, 1999;

''(iv) ensure access to the scientific and technical expertise necessary to ensure compliance by the Secretary with the statutory obligations described in subparagraph (A);

''(v) establish a schedule to bring the Administration into full compliance by July 1, 1999, with the time periods specified in this Act for the review of all applications and submissions described in clause (ii) and submitted after the date of enactment of this paragraph; and

''(vi) reduce backlogs in the review of all applications and submissions described in clause (ii) for any article with the objective of eliminating all backlogs in the review of the applications and submissions by January 1, 2000.

''(5) ANNUAL REPORT.—

''(A) CONTENTS.—The Secretary shall prepare and publish in the Federal Register and solicit public comment on an annual report that—

''(i) provides detailed statistical information on the performance of the Secretary under the plan described in paragraph (4);

''(ii) compares such performance of the Secretary with the objectives of the plan and with the statutory obligations of the Secretary;

''(iii) analyzes any failure of the Secretary to achieve any objective of the plan or to meet any statutory obligation;

''(iv) identifies any regulatory policy that has a significant impact on compliance with any objective of the plan or any statutory obligation; and

''(v) sets forth any proposed revision to any such regulatory policy, or objective of the plan that has not been met.

''(B) STATISTICAL INFORMATION.—The statistical information described in subparagraph (A)(i) shall include a full statistical presentation relating to all applications and submissions (including petitions, notifications, and any other similar forms of request) made under this Act and approved or subject to final action by the Secretary during the year covered by the report. In preparing the statistical presentation, the Secretary shall take into account the date of—

''(i) the submission of any investigational application;

''(ii) the application of any clinical hold;

''(iii) the submission of any application or submission (including a petition, notification, and any other similar form of request) made under this Act for approval or clearance;

''(iv) the acceptance for filing of any application or submission described in clause (iii) for approval or clearance;

''(v) the occurrence of any unapprovable action;

''(vi) the occurrence of any approvable action; and

''(vii) the approval or clearance of any application or submission described in clause (iii).

''(C) SPECIAL RULE.—If the Secretary provides information in a report required by section 705 of the Food and Drug Administration Modernization and Accountability Act of 1997 or a report required by the amendments made by the Government Performance and Results Act of 1993 and that information is required by this paragraph, the report shall be deemed to satisfy the requirements of this paragraph relating to that information.''.

TITLE VI—BETTER ALLOCATION OF RESOURCES BY SETTING PRIORITIES

SEC. 601. MINOR MODIFICATIONS.

(a) ACTION ON INVESTIGATIONAL DEVICE EXEMPTIONS.—Section 520(g) (21 U.S.C. 360j(g)) is amended by adding at the end the following:

''(6)(A) The Secretary shall, not later than 120 days after the date of enactment of this paragraph, by regulation modify parts 812 and 813 of title 21, Code of Federal Regulations to update the procedures and conditions under which a device intended for human use may, upon application by the sponsor of the device, be granted an exemption from the requirements of this Act.

''(B) The regulation shall permit developmental changes in a device (including manufacturing changes) in response to information collected during an investigation without requiring an additional approval of an application for an investigational device exemption or the approval of a supplement to such application, if the sponsor of the investigation determines, based on credible information, prior to making any such changes, that the changes—

''(i) do not affect the scientific soundness of an investigational plan submitted under paragraph (3)(A) or the rights, safety, or welfare of the human subjects involved in the investigation; and

''(ii) do not constitute a significant change in design, or a significant change in basic principles of operation, of the device.''.

(b) ACTION ON APPLICATION.—Section 515(d)(1)(B) (21 U.S.C. 360e(d)(1)(B)) is amended by adding at the end the following:

''(iii) The Secretary shall accept and review data and any other information from investigations conducted under the authority of regulations required by section 520(g), to make a determination of whether there is a reasonable assurance of safety and effectiveness of a device subject to a pending application under this section if—

''(I) the data or information is derived from investigations of an earlier version of the device, the device has been modified during or after the investigations (but prior to submission of an application under subsection (c)) and such a modification of the device does not constitute a significant change in the design or in the basic principles of operation of the device that would invalidate the data or information; or

''(II) the data or information relates to a device approved under this section, is available for use under this Act, and is relevant to the design and intended use of the device for which the application is pending.''.

(c) ACTION ON SUPPLEMENTS.—Section 515(d) (21 U.S.C. 360e(d)), as amended by section 302, is further amended by adding at the end the following:

''(6)(A)(i) A supplemental application shall be required for any change to a device subject to an approved application under this subsection that affects safety or effectiveness, unless such change is a modification in a manufacturing procedure or method of manufacturing and the holder of the approved application submits a written notice to the Secretary that describes in detail the change, summarizes the data or information supporting the change, and informs the Secretary that the change has been made under the requirements of section 520(f).

''(ii) The holder of an approved application who submits a notice under clause (i) with respect to a manufacturing change of a device may distribute the device 30 days after the date on which the Secretary receives the notice, unless the Secretary within such 30-day period notifies the holder that the notice is not adequate and describes such further information or action that is required for acceptance of such change. If the Secretary notifies the holder that a premarket approval supplement is required, the Secretary shall review the supplement within 135 days after the receipt of the supplement. The time used by the Secretary to review the notice of the manufacturing change shall be deducted from the 135-day review period if the notice meets appropriate content requirements for premarket approval supplements.

''(B)(i) Subject to clause (ii), in reviewing a supplement to an approved application, for an incremental change to the design of a device that affects safety or effectiveness, the Secretary shall approve such supplement if—

''(I) nonclinical data demonstrate that the design modification creates the intended additional capacity, function, or performance of the device; and

''(II) clinical data from the approved application and any supplement to the approved application provide a reasonable assurance of safety and effectiveness for the changed device.

''(ii) The Secretary may require, when necessary, additional clinical data to evaluate the design modification of the device to provide a reasonable assurance of safety and effectiveness.''.

SEC. 602. ENVIRONMENTAL IMPACT REVIEW.

Chapter VII (21 U.S.C. 371 et seq.), as amended by section 402, is further amended by adding at the end the following:

''SEC. 742. ENVIRONMENTAL IMPACT REVIEW.

''Notwithstanding any other provision of law, an environmental impact statement prepared in accordance with the regulations published in part 25 of title 21, Code of Federal Regulations (as in effect on August 31, 1997) in connection with an action carried out under (or a recommendation or report relating to) this Act, shall be considered to meet the requirements for a detailed statement under section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332(2)(C)).''.

SEC. 603. EXEMPTION OF CERTAIN CLASSES OF DEVICES FROM PREMARKET NOTIFICATION REQUIREMENT.

(a) CLASS I AND CLASS II DEVICES.—Section 510(k) (21 U.S.C. 360(k)) is amended by striking ''intended for human use'' and inserting ''intended for human use (except a device that is classified into class I under section 513 or 520 unless the Secretary determines such device is intended for a use that is of substantial importance in preventing impairment of human health or such device presents a potential unreasonable risk of illness or injury, or a device that is classified into class II under section 513 or 520 and is exempt from the requirements of this subsection under subsection (l))''.

(b) PUBLICATION OF EXEMPTION.—Section 510 (21 U.S.C. 360) is amended by inserting after subsection (k) the following:

''(l)(1) Not later than 30 days after the date of enactment of this subsection, the Secretary shall publish in the Federal Register a list of each type of class II device that does not require a notification under subsection (k) to provide reasonable assurance of safety and effectiveness. Each type of class II device identified by the Secretary not to require the notification shall be exempt from the requirement to provide notification under subsection (k) as of the date of the publication of the list in the Federal Register.

''(2) Beginning on the date that is 1 day after the date of the publication of a list under this subsection, the Secretary may exempt a class II device from the notification requirement of subsection (k), upon the Secretary's own initiative or a petition of an interested person, if the Secretary determines that such notification is not necessary to assure the safety and effectiveness of the device. The Secretary shall publish in the Federal Register notice of the intent of the Secretary to exempt the device, or of the petition, and provide a 30-day period for public comment. Within 120 days after the issuance of the notice in the Federal Register, the Secretary shall publish an order in the Federal Register that sets forth the final determination of the Secretary regarding the exemption of the device that was the subject of the notice.''.

SEC. 604. EVALUATION OF AUTOMATIC CLASS III DESIGNATION.

Section 513(f) (21 U.S.C. 360c(f)) is amended—

(1) in paragraph (1)—

(A) in subparagraph (B), by striking ''paragraph (2)'' and inserting ''paragraph (3)''; and

(B) in the last sentence, by striking ''paragraph (2)'' and inserting ''paragraph (2) or (3)'';

(2) by redesignating paragraphs (2) and (3) as paragraphs (3) and (4), respectively; and

(3) by inserting after paragraph (1) the following:

''(2)(A) Any person who submits a report under section 510(k) for a type of device that has not been previously classified under this Act, and that is classified into class III under paragraph (1), may request, within 30 days after receiving written notice of such a classification, the Secretary to classify the device under the criteria set forth in subparagraphs (A) through (C) subsection (a)(1). The

person may, in the request, recommend to the Secretary a classification for the device. Any such request shall describe the device and provide detailed information and reasons for the recommended classification.

''(B)(i) Not later than 60 days after the date of the submission of the request under subparagraph (A) for classification of a device under the criteria set forth in subparagraphs (A) through (C) of subsection (a)(1), the Secretary shall by written order classify the device. Such classification shall be the initial classification of the device for purposes of paragraph (1) and any device classified under this paragraph shall be a predicate device for determining substantial equivalence under paragraph (1).

''(ii) A device that remains in class III under this subparagraph shall be deemed to be adulterated within the meaning of section 501(f)(1)(B) until approved under section 515 or exempted from such approval under section 520(g).

''(C) Within 30 days after the issuance of an order classifying a device under this paragraph, the Secretary shall publish a notice in the Federal Register announcing such classification.''.

SEC. 605. SECRETARY'S DISCRETION TO TRACK DEVICES.

(a) RELEASE OF INFORMATION.—Section 519(e) (21 U.S.C. 360i(e)) is amended by adding at the end the following flush sentence:

''Any patient receiving a device subject to tracking under this section may refuse to release, or refuse permission to release, the patient's name, address, social security number, or other identifying information for the purpose of tracking.''.

(b) PUBLICATION OF CERTAIN DEVICES.—Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services shall develop and publish in the Federal Register a list that identifies each type of device subject to tracking under section 519(e)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i(e)(1)). Each device not identified by the Secretary of Health and Human Services under this subsection or designated by the Secretary under section 519(e)(2) shall be deemed to be exempt from the mandatory tracking requirement under section 519 of such Act. The Secretary of Health and Human Services shall have authority to modify the list of devices exempted from the mandatory tracking requirements.

SEC. 606. SECRETARY'S DISCRETION TO CONDUCT POSTMARKET SURVEILLANCE.

(a) IN GENERAL.—Section 522 (21 U.S.C. 360l) is amended by striking ''SEC. 522.'' and all that follows through ''(2) DISCRETIONARY SURVEILLANCE.—The'' and inserting the following:

''SEC. 522. (a) DISCRETIONARY SURVEILLANCE.—The''.

(b) SURVEILLANCE APPROVAL.—Section 522(b) (21 U.S.C. 360l(b)) is amended to read as follows:

''(b) SURVEILLANCE APPROVAL.—

''(1) IN GENERAL.—Each manufacturer that receives notice from the Secretary that the manufacturer is required to conduct surveillance of a device under subsection (a) shall, not later than 30 days after receiving the notice, submit for the approval of the Secretary, a plan for the required surveillance.

''(2) DETERMINATION.—Not later than 60 days after the receipt of the plan, the Secretary shall determine if a person proposed in the plan to conduct the surveillance has sufficient qualifications and experience to conduct the surveillance and if the plan will result in the collection of useful data that can reveal unforeseen adverse events or other information necessary to protect the public health and to provide safety and effectiveness information for the device.

''(3) LIMITATION ON PLAN APPROVAL.—The Secretary may not approve the plan until the plan has been reviewed by a qualified scientific and technical review committee established by the Secretary.''.

SEC. 607. REPORTING.

(a) REPORTS.—Section 519 (21 U.S.C. 360i) is amended—

(1) in subsection (a)—

(A) in the first sentence by striking ''make such reports, and provide such information,'' and inserting ''and each such manufacturer or importer shall make such reports, provide such information, and submit such samples and components of devices (as required by paragraph (10)),'';

(B) in paragraph (8), by striking ''; and'' and inserting a semicolon; and

(C) by striking paragraph (9) and inserting the following:

''(9) shall require distributors to keep records and make such records available to the Secretary upon request; and'';

(2) by striking subsection (d); and

(3) in subsection (f), by striking '', importer, or distributor'' each place it appears and inserting ''or importer''.

(b) REGISTRATION.—Section 510(g) (21 U.S.C. 360(g)) is amended—

(1) by redesignating paragraph (4) as paragraph (5);

(2) by inserting after paragraph (3), the following:

''(4) any distributor who acts as a wholesale distributor of devices, and who does not manufacture, repackage, process, or relabel a device; or''; and

(3) by adding at the end the following flush sentence:

''In this subsection, the term 'wholesale distributor' means any person who distributes a device from the original place of manufacture to the person who makes the final delivery or sale of the device to the ultimate consumer or user.''.

SEC. 608. PILOT AND SMALL-SCALE MANUFACTURE.

(a) NEW DRUGS.—Section 505(c) (21 U.S.C. 355(c)) is amended by adding at the end the following:

''(4) A new drug manufactured in a pilot or other small facility may be used to demonstrate the safety and effectiveness of the new drug and to obtain approval of the new drug prior to scaling up to a larger facility, unless the Secretary determines that a full scale production facility is necessary to ensure the safety or effectiveness of the new drug.''.

(b) NEW ANIMAL DRUGS.—Section 512(c) (21 U.S.C. 360b(c)) is amended by adding at the end the following:

''(4) A new animal drug manufactured in a pilot or other small facility may be used to demonstrate the safety and effectiveness of the new drug and to obtain approval of the new drug prior to scaling up to a larger facility, unless the Secretary determines that a full scale production facility is necessary to ensure the safety or effectiveness of the new drug.''.

SEC. 609. REQUIREMENTS FOR RADIOPHARMACEUTICALS.

(a) REQUIREMENTS.—

(1) REGULATIONS.—

(A) PROPOSED REGULATIONS.—Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services, after consultation with patient advocacy groups, associations, physicians licensed to use radiopharmaceuticals, and the regulated industry, shall issue proposed regulations governing the approval of radiopharmaceuticals designed for diagnosis and monitoring of diseases and conditions. The regulations shall provide that the determination of the safety and effectiveness of such a radiopharmaceutical under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or section 351 of the Public Health Service Act (42 U.S.C. 262) shall include (but not be limited to) consideration of the proposed use of the radiopharmaceutical in the practice of medicine, the pharmacological and toxicological activity of the radiopharmaceutical (including any carrier or ligand component of the radiopharmaceutical), and the estimated absorbed radiation dose of the radiopharmaceutical.

(B) FINAL REGULATIONS.—Not later than 18 months after the date of enactment of this Act, the Secretary shall promulgate final regulations governing the approval of the radiopharmaceuticals.

(2) SPECIAL RULE.—In the case of a radiopharmaceutical intended to be used for diagnostic or monitoring purposes, the indications for which such radiopharmaceutical is approved for marketing may, in appropriate cases, refer to manifestations of disease (such as biochemical, physiological, anatomic, or pathological processes) common to, or present in, 1 or more disease states.

(b) DEFINITION.—In this section, the term ''radiopharmaceutical'' means—

(1) an article—

(A) that is intended for use in the diagnosis or monitoring of a disease or a manifestation of a disease in humans; and

(B) that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons; or

(2) any nonradioactive reagent kit or nuclide generator that is intended to be used in the preparation of any such article.

SEC. 610. MODERNIZATION OF REGULATION OF BIOLOGICAL PRODUCTS.

(a) LICENSES.—

(1) IN GENERAL.—Section 351(a) of the Public Health Service (42 U.S.C. 262(a)) is amended to read as follows:

''(a)(1) Except as provided in paragraph (4), no person shall introduce or deliver for introduction into interstate commerce any biological product unless—

''(A) a biologics license is in effect for the biological product; and

''(B) each package of the biological product is plainly marked with—

''(i) the proper name of the biological product contained in the package;

''(ii) the name, address, and applicable license number of the manufacturer of the biological product; and

''(iii) the expiration date of the biological product.

''(2)(A) The Secretary shall establish, by regulation, requirements for the approval, suspension, and revocation of biologics licenses.

''(B) The Secretary shall approve a biologics license application on the basis of a demonstration that—

''(i) the biological product that is the subject of the application is safe, pure, and potent; and

''(ii) the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent.

''(3) A biologics license application shall be approved only if the applicant (or other appropriate person) consents to the inspection of the facility that is the subject of the application, in accordance with subsection (c).

''(4) The Secretary shall prescribe requirements under which a biological product undergoing investigation shall be exempt from the requirements of paragraph (1).''.

(2) ELIMINATION OF EXISTING LICENSE REQUIREMENT.—Section 351(d) of the Public Health Service Act (42 U.S.C. 262(d)) is amended—

(A) by striking ''(d)(1)'' and all that follows through ''of this section.'';

(B) in paragraph (2)—

(i) by striking ''(2)(A) Upon'' and inserting ''(d)(1) Upon;'' and

(ii) by redesignating subparagraph (B) as paragraph (2); and

(C) in paragraph (2) (as so redesignated by subparagraph (B)(ii))—

(i) by striking ''subparagraph (A)'' and inserting ''paragraph (1)''; and

(ii) by striking ''this subparagraph'' each place it appears and inserting ''this paragraph''.

(b) LABELING.—Section 351(b) of the Public Health Service Act (42 U.S.C. 262(b)) is amended to read as follows:

''(b) No person shall falsely label or mark any package or container of any biological product or alter any label or mark on the package or container of the biological product so as to falsify the label or mark.''.

(c) INSPECTION.—Section 351(c) of the Public Health Service Act (42 U.S.C. 262(c)) is amended by striking ''virus, serum,'' and all that follows and inserting ''biological product.''.

(d) DEFINITION; APPLICATION.—Section 351 of the Public Health Service Act (42 U.S.C. 262) is amended by adding at the end the following:

''(i) In this section, the term 'biological product' means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.''.

(e) CONFORMING AMENDMENT.—Section 503(g)(4) (21 U.S.C. 353(g)(4)) is amended—

(1) in subparagraph (A)—

(A) by striking ''section 351(a)'' and inserting ''section 351(i)''; and

(B) by striking ''262(a)'' and inserting ''262(i)''; and

(2) in subparagraph (B)(iii), by striking ''product or establishment license under subsection (a) or (d)'' and inserting ''biologics license application under subsection (a)''.

(f) SPECIAL RULE.—The Secretary of Health and Human Services shall take measures to minimize differences in the review and approval of products required to have approved biologics license applications under section 351 of the Public Health Service Act (42 U.S.C. 262) and products required to have approved full new drug applications under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(1)).

SEC. 611. APPROVAL OF SUPPLEMENTAL APPLICATIONS FOR APPROVED PRODUCTS.

(a) PERFORMANCE STANDARDS.—Not later than 180 days after the date of enactment of this section, the Secretary of Health and Human Services shall publish in the Federal Register performance standards for the prompt review of supplemental applications submitted for approved articles under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.).

(b) GUIDANCE TO INDUSTRY.—Not later than 180 days after the date of enactment of this section, the Secretary of Health and Human Services shall issue final guidances to clarify the requirements for, and facilitate the submission of data to support, the approval of supplemental applications for the approved articles described in subsection (a). The guidances shall—

(1) clarify circumstances in which published matter may be the basis for approval of a supplemental application;

(2) specify data requirements that will avoid duplication of previously submitted data by recognizing the availability of data previously submitted in support of an original application; and

(3) define supplemental applications that are eligible for priority review.

(c) RESPONSIBILITIES OF CENTERS.—The Secretary of Health and Human Services shall designate an individual in each center within the Food and Drug Administration (except the Center for Food Safety and Applied Nutrition) to be responsible for—

(1) encouraging the prompt review of supplemental applications for approved articles; and

(2) working with sponsors to facilitate the development and submission of data to support supplemental applications.

(d) COLLABORATION.—The Secretary of Health and Human Services shall implement programs and policies that will foster collaboration between the Food and Drug Administration, the National Institutes of Health, professional medical and scientific societies, and other persons, to identify published and unpublished studies that may support a supplemental application, and to encourage sponsors to make supplemental applications or conduct further research in support of a supplemental application based, in whole or in part, on such studies.

SEC. 612. HEALTH CARE ECONOMIC INFORMATION.

(a) IN GENERAL.—Section 502(a) (21 U.S.C. 352(a)) is amended by adding at the end the following: ''Health care economic information provided to a formulary committee, or other similar entity, in the course of the committee or the entity carrying out its responsibilities for the selection of drugs for managed care or other similar organizations, shall not be considered to be false or misleading if the health care economic information directly relates to an indication approved under section 505 or 507 or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) for such drug and is based on competent and reliable scientific evidence. The requirements set forth in section 505(a), 507, or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) shall not apply to health care economic information provided to such a committee or entity in accordance with this paragraph. Information that is relevant to the substantiation of the health care economic information presented pursuant to this paragraph shall be made available to the Secretary upon request. In this paragraph, the term 'health care economic information' means any analysis that identifies, measures, or compares the economic consequences, including the costs of the represented health outcomes, of the use of a drug to the use of another drug, to another health care intervention, or to no intervention.''.

(b) STUDY AND REPORT.—The Comptroller General of the United States shall conduct a study of the implementation of the provisions added by the amendment made by subsection (a). Not later than 4 years and 6 months after the date of enactment of this Act, the Comptroller General of the United States shall prepare and submit to Congress a report containing the findings of the study.

SEC. 613. EXPEDITING STUDY AND APPROVAL OF FAST TRACK DRUGS.

(a) IN GENERAL.—Chapter V (21 U.S.C. 351 et seq.), as amended by section 102, is further amended by adding at the end the following:

''Subchapter E—Fast Track Drugs and Reports of Post-Market Approval Studies

''SEC. 561. FAST TRACK DRUGS.

''(a) DESIGNATION OF DRUG AS A FAST TRACK DRUG.—

''(1) IN GENERAL.—The Secretary shall facilitate development, and expedite review and approval of new drugs and biological products that are intended for the treatment of serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs for such conditions. In this Act, such products shall be known as 'fast track drugs'.

''(2) REQUEST FOR DESIGNATION.—The sponsor of a drug (including a biological product) may request the Secretary to designate the drug as a fast track drug. A request for the designation may be made concurrently with, or at any time after, submission of an application for the investigation of the drug under section 505(i) or section 351(a)(4) of the Public Health Service Act.

''(3) DESIGNATION.—Within 30 calendar days after the receipt of a request under paragraph (2), the Secretary shall determine whether the drug that is the subject of the request meets the criteria described in paragraph (1). If the Secretary finds that the drug meets the criteria, the Secretary shall designate the drug as a fast track drug and shall take such actions as are appropriate to expedite the development and review of the drug.

''(b) APPROVAL OF APPLICATION FOR A FAST TRACK DRUG.—

''(1) IN GENERAL.—The Secretary may approve an application for approval of a fast track drug under section 505(b) or section 351 of the Public Health Service Act (21 U.S.C. 262) upon a determination that the drug has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit.

''(2) LIMITATION.—Approval of a fast track drug under this subsection may be subject to the requirements—

''(A) that the sponsor conduct appropriate post-approval studies to validate the surrogate endpoint or otherwise confirm the clinical benefit of the drug; and

''(B) that the sponsor submit copies of all promotional materials related to the fast track drug during the preapproval review period and following approval, at least 30 days prior to dissemination of the materials for such period of time as the Secretary deems appropriate.

''(3) EXPEDITED WITHDRAWAL OF APPROVAL.—The Secretary may withdraw approval of a fast track drug using expedited procedures (as prescribed by the Secretary in regulations) including a procedure that provides an opportunity for an informal hearing, if—

''(A) the sponsor fails to conduct any required post-approval study of the fast track drug with due diligence;

''(B) a post-approval study of the fast track drug fails to verify clinical benefit of the fast track drug;

''(C) other evidence demonstrates that the fast track drug is not safe or effective under conditions of use of the drug; or

''(D) the sponsor disseminates false or misleading promotional materials with respect to the fast track drug.

''(c) REVIEW OF INCOMPLETE APPLICATIONS FOR APPROVAL OF A FAST TRACK DRUG.—

''(1) IN GENERAL.—If preliminary evaluation by the Secretary of clinical efficacy data for a fast track drug under investigation shows evidence of effectiveness, the Secretary shall evaluate for filing, and may commence review of, portions of an application for the approval of the drug if the applicant provides a schedule for submission of information necessary to make the application complete and any fee that may be required under section 736.

''(2) EXCEPTION.—Any time period for review of human drug applications that has been agreed to by the Secretary and that has been set forth in goals identified in letters of the Secretary (relating to the use of fees collected under section 736 to expedite the drug development process and the review of human drug applications) shall not apply to

an application submitted under paragraph (1) until the date on which the application is complete.

''(d) AWARENESS EFFORTS.—The Secretary shall—

''(1) develop and widely disseminate to physicians, patient organizations, pharmaceutical and biotechnology companies, and other appropriate persons a comprehensive description of the provisions applicable to fast track drugs established under this section; and

''(2) establish an ongoing program to encourage the development of surrogate endpoints that are reasonably likely to predict clinical benefit for serious or life-threatening conditions for which there exist significant unmet medical needs.''.

(b) GUIDANCE.—Within 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall issue guidance for fast track drugs that describes the policies and procedures that pertain to section 561 of the Federal Food, Drug, and Cosmetic Act.

SEC. 614. MANUFACTURING CHANGES FOR DRUGS AND BIOLOGICS.

(a) IN GENERAL.—Chapter VII (21 U.S.C. 371 et seq.), as amended by section 602, is further amended by adding at the end the following:

''Subchapter E—Manufacturing Changes

''SEC. 751. MANUFACTURING CHANGES.

''(a) IN GENERAL.—A change in the manufacture of a new drug, including a biological product, or a new animal drug may be made in accordance with this section.

''(b) CHANGES.—

''(1) VALIDATION.—Before distributing a drug made after a change in the manufacture of the drug from the manufacturing process established in the approved new drug application under section 505, the approved new animal drug application under section 512, or the license application under section 351 of the Public Health Service Act, the applicant shall validate the effect of the change on the identity, strength, quality, purity, and potency of the drug as the identity, strength, quality, purity, and potency may relate to the safety or effectiveness of the drug.

''(2) REPORTS.—The applicant shall report the change described in paragraph (1) to the Secretary and may distribute a drug made after the change as follows:

''(A) MAJOR MANUFACTURING CHANGES.—

''(i) IN GENERAL.—Major manufacturing changes, which are of a type determined by the Secretary to have substantial potential to adversely affect the identity, strength, quality, purity, or potency of the drug as the identity, strength, quality, purity, and potency may relate to the safety or effectiveness of a drug, shall be submitted to the Secretary in a supplemental application and drugs made after such changes may not be distributed until the Secretary approves the supplemental application.

''(ii) DEFINITION.—In this subparagraph, the term 'major manufacturing changes' means—

''(I) changes in the qualitative or quantitative formulation of a drug or the specifications in the approved marketing application for the drug (unless exempted by the Secretary from the requirements of this subparagraph);

''(II) changes that the Secretary determines by regulation or issuance of guidance require completion of an appropriate human study demonstrating equivalence of the drug to the drug manufactured before such changes; and

''(III) other changes that the Secretary determines by regulation or issuance of guidance have a substantial potential to adversely affect the safety or effectiveness of the drug.

''(B) OTHER MANUFACTURING CHANGES.—

''(i) IN GENERAL.—As determined by the Secretary, manufacturing changes other than major manufacturing changes shall—

''(I) be made at any time and reported annually to the Secretary, with supporting data; or

''(II) be reported to the Secretary in a supplemental application.

''(ii) DISTRIBUTION OF THE DRUG.—In the case of changes reported in accordance with clause (i)(II)—

''(I) the applicant may distribute the drug 30 days after the Secretary receives the supplemental application unless the Secretary notifies the applicant within such 30-day period that prior approval of such supplemental application is required;

''(II) the Secretary shall approve or disapprove each such supplemental application; and

''(III) the Secretary may determine types of manufacturing changes after which distribution of a drug may commence at the time of submission of such supplemental application.''.

(b) EXISTING LAW.—The requirements of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.) and the Public Health Service Act (42 U.S.C. 201 et seq.) that are in effect on the date of enactment of this Act with respect to manufacturing changes shall remain in effect—

(1) for a period of 24 months after the date of enactment of this Act; or

(2) until the effective date of regulations promulgated by the Secretary of Health and Human Services implementing section 751 of the Federal Food, Drug, and Cosmetic Act,

whichever is sooner.

SEC. 615. DATA REQUIREMENTS FOR DRUGS AND BIOLOGICS.

Within 12 months after the date of enactment of this Act, the Secretary of the Health and Human Services, acting through the Commissioner of Food and Drugs, shall issue guidance that describes when abbreviated study reports may be submitted, in lieu of full reports, with a new drug application under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) and with a biologics license application under section 351 of the Public Health Service Act (42 U.S.C. 262) for certain types of studies. Such guidance shall describe the kinds of studies for which abbreviated reports are appropriate and the appropriate abbreviated report formats.

SEC. 616. FOOD CONTACT SUBSTANCES.

(a) FOOD CONTACT SUBSTANCES.—Section 409(a) (21 U.S.C. 348(a)) is amended—

(1) in paragraph (1)—

(A) by striking ''subsection (i)'' and inserting ''subsection (j)''; and

(B) by striking at the end ''or'';

(2) by striking the period at the end of paragraph (2) and inserting ''; or''; and

(3) by inserting after paragraph (2) the following:

''(3) in the case of a food additive as defined in this Act that is a food contact substance, there is—

''(A) in effect, and such substance and the use of such substance are in conformity with, a regulation issued under this section prescribing the conditions under which such additive may be safely used; or

''(B) a notification submitted under subsection (h) that is effective.''; and

(4) by striking the matter following paragraph (3) (as added by paragraph (2)) and inserting the following flush sentence:

''While such a regulation relating to a food additive, or such a notification under subsection (h) relating to a food additive that is a food contact substance, is in effect, and has not been revoked pursuant to subsection (i), a food shall not, by reason of bearing or containing such a food additive in accordance with the regulation or notification, be considered adulterated under section 402(a)(1).''.

(b) NOTIFICATION FOR FOOD CONTACT SUBSTANCES.—Section 409 (21 U.S.C. 348), as amended by subsection (a), is further amended—

(1) by redesignating subsections (h) and (i), as subsections (i) and (j), respectively;

(2) by inserting after subsection (g) the following:

''Notification Relating to a Food Contact Substance

''(h)(1) Subject to such regulations as may be promulgated under paragraph (3), a manufacturer or supplier of a food contact substance may, at least 120 days prior to the introduction or delivery for introduction into interstate commerce of the food contact substance, notify the Secretary of the identity and intended use of the food contact substance, and of the determination of the manufacturer or supplier that the intended use of such food contact substance is safe under the standard described in subsection (c)(3)(A). The notification shall contain the information that forms the basis of the determination, the fee required under paragraph (5), and all information required to be submitted by regulations promulgated by the Secretary.

''(2)(A) A notification submitted under paragraph (1) shall become effective 120 days after the date of receipt by the Secretary and the food contact substance may be introduced or delivered for introduction into interstate commerce, unless the Secretary makes a determination within the 120-day period that, based on the data and information before the Secretary, such use of the food contact substance has not been shown to be safe under the standard described in subsection (c)(3)(A), and informs the manufacturer or supplier of such determination.

''(B) A decision by the Secretary to object to a notification shall constitute final agency action subject to judicial review.

''(C) In this paragraph, the term 'food contact substance' means the substance that is the subject of a notification submitted under paragraph (1), and does not include a similar or identical substance manufactured or prepared by a person other than the manufacturer identified in the notification.

''(3)(A) The process in this subsection shall be utilized for authorizing the marketing of a food contact substance except where the Secretary determines that submission and review of a petition under subsection (b) is necessary to provide adequate assurance of safety, or where the Secretary and any manufacturer or supplier agree that such manufacturer or supplier may submit a petition under subsection (b).

''(B) The Secretary is authorized to promulgate regulations to identify the circumstances in which a petition shall be filed under subsection (b), and shall consider criteria such as the probable consumption of such food contact substance and potential toxicity of the food contact substance in determining the circumstances in which a petition shall be filed under subsection (b).

''(4) The Secretary shall keep confidential any information provided in a notification under paragraph (1) for 120 days after receipt by the Secretary of the notification. After the expiration of such 120 days, the information shall be available to any interested party except for any matter in the notification that is a trade secret or confidential commercial information.

''(5)(A) Each person that submits a notification regarding a food contact substance under this section shall be subject to the payment of a reasonable fee. The fee shall be

based on the resources required to process the notification including reasonable administrative costs for such processing.

''(B) The Secretary shall conduct a study of the costs of administering the notification program established under this section and, on the basis of the results of such study, shall, within 18 months after the date of enactment of the Food and Drug Administration Modernization and Accountability Act of 1997, promulgate regulations establishing the fee required by subparagraph (A).

''(C) A notification submitted without the appropriate fee is not complete and shall not become effective for the purposes of subsection (a)(3) until the appropriate fee is paid.

''(D) Fees collected pursuant to this subsection—

''(i) shall not be deposited as an offsetting collection to the appropriations for the Department of Health and Human Services;

''(ii) shall be credited to the appropriate account of the Food and Drug Administration; and

''(iii) shall be available in accordance with appropriation Acts until expended, without fiscal year limitation.

''(6) In this section, the term 'food contact substance' means any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food.'';

(3) in subsection (i), as so redesignated by paragraph (1), by adding at the end the following: ''The Secretary shall by regulation prescribe the procedure by which the Secretary may deem a notification under subsection (h) to no longer be effective.''; and

(4) in subsection (j), as so redesignated by paragraph (1), by striking ''subsections (b) to (h)'' and inserting ''subsections (b) to (i)''.

(c) EFFECTIVE DATE.—Notifications under section 409(h) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (b), may be submitted beginning 18 months after the date of enactment of this Act.

SEC. 617. HEALTH CLAIMS FOR FOOD PRODUCTS.

Section 403(r)(3) (21 U.S.C. 343(r)(3)) is amended by adding at the end the following:

''(C) Notwithstanding the provisions of clauses (A)(i) and (B), a claim of the type described in subparagraph (1)(B) that is not authorized by the Secretary in a regulation promulgated in accordance with clause (B) shall be authorized and may be made if—

''(i) an authoritative scientific body of the Federal Government with official responsibility for public health protection or research directly relating to human nutrition (such as the National Institutes of Health or the Centers for Disease Control and Prevention), the National Academy of Sciences, or a subdivision of the scientific body or the National Academy of Sciences, has published an authoritative statement, which is currently in effect, about the relationship between a nutrient and a disease or health-related condition to which the claim refers;

''(ii) a person has submitted to the Secretary at least 120 days before the first introduction of a food into interstate commerce a notice of the claim, including a concise description of the basis upon which such person relied for determining that the requirements of subclause (i) have been satisfied;

''(iii) the claim and the food for which the claim is made are in compliance with clause (A)(ii), and are otherwise in compliance with paragraph (a) and section 201(n); and

''(iv) the claim is stated in a manner so that the claim is an accurate representation of the authoritative statement referred to in subclause (i) and so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet.

For purposes of this paragraph, a statement shall be regarded as an authoritative statement of such a scientific body described in subclause (i) only if the statement is published by the scientific body and shall not include a statement of an employee of the scientific body made in the individual capacity of the employee.

''(D) A claim submitted under the requirements of clause (C), may be made until—

''(i) such time as the Secretary issues an interim final regulation—

''(I) under the standard in clause (B)(i), prohibiting or modifying the claim; or

''(II) finding that the requirements of clause (C) have not been met; or

''(ii) a district court of the United States in an enforcement proceeding under chapter III has determined that the requirements of clause (C) have not been met.

Where the Secretary issues a regulation under subclause (i), good cause shall be deemed to exist for the purposes of subsections (b)(B) and (d)(3) of section 553 of title 5, United States Code. The Secretary shall solicit comments in response to a regulation promulgated under subclause (i) and shall publish a response to such comments.''.

SEC. 618. PEDIATRIC STUDIES MARKETING EXCLUSIVITY.

(a) GENERAL AUTHORITY.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 505 the following:

''SEC. 505A. PEDIATRIC STUDIES OF DRUGS.

''(a) MARKET EXCLUSIVITY FOR NEW DRUGS.—If, prior to approval of an application that is submitted under section 505(b)(1), the Secretary determines that information relating to the use of a drug in the pediatric population may produce health benefits in that population, the Secretary makes a written request for pediatric studies (which may include a timeframe for completing such studies), and such studies are completed within any such timeframe and the reports thereof submitted in accordance with subsection (d)(2) or completed within any such timeframe and the reports thereof are accepted in accordance with subsection (d)(3)—

''(1)(A) the period during which an application may not be submitted under subsections (c)(3)(D)(ii) and (j)(4)(D)(ii) of section 505 shall be five years and six months rather than five years, and the references in subsections (c)(3)(D)(ii) and (j)(4)(D)(ii) of section 505 to four years, to forty-eight months, and to seven and one-half years shall be deemed to be four and one-half years, fifty-four months, and eight years, respectively; or

''(B) the period of market exclusivity under subsections (c)(3)(D) (iii) and (iv) and (j)(4)(D) (iii) and (iv) of section 505 shall be three years and six months rather than three years; and

''(2)(A) if the drug is the subject of—

''(i) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of section 505 and for which pediatric studies were submitted prior to the expiration of the patent (including any patent extensions); or

''(ii) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iii) or (j)(2)(A)(vii)(III) of section 505,

the period during which an application may not be approved under subsection (c)(3) or (j)(4)(B) of section 505 shall be extended by a period of six months after the date the patent expires (including any patent extensions); or

''(B) if the drug is the subject of a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505, and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed, the period during which an application may not be approved under subsection (c)(3) or (j)(4)(B) of section 505 shall be extended by a period of six months after the date the patent expires (including any patent extensions).

''(b) SECRETARY TO DEVELOP LIST OF DRUGS FOR WHICH ADDITIONAL PEDIATRIC INFORMATION MAY BE BENEFICIAL.—Not later than 180 days after the date of enactment of this section, the Secretary, after consultation with experts in pediatric research (such as the American Academy of Pediatrics, the Pediatric Pharmacology Research Unit Network, and the United States Pharmacopoeia) shall develop, prioritize, and publish an initial list of approved drugs for which additional pediatric information may produce health benefits in the pediatric population. The Secretary shall annually update the list.

''(c) MARKET EXCLUSIVITY FOR ALREADY-MARKETED DRUGS.—If the Secretary makes a written request for pediatric studies (which may include a timeframe for completing such studies) concerning a drug identified in the list described in subsection (b) to the holder of an approved application under section 505(b)(1) for the drug, the holder agrees to the request, and the studies are completed within any such timeframe and the reports thereof submitted in accordance with subsection (d)(2) or completed within any such timeframe and the reports thereof accepted in accordance with subsection (d)(3)—

''(1)(A) the period during which an application may not be submitted under subsections (c)(3)(D)(ii) and (j)(4)(D)(ii) of section 505 shall be five years and six months rather than five years, and the references in subsections (c)(3)(D)(ii) and (j)(4)(D)(ii) of section 505 to four years, to forty-eight months, and to seven and one-half years shall be deemed to be four and one-half years, fifty-four months, and eight years, respectively; or

''(B) the period of market exclusivity under subsections (c)(3)(D) (iii) and (iv) and (j)(4)(D) (iii) and (iv) of section 505 shall be three years and six months rather than three years; and

''(2)(A) if the drug is the subject of—

''(i) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of section 505 and for which pediatric studies were submitted prior to the expiration of the patent (including any patent extensions); or

''(ii) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iii) or (j)(2)(A)(vii)(III) of section 505,

the period during which an application may not be approved under subsection (c)(3) or (j)(4)(B) of section 505 shall be extended by a period of six months after the date the patent expires (including any patent extensions); or

''(B) if the drug is the subject of a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505, and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed, the period during which an application may not be approved under subsection (c)(3) or (j)(4)(B) of section 505 shall be extended by a period of six months after the date the patent expires (including any patent extensions).

''(d) CONDUCT OF PEDIATRIC STUDIES.—

''(1) AGREEMENT FOR STUDIES.—The Secretary may, pursuant to a written request for studies, after consultation with—

''(A) the sponsor of an application for an investigational new drug under section 505(i);

''(B) the sponsor of an application for a drug under section 505(b)(1); or

''(C) the holder of an approved application for a drug under section 505(b)(1),

agree with the sponsor or holder for the conduct of pediatric studies for such drug.

''(2) WRITTEN PROTOCOLS TO MEET THE STUDIES REQUIREMENT.—If the sponsor or holder and the Secretary agree upon written protocols for the studies, the studies requirement of subsection (a) or (c) is satisfied upon the completion of the studies and submission of the reports thereof in accordance with the original written request and the written agreement referred to in paragraph (1). Not later than 60 days after the submission of the report of the studies, the Secretary shall determine if such studies were or were not conducted in accordance with the original written request and the written agreement and reported in accordance with the requirements of the Secretary for filing and so notify the sponsor or holder.

''(3) OTHER METHODS TO MEET THE STUDIES REQUIREMENT.—If the sponsor or holder and the Secretary have not agreed in writing on the protocols for the studies, the studies requirement of subsection (a) or (c) is satisfied when such studies have been completed and the reports accepted by the Secretary. Not later than 90 days after the submission of the reports of the studies, the Secretary shall accept or reject such reports and so notify the sponsor or holder. The Secretary's only responsibility in accepting or rejecting the reports shall be to determine, within the 90 days, whether the studies fairly respond to the written request, whether such studies have been conducted in accordance with commonly accepted scientific principles and protocols, and whether such studies have been reported in accordance with the requirements of the Secretary for filing.

''(e) DELAY OF EFFECTIVE DATE FOR CERTAIN APPLICATIONS; PERIOD OF MARKET EXCLUSIVITY.—If the Secretary determines that the acceptance or approval of an application under subsection (b)(2) or (j) of section 505 for a drug may occur after submission of reports of pediatric studies under this section, which were submitted prior to the expiration of the patent (including any patent extension) or market exclusivity protection, but before the Secretary has determined whether the requirements of subsection (d) have been satisfied, the Secretary shall delay the acceptance or approval under subsection (b)(2) or (j), respectively, of section 505 until the determination under subsection (d) is made, but such delay shall not exceed 90 days. In the event that requirements of this section are satisfied, the applicable period of market exclusivity referred to in subsection (a) or (c) shall be deemed to have been running during the period of delay.

''(f) NOTICE OF DETERMINATIONS ON STUDIES REQUIREMENT.—The Secretary shall publish a notice of any determination that the requirements of subsection (d) have been met and that submissions and approvals under subsection (b)(2) or (j) of section 505 for a drug will be subject to the provisions of this section.

''(g) LIMITATION.—The holder of an approved application for a new drug that has already received six months of market exclusivity under subsection (a) or (c) may, if otherwise eligible, obtain six months of market exclusivity under subsection (c)(1)(B) for a supplemental application, except that the holder is not eligible for exclusivity under subsection (c)(2).

''(h) STUDY AND REPORT.—The Secretary shall conduct a study and report to Congress not later than January 1, 2003 based on the experience under the program. The study and report shall examine all relevant issues, including—

''(1) the effectiveness of the program in improving information about important pediatric uses for approved drugs;

''(2) the adequacy of the incentive provided under this section;

''(3) the economic impact of the program; and

''(4) any suggestions for modification that the Secretary deems appropriate.

''(i) TERMINATION OF MARKET EXCLUSIVITY EXTENSION AUTHORITY FOR NEW DRUGS.—Except as provided in section 618(b) of the Food and Drug Administration Modernization and Accountability Act of 1997, no period of market exclusivity shall be extended under subsection (a) for a drug if—

''(1) the extension would be based on studies commenced after January 1, 2004; and

''(2) the application submitted for the drug under section 505(b)(1) was not approved by January 1, 2004.

''(j) DEFINITIONS.—In this section, the term 'pediatric studies' or 'studies' means at least 1 clinical investigation (that, at the Secretary's discretion, may include pharmacokinetic studies) in pediatric age-groups in which a drug is anticipated to be used.''.

(b) MARKET EXCLUSIVITY UNDER OTHER AUTHORITY.—

(1) THROUGH CALENDAR YEAR 2003.—

(A) DETERMINATION.—If the Secretary requests or requires pediatric studies, prior to January 1, 2004, under Federal law other than section 505A of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)), from the sponsor of an application, or the holder of an approved application, for a drug under section 505(b) of such Act (21 U.S.C. 355(b)), the Secretary shall determine whether the studies meet the completeness, timeliness, and other submission requirements of the Federal law involved.

(B) MARKET EXCLUSIVITY.—If the Secretary determines that the studies meet the requirements involved, the Secretary shall ensure that the period of market exclusivity for the drug involved is extended for 6 months in accordance with the requirements of subsection (a), (c), (e), and (g) (as appropriate) of section 505A of such Act (as in effect on the date of enactment of this Act.).

(2) CALENDAR YEAR 2004 AND SUBSEQUENT YEARS.—

(A) NEW DRUGS.—Effective January 1, 2004, if the Secretary requests or requires pediatric studies, under Federal law other than section 505A of the Federal Food, Drug, and Cosmetic Act, from the sponsor of an application for a drug under section 505(b) of such Act, nothing in such law shall be construed to permit or require the Secretary to ensure that the period of market exclusivity for the drug is extended.

(B) ALREADY MARKETED DRUGS.—

(i) DETERMINATION.—Effective January 1, 2004, if the Secretary requests or requires pediatric studies, under Federal law other than section 505A of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)), from the holder of an approved application for a drug under section 505(b) of such Act, the Secretary shall determine whether the studies meet the completeness, timeliness, and other submission requirements of the Federal law involved.

(ii) MARKET EXCLUSIVITY.—If the Secretary determines that the studies meet the requirements involved, the Secretary shall ensure that the period of market exclusivity for the drug involved is extended for 6 months in accordance with the requirements of subsection (a), (c), (e), and (g) (as appropriate) of section 505A of such Act (as in effect on the date of enactment of this Act.).

(3) DEFINITIONS.—In this subsection:

(A) DRUG.—The term ''drug'' has the meaning given the term in section 201 of such Act.

(B) PEDIATRIC STUDIES.—The term ''pediatric studies'' has the meaning given the term in section 505A of such Act.

(C) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

SEC. 619. POSITRON EMISSION TOMOGRAPHY.

(a) REGULATION OF COMPOUNDED POSITRON EMISSION TOMOGRAPHY DRUGS UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.—

(1) DEFINITION.—Section 201 (21 U.S.C. 321) is amended by adding at the end the following:

''(ii) The term 'compounded positron emission tomography drug'—

''(1) means a drug that—

''(A) exhibits spontaneous disintegration of unstable nuclei by the emission of positrons and is used for the purpose of providing dual photon positron emission tomographic diagnostic images; and

''(B) has been compounded by or on the order of a practitioner who is licensed by a State to compound or order compounding for a drug described in subparagraph (A), and is compounded in accordance with that State's law, for a patient or for research, teaching, or quality control; and

''(2) includes any nonradioactive reagent, reagent kit, ingredient, nuclide generator, accelerator, target material, electronic synthesizer, or other apparatus or computer program to be used in the preparation of such a drug.''.

(b) ADULTERATION.—

(1) IN GENERAL.—Section 501(a)(2) (21 U.S.C. 351(a)(2)) is amended by striking ''; or (3)'' and inserting the following: ''; or (C) if it is a compounded positron emission tomography drug and the methods used in, or the facilities and controls used for, its compounding, processing, packing, or holding do not conform to or are not operated or administered in conformity with the positron emission tomography compounding standards and the official monographs of the United States Pharmacopeia to assure that such drug meets the requirements of this Act as to safety and has the identity and strength, and meets the quality and purity characteristics, that it purports or is represented to possess; or (3)''.

(2) SUNSET.—Section 501(a)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351(a)(2)(C)) shall not apply 4 years after the date of enactment of this Act or 2 years after the date or which the Secretary of Health and Human Services establishes the requirements described in subsection (c)(1)(B), whichever is later.

(c) REQUIREMENTS FOR REVIEW OF APPROVAL PROCEDURES AND CURRENT GOOD MANUFACTURING PRACTICES FOR POSITRON EMISSION TOMOGRAPHY.—

(1) PROCEDURES AND REQUIREMENTS.—

(A) IN GENERAL.—In order to take account of the special characteristics of compounded positron emission tomography drugs and the special techniques and processes required to produce these drugs, not later than 2 years after the date of enactment of this Act, the Secretary of Health and Human Services shall establish—

(i) appropriate procedures for the approval of compounded positron emission tomography drugs pursuant to section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355); and

(ii) appropriate current good manufacturing practice requirements for such drugs.

(B) CONSIDERATIONS AND CONSULTATION.—In establishing the procedures and requirements required by subparagraph (A), the Secretary of Health and Human Services shall take due account of any relevant differences between not-for-profit institutions that compound the drugs for their patients and commercial manufacturers of the drugs. Prior to establishing the procedures and requirements, the Secretary of Health and Human Services shall consult with patient advocacy groups, professional associations, manufacturers, and physicians and scientists licensed to make or use compounded positron emission tomography drugs.

(2) SUBMISSION OF NEW DRUG APPLICATIONS AND ABBREVIATED NEW DRUG APPLICATIONS.—

(A) IN GENERAL.—Except as provided in subparagraph (B), the Secretary of Health and Human Services shall not require the submission of new drug applications or abbreviated new drug applications under subsection (b) or (j) of section 505 (21 U.S.C. 355), for compounded positron emission tomography drugs that are not adulterated drugs described in section 501(a)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351(a)(2)(C)) (as amended by subsection (b)), for a period of 4 years after the date of enactment of this Act, or for 2 years after the date or which the Secretary establishes procedures and requirements under paragraph (1), whichever is later.

(B) EXCEPTION.—Nothing in this Act shall prohibit the voluntary submission of such applications or the review of such applications by the Secretary of Health and Human Services. Nothing in this Act shall constitute an exemption for a compounded positron emission tomography drug from the requirements of regulations issued under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) for such drugs.

(d) REVOCATION OF CERTAIN INCONSISTENT DOCUMENTS.—Within 30 days after the date of enactment of this Act, the Secretary of Health and Human Services shall publish in the Federal Register a notice terminating the application of the following notices and rule, to the extent the notices and rule relate to compounded positron emission tomography drugs:

(1) A notice entitled ''Regulation of Positron Emission Tomographic Drug Products: Guidance; Public Workshop'', published in the Federal Register on February 27, 1995.

(2) A notice entitled ''Guidance for Industry: Current Good Manufacturing Practices for Positron Emission Tomographic (PET) Drug Products; Availability'', published in the Federal Register on April 22, 1997.

(3) A final rule entitled ''Current Good Manufacturing Practice for Finished Pharmaceuticals; Positron Emission Tomography'', published in the Federal Register on April 22, 1997.

(e) DEFINITION.—As used in this section, the term ''compounded positron emission tomography drug'' has the meaning given the term in section 201 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321).

SEC. 620. DISCLOSURE.

Chapter IV (21 U.S.C. 341 et seq.) is amended by adding after section 403B the following:

''DISCLOSURE

''SEC. 403C. (a) No provision of section 403(a), 201(n), or 409 shall be construed to require on the label or labeling of a food a separate radiation disclosure statement that is more prominent than the declaration of ingredients required by section 403(i)(2).

''(b) In this section, the term 'radiation disclosure statement' means a written statement that discloses that a food or a component of the food has been intentionally subject to radiation.''.

SEC. 621. REFERRAL STATEMENTS RELATING TO FOOD NUTRIENTS.

Section 403(r)(2)(B) (21 U.S.C. 343(r)(2)(B)) is amended to read as follows:

''(B) If a claim described in subparagraph (1)(A) is made with respect to a nutrient in a food, and the Secretary makes a determination that the food contains a nutrient at a level that increases to persons in the general population the risk of a disease or health-related condition that is diet related, then the label or labeling of such food shall contain, prominently and in immediate proximity to such claim, the following statement: 'See nutrition information panel for ____ content.' The blank shall identify the nutrient associated with the increased disease or health-related condition risk. In making the determination described in this clause, the Secretary shall take into account the significance of the food in the total daily diet.''.

TITLE VII—FEES RELATING TO DRUGS

SEC. 701. SHORT TITLE.

This title may be cited as the ''Prescription Drug User Fee Reauthorization Act of 1997''.

SEC. 702. FINDINGS.

Congress finds that—

(1) prompt approval of safe and effective new drugs and other therapies is critical to the improvement of the public health so that patients may enjoy the benefits provided by these therapies to treat and prevent illness and disease;

(2) the public health will be served by making additional funds available for the purpose of augmenting the resources of the Food and Drug Administration that are devoted to the process for review of human drug applications;

(3) the provisions added by the Prescription Drug User Fee Act of 1992 have been successful in substantially reducing review times for human drug applications and should be—

(A) reauthorized for an additional 5 years, with certain technical improvements; and

(B) carried out by the Food and Drug Administration with new commitments to implement more ambitious and comprehensive improvements in regulatory processes of the Food and Drug Administration; and

(4) the fees authorized by amendments made in this title will be dedicated toward expediting the drug development process and the review of human drug applications as set forth in the goals identified in appropriate letters from the Secretary of Health and Human Services to the chairman of the Committee on Commerce of the House of Representatives and the chairman of the Committee on Labor and Human Resources of the Senate.

SEC. 703. DEFINITIONS.

Section 735 (21 U.S.C. 379g) is amended—

(1) in the second sentence of paragraph (1)—

(A) by striking ''Service Act, and'' and inserting ''Service Act,''; and

(B) by striking ''September 1, 1992.'' and inserting the following: ''September 1, 1992, does not include an application for a licensure of a biological product for further manufacturing use only, and does not include an application or supplement submitted by a State or Federal Government entity for a drug or biological product that is not distributed commercially. Such term does include an application for licensure, as described in subparagraph (D), of a large volume biological product intended for single dose injection for intravenous use or infusion.'';

(2) in the second sentence of paragraph (3)—

(A) by striking ''Service Act, and'' and inserting ''Service Act,''; and

(B) by striking ''September 1, 1992.'' and inserting the following: ''September 1, 1992, does not include a biological product that is licensed for further manufacturing use only, and does not include a drug or biological product that is not distributed commercially and is the subject of an application or supplement submitted by a State or Federal Government entity. Such term does include a large volume biological product intended for single dose injection for intravenous use or infusion.'';

(3) in paragraph (4), by striking ''without'' and inserting ''without substantial'';

(4) by striking paragraph (5) and inserting the following:

''(5) The term 'prescription drug establishment' means a foreign or domestic place of business which is at 1 general physical location consisting of 1 or more buildings all of which are within 5 miles of each other, at which 1 or more prescription drug products are manufactured in final dosage forms.'';

(5) in paragraph (7)(A)—

(A) by striking ''employees under contract'' and all that follows through ''Administration,'' and inserting ''contractors of the Food and Drug Administration,''; and

(B) by striking ''and committees,'' and inserting ''and committees and to contracts with such contractors,'';

(6) in paragraph (8)—

(A) in subparagraph (A)—

(i) by striking ''August of'' and inserting ''April of''; and

(ii) by striking ''August 1992'' and inserting ''April 1997'';

(B) by striking subparagraph (B) and inserting the following:

''(B) 1 plus the decimal expression of the total percentage increase for such fiscal year since fiscal year 1997 in basic pay under the General Schedule in accordance with section 5332 of title 5, United States Code, as adjusted by any locality-based comparability payment pursuant to section 5304 of such title for Federal employees stationed in the District of Columbia.''; and

(C) by striking the second sentence; and

(7) by adding at the end the following:

''(9) The term 'affiliate' means a business entity that has a relationship with a second business entity if, directly or indirectly—

''(A) 1 business entity controls, or has the power to control, the other business entity; or

''(B) a third party controls, or has power to control both of the business entities.''.

SEC. 704. AUTHORITY TO ASSESS AND USE DRUG FEES.

(a) TYPES OF FEES.—Section 736(a) (21 U.S.C. 379h(a)) is amended—

(1) by striking ''Beginning in fiscal year 1993'' and inserting ''Beginning in fiscal year 1998'';

(2) in paragraph (1)—

(A) by striking subparagraph (B) and inserting the following:

''(B) PAYMENT.—The fee required by subparagraph (A) shall be due upon submission of the application or supplement.'';

(B) in subparagraph (D)—

(i) in the subparagraph heading, by striking ''NOT ACCEPTED'' and inserting ''REFUSED'';

(ii) by striking ''50 percent'' and inserting ''75 percent'';

(iii) by striking ''subparagraph (B)(i)'' and inserting ''subparagraph (B)''; and

(iv) by striking ''not accepted'' and inserting ''refused''; and

(C) by adding at the end the following:

''(E) EXCEPTION FOR DESIGNATED ORPHAN DRUG OR INDICATION.—A human drug application for a prescription drug product that has been designated as a drug for a rare disease or condition pursuant to section 526 shall not be subject to a fee under subparagraph (A),

unless the human drug application includes indications for other than rare diseases or conditions. A supplement proposing to include a new indication for a rare disease or condition in a human drug application shall not be subject to a fee under subparagraph (A), provided that the drug has been designated pursuant to section 526 as a drug for a rare disease or condition with regard to the indication proposed in such supplement.

''(F) EXCEPTION FOR SUPPLEMENTS FOR PEDIATRIC INDICATIONS.—A supplement to a human drug application for an indication for use in pediatric populations shall not be assessed a fee under subparagraph (A).

''(G) REFUND OF FEE IF APPLICATION WITHDRAWN.—If an application or supplement is withdrawn after the application or supplement is filed, the Secretary may waive and refund the fee or a portion of the fee if no substantial work was performed on the application or supplement after the application or supplement was filed. The Secretary shall have the sole discretion to waive and refund a fee or a portion of the fee under this subparagraph. A determination by the Secretary concerning a waiver or refund under this paragraph shall not be reviewable.'';

(3) by striking paragraph (2) and inserting the following:

''(2) PRESCRIPTION DRUG ESTABLISHMENT FEE.—

''(A) IN GENERAL.—Each person that—

''(i) is named as the applicant in a human drug application; and

''(ii) after September 1, 1992, had pending before the Secretary a human drug application or supplement;

shall be assessed an annual fee established in subsection (b) for each prescription drug establishment listed in its approved human drug application as an establishment that manufactures the prescription drug product named in the application. The annual establishment fee shall be assessed in each fiscal year in which the prescription drug product named in the application is assessed a fee under paragraph (3) unless the prescription drug establishment listed in the application does not engage in the manufacture of the prescription drug product during the fiscal year. The establishment fee shall be payable on or before January 31 of each year. Each such establishment shall be assessed only 1 fee per establishment, notwithstanding the number of prescription drug products manufactured at the establishment. In the event an establishment is listed in a human drug application by more than 1 applicant, the establishment fee for the fiscal year shall be divided equally and assessed among the applicants whose prescription drug products are manufactured by the establishment during the fiscal year and assessed product fees under paragraph (3).

''(B) EXCEPTION.—If, during the fiscal year, an applicant initiates or causes to be initiated the manufacture of a prescription drug product at an establishment listed in its human drug application—

''(i) that did not manufacture the product in the previous fiscal year; and

''(ii) for which the full establishment fee has been assessed in the fiscal year at a time before manufacture of the prescription drug product was begun;

the applicant will not be assessed a share of the establishment fee for the fiscal year in which manufacture of the product began.''; and

(4) in paragraph (3)—

(A) in subparagraph (A)—

(i) in clause (i), by striking ''is listed'' and inserting ''has been submitted for listing''; and

(ii) by striking ''Such fee shall be payable'' and all that follows through ''section 510.'' and inserting the following: ''Such fee shall be payable for the fiscal year in which the product is first submitted for listing under section 510, or for relisting under section 510 if the product has been withdrawn from listing and relisted. After such fee is paid for that fiscal year, such fee shall be payable on or before January 31 of each year. Such fee shall be paid only once for each product for a fiscal year in which the fee is payable.''; and

(B) in subparagraph (B), by striking ''505(j).'' and inserting the following: ''505(j), or under an abbreviated new drug application pursuant to regulations in effect prior to the implementation of the Drug Price Competition and Patent Term Restoration Act of 1984, or is a product approved under an application filed under section 507 that is abbreviated.''.

(b) FEE AMOUNTS.—Section 736(b) (21 U.S.C. 379h(b)) is amended to read as follows:

''(b) FEE AMOUNTS.—Except as provided in subsections (c), (d), (f), and (g), the fees required under subsection (a) shall be determined and assessed as follows:

''(1) APPLICATION AND SUPPLEMENT FEES.—

''(A) FULL FEES.—The application fee under subsection (a)(1)(A)(i) shall be $250,704 in fiscal year 1998, $256,338 in each of fiscal years 1999 and 2000, $267,606 in fiscal year 2001, and $258,451 in fiscal year 2002.

''(B) OTHER FEES.—The fee under subsection (a)(1)(A)(ii) shall be $125,352 in fiscal year 1998, $128,169 in each of fiscal years 1999 and 2000, $133,803 in fiscal year 2001, and $129,226 in fiscal year 2002.

''(2) FEE REVENUES FOR ESTABLISHMENT FEES.—The total fee revenues to be collected in establishment fees under subsection (a)(2) shall be $35,600,000 in fiscal year 1998, $36,400,000 in each of fiscal years 1999 and 2000, $38,000,000 in fiscal year 2001, and $36,700,000 in fiscal year 2002.

''(3) TOTAL FEE REVENUES FOR PRODUCT FEES.—The total fee revenues to be collected in product fees under subsection (a)(3) in a fiscal year shall be equal to the total fee revenues collected in establishment fees under subsection (a)(2) in that fiscal year.''.

(c) INCREASES AND ADJUSTMENTS.—Section 736(c) (21 U.S.C. 379h(c)) is amended—

(1) in the subsection heading, by striking ''INCREASES AND'';

(2) in paragraph (1)—

(A) by striking ''(1) REVENUE'' and all that follows through ''increased by the Secretary'' and inserting the following: ''(1) INFLATION ADJUSTMENT.—The fees and total fee revenues established in subsection (b) shall be adjusted by the Secretary'';

(B) in subparagraph (A), by striking ''increase'' and inserting ''change'';

(C) in subparagraph (B), by striking ''increase'' and inserting ''change''; and

(D) by adding at the end the following flush sentence:

''The adjustment made each fiscal year by this subsection will be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 1997 under this subsection.'';

(3) in paragraph (2), by striking ''October 1, 1992,'' and all that follows through ''such schedule.'' and inserting the following: ''September 30, 1997, adjust the establishment and product fees described in subsection (b) for the fiscal year in which the adjustment occurs so that the revenues collected from each of the categories of fees described in paragraphs (2) and (3) of subsection (b) shall be set to be equal to the revenues collected from the category of application and supplement fees described in paragraph (1) of subsection (b).''; and

(4) in paragraph (3), by striking ''paragraph (2)'' and inserting ''this subsection''.

(d) FEE WAIVER OR REDUCTION.—Section 736(d) (21 U.S.C. 379h(d)) is amended—

(1) by redesignating paragraphs (1), (2), (3), and (4) as subparagraphs (A), (B), (C), and (D), respectively, and indenting appropriately;

(2) by striking ''The Secretary shall grant a'' and all that follows through ''finds that—'' and inserting the following:

''(1) IN GENERAL.—The Secretary shall grant a waiver from or a reduction of 1 or more fees assessed under subsection (a) where the Secretary finds that—'';

(3) in subparagraph (C) (as so redesignated by paragraph (1)), by striking '', or'' and inserting a comma;

(4) in subparagraph (D) (as so redesignated by paragraph (1)), by striking the period and inserting '', or'';

(5) by inserting after subparagraph (D) (as so redesignated by paragraph (1)) the following:

''(E) the applicant is a small business submitting its first human drug application to the Secretary for review.''; and

(6) by striking ''In making the finding in paragraph (3),'' and all that follows through ''standard costs.'' and inserting the following:

''(2) USE OF STANDARD COSTS.—In making the finding in paragraph (1)(C), the Secretary may use standard costs.

''(3) RULES RELATING TO SMALL BUSINESSES.—

''(A) DEFINITION.—In paragraph (1)(E), the term 'small business' means an entity that has fewer than 500 employees, including employees of affiliates.

''(B) WAIVER OF APPLICATION FEE.—The Secretary shall waive under paragraph (1)(E) the application fee for the first human drug application that a small business or its affiliate submits to the Secretary for review. After a small business or its affiliate is granted such a waiver, the small business or its affiliate shall pay—

''(i) application fees for all subsequent human drug applications submitted to the Secretary for review in the same manner as an entity that does not qualify as a small business; and

''(ii) all supplement fees for all supplements to human drug applications submitted to the Secretary for review in the same manner as an entity that does not qualify as a small business.''.

(e) ASSESSMENT OF FEES.—Section 736(f)(1) (21 U.S.C. 379h(f)(1)) is amended—

(1) by striking ''fiscal year 1993'' and inserting ''fiscal year 1997''; and

(2) by striking ''fiscal year 1992'' and inserting ''fiscal year 1997 (excluding the amount of fees appropriated for such fiscal year)''.

(f) CREDITING AND AVAILABILITY OF FEES.—Section 736(g) (21 U.S.C. 379h(g)) is amended—

(1) in paragraph (1), by adding at the end the following: ''Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for the process for the review of human drug applications within the meaning of section 735(6).'';

(2) in paragraph (2)—

(A) in subparagraph (A), by striking ''Acts'' and inserting ''Acts, or otherwise made available for obligation,''; and

(B) in subparagraph (B), by striking ''over such costs for fiscal year 1992'' and inserting ''over such costs, excluding costs paid from fees collected under this section, for fiscal year 1997''; and

(3) by striking paragraph (3) and inserting the following:

''(3) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated for fees under this section—

''(A) $106,800,000 for fiscal year 1998;

''(B) $109,200,000 for fiscal year 1999;

''(C) $109,200,000 for fiscal year 2000;

''(D) $114,000,000 for fiscal year 2001; and

''(E) $110,100,000 for fiscal year 2002,

as adjusted to reflect adjustments in the total fee revenues made under this section and changes in the total amounts collected by application, supplement, establishment, and product fees.

''(4) OFFSET.—Any amount of fees collected for a fiscal year which exceeds the amount of fees specified in appropriation Acts for such fiscal year, shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under appropriation Acts for a subsequent fiscal year.''.

(g) REQUIREMENT FOR WRITTEN REQUESTS FOR WAIVERS, REDUCTIONS, AND FEES.—Section 736 (21 U.S.C. 379h) is amended—

(1) by redesignating subsection (i) as subsection (j); and

(2) by inserting after subsection (h) the following:

''(i) WRITTEN REQUESTS FOR WAIVERS, REDUCTIONS, AND REFUNDS.—To qualify for consideration for a waiver or reduction under subsection (d), or for a refund, of any fee collected in accordance with subsection (a), a person shall submit to the Secretary a written request for such waiver, reduction, or refund not later than 180 days after such fee is due.''.

(h) SPECIAL RULE FOR WAIVER, REFUNDS, AND EXCEPTIONS.—Any requests for waivers, refunds, or exceptions for fees paid prior to the date of enactment of this Act shall be submitted in writing to the Secretary of Health and Human Services within 1 year after the date of enactment of this Act.

SEC. 705. ANNUAL REPORTS.

(a) FIRST REPORT.—Beginning with fiscal year 1998, not later than 60 days after the end of each fiscal year during which fees are collected under part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g et seq.), the Secretary of Health and Human Services shall prepare and submit to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letter described in section 702(4) during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals.

(b) SECOND REPORT.—Beginning with fiscal year 1998, not later than 120 days after the end of each fiscal year during which fees are collected under the part described in subsection (a), the Secretary of Health and Human Services shall prepare and submit to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected during such fiscal year for which the report is made.

SEC. 706. EFFECTIVE DATE.

The amendments made by this title shall take effect October 1, 1997.

SEC. 707. TERMINATION OF EFFECTIVENESS.

The amendments made by sections 703 and 704 cease to be effective October 1, 2002 and section 705 ceases to be effective 120 days after such date.

TITLE VIII—MISCELLANEOUS

SEC. 801. REGISTRATION OF FOREIGN ESTABLISHMENTS.

Section 510(i) (21 U.S.C. 360(i)) is amended to read as follows:

''(i)(1) Any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or a device that is imported or offered for import into the United States shall register with the Secretary the name and place of business of the establishment and the name of the United States agent for the establishment.

''(2) The establishment shall also provide the information required by subsection (j).

''(3) The Secretary is authorized to enter into cooperative arrangements with foreign countries to ensure that adequate and effective means are available for purposes of determining, from time to time, whether drugs or devices manufactured, prepared, propagated, compounded, or processed by an establishment described in paragraph (1), if imported or offered for import into the United States, shall be refused admission on any of the grounds set forth in section 801(a).''.

SEC. 802. ELIMINATION OF CERTAIN LABELING REQUIREMENTS.

(a) PRESCRIPTION DRUGS.—Section 503(b)(4) (21 U.S.C. 353(b)(4)) is amended to read as follows:

''(4)(A) A drug that is subject to paragraph (1) shall be deemed to be misbranded if at any time prior to dispensing the label of the drug fails to bear, at a minimum, the symbol 'Rx only'.

''(B) A drug to which paragraph (1) does not apply shall be deemed to be misbranded if at any time prior to dispensing the label of the drug bears the symbol described in subparagraph (A).''.

(b) MISBRANDED DRUG.—Section 502(d) (21 U.S.C. 352(d)) is repealed.

(c) CONFORMING AMENDMENTS.—

(1) Section 503(b)(1) (21 U.S.C. 353(b)(1)) is amended—

(A) by striking subparagraph (A); and

(B) by redesignating subparagraphs (B) and (C) as subparagraphs (A) and (B), respectively.

(2) Section 503(b)(3) (21 U.S.C. 353(b)(3)) is amended by striking ''section 502(d) and''.

(3) Section 102(9)(A) of the Controlled Substances Act (21 U.S.C. 802(9)(A)) is amended—

(A) in clause (i), by striking ''(i)''; and

(B) by striking ''(ii)'' and all that follows.

SEC. 803. CLARIFICATION OF SEIZURE AUTHORITY.

Section 304(d)(1) (21 U.S.C. 334(d)(1)) is amended—

(1) in the fifth sentence, by striking ''paragraphs (1) and (2) of section 801(e)'' and inserting ''subparagraphs (A) and (B) of section 801(e)(1)''; and

(2) by inserting after the fifth sentence the following: ''Any person seeking to export an imported article pursuant to any of the provisions of this subsection shall establish that the article was intended for export at the time the article entered commerce.''.

SEC. 804. INTRAMURAL RESEARCH TRAINING AWARD PROGRAM.

Chapter IX (21 U.S.C. 391 et seq.), as amended by section 203, is further amended by adding at the end the following:

''SEC. 907. INTRAMURAL RESEARCH TRAINING AWARD PROGRAM.

''(a) IN GENERAL.—The Secretary, acting through the Commissioner of Food and Drugs, may, directly or through grants, contracts, or cooperative agreements, conduct and support intramural research training in regulatory scientific programs by predoctoral and postdoctoral scientists and physicians, including support through the use of fellowships.

''(b) LIMITATION ON PARTICIPATION.—A recipient of a fellowship under subsection (a) may not be an employee of the Federal Government.

''(c) SPECIAL RULE.—The Secretary, acting through the Commissioner of Food and Drugs, may support the provision of assistance for fellowships described in subsection (a) through a Cooperative Research and Development Agreement.''.

SEC. 805. DEVICE SAMPLES.

(a) RECALL AUTHORITY.—

(1) IN GENERAL.—Section 518(e)(2) (21 U.S.C. 360h(e)(2)) is amended by adding at the end the following:

''(C) If the Secretary issues an amended order under subparagraph (A), the Secretary may require the person subject to the order to submit such samples of the device and of components of the device as the Secretary may reasonably require. If the submission of such samples is impracticable or unduly burdensome, the requirement of this subparagraph may be met by the submission of complete information concerning the location of 1 or more such devices readily available for examination and testing.''.

(2) TECHNICAL AMENDMENT.—Section 518(e)(2)(A) (21 U.S.C. 360h(e)(2)(A)) is amended by striking ''subparagraphs (B) and (C)'' and inserting ''subparagraph (B)''.

(b) RECORDS AND REPORTS ON DEVICES.—Section 519(a) (21 U.S.C. 360i(a)) is amended by inserting after paragraph (9) the following:

''(10) may reasonably require a manufacturer or importer to submit samples of a device and of components of the device that may have caused or contributed to a death or serious injury, except that if the submission of such samples is impracticable or unduly burdensome, the requirement of this paragraph may be met by the submission of complete information concerning the location of 1 or more such devices readily available for examination and testing.''.

SEC. 806. INTERSTATE COMMERCE.

Section 709 (21 U.S.C. 379a) is amended by striking ''a device'' and inserting ''a device, food, drug, or cosmetic''.

SEC. 807. NATIONAL UNIFORMITY FOR NONPRESCRIPTION DRUGS AND COSMETICS.

(a) NONPRESCRIPTION DRUGS.—Chapter VII (21 U.S.C. 371 et seq.), as amended by section 614(a), is further amended by adding at the end the following:

''Subchapter F—National Uniformity for Nonprescription Drugs and Preemption for Labeling or Packaging of Cosmetics

''SEC. 761. NATIONAL UNIFORMITY FOR NONPRESCRIPTION DRUGS.

''(a) IN GENERAL.—Except as provided in subsection (b), (c)(1), (d), (e), or (f), no State or political subdivision of a State may establish or continue in effect any requirement—

''(1) that relates to the regulation of a drug that is not subject to the requirements of section 503(b)(1) or 503(f)(1)(A); and

''(2) that is different from or in addition to, or that is otherwise not identical with, a requirement under this Act, the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.), or the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.).

''(b) EXEMPTION.—

''(1) IN GENERAL.—Upon application of a State or political subdivision thereof, the Secretary may by regulation, after notice and opportunity for written and oral presentation of views, exempt from subsection (a), under such conditions as may be prescribed in such regulation, a State or political subdivision requirement that—

''(A) protects an important public interest that would otherwise be unprotected, including the health and safety of children;

''(B) would not cause any drug to be in violation of any applicable requirement or prohibition under Federal law; and

''(C) would not unduly burden interstate commerce.

''(2) TIMELY ACTION.—The Secretary shall make a decision on the exemption of a State or political subdivision requirement under paragraph (1) not later than 120 days after receiving the application of the State or political subdivision under paragraph (1).

''(c) SCOPE.—

''(1) IN GENERAL.—This section shall not apply to—

''(A) any State or political subdivision requirement that relates to the practice of pharmacy; or

''(B) any State or political subdivision requirement that a drug be dispensed only upon the prescription of a practitioner licensed by law to administer such drug.

''(2) SAFETY OR EFFECTIVENESS.—For purposes of subsection (a), a requirement that relates to the regulation of a drug shall be deemed to include any requirement relating to public information or any other form of public communication relating to a warning of any kind for a drug.

''(d) EXCEPTIONS.—

''(1) IN GENERAL.—In the case of a drug described in subsection (a)(1) that is not the subject of an application approved under section 505 or 507 or a final regulation promulgated by the Secretary establishing conditions under which the drug is generally recognized as safe and effective and not misbranded, subsection (a) shall apply only with respect to a requirement of a State or political subdivision of a State that relates to the same subject as, but is different from or in addition to, or that is otherwise not identical with—

''(A) a regulation in effect with respect to the drug pursuant to a statute described in subsection (a)(2); or

''(B) any other requirement in effect with respect to the drug pursuant to an amendment to such a statute made on or after the date of enactment of this section.

''(2) STATE INITIATIVES.—This section shall not apply to a State public initiative enacted prior to the date of enactment of this section.

''(e) NO EFFECT ON PRODUCT LIABILITY LAW.—Nothing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.

''(f) STATE ENFORCEMENT AUTHORITY.—Nothing in this section shall prevent a State or political subdivision thereof from enforcing, under any relevant civil or other enforcement authority, a requirement that is identical to a requirement of this Act.''.

(b) INSPECTIONS.—Section 704(a)(1) (21 U.S.C. 374(a)(1)) is amended by striking ''prescription drugs'' each place it appears and inserting ''prescription drugs, nonprescription drugs intended for human use,''.

(c) MISBRANDING.—Paragraph (1) of section 502(e) (21 U.S.C. 352(e)(1)) is amended to read as follows:

''(1)(A) If it is a drug, unless its label bears, to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula)—

''(i) the established name (as defined in subparagraph (3)) of the drug, if there is such a name;

''(ii) the established name and quantity or, if deemed appropriate by the Secretary, the proportion of each active ingredient, including the quantity, kind, and proportion of any alcohol, and also including whether active or not the established name and quantity or if deemed appropriate by the Secretary, the proportion of any bromides, ether, chloroform, acetanilide, acetophenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein: *Provided*, That the requirement for stating the quantity of the active ingredients, other than the quantity of those specifically named in this paragraph, shall not apply to nonprescription drugs not intended for human use; and

''(iii) the established name of each inactive ingredient listed in alphabetical order on the outside container of the retail package and, if deemed appropriate by the Secretary, on the immediate container, as prescribed in regulation promulgated by the Secretary, but nothing in this clause shall be deemed to require that any trade secret be divulged: *Provided*, That the requirements of this clause with respect to alphabetical order shall apply only to nonprescription drugs that are not also cosmetics: and *Provided further*, That this clause shall not apply to nonprescription drugs not intended for human use.

''(B) For any prescription drug the established name of such drug or ingredient, as the case may be, on such label (and on any labeling on which a name for such drug or ingredient is used) shall be printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug or ingredient: *Provided*, That to the extent that compliance with the requirements of clause (A)(ii) or (iii) or this clause of this subparagraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary.''.

(d) COSMETICS.—Subchapter F of chapter VII, as amended by subsection (a), is further amended by adding at the end the following:

''SEC. 762. PREEMPTION FOR LABELING OR PACKAGING OF COSMETICS.

''(a) IN GENERAL.—Except as provided in subsection (b), (d), or (e), a State or political subdivision of a State shall not impose or continue in effect any requirement for labeling or packaging of a cosmetic that is different from or in addition to, or that is otherwise not identical with a requirement specifically applicable to a particular cosmetic or class of cosmetics under this Act, the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.), or the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.).

''(b) EXEMPTION.—Upon application of a State or political subdivision thereof, the Secretary may by regulation after notice and opportunity for written and oral presentation of views, exempt from subsection (a), under such conditions as may be prescribed in such regulation, a State or political subdivision requirement for labeling and packaging that—

''(1) protects an important public interest that would otherwise be unprotected;

''(2) would not cause a cosmetic to be in violation of any applicable requirements or prohibition under Federal law; and

''(3) would not unduly burden interstate commerce.

''(c) SCOPE.—For purposes of subsection (a), a reference to a State requirement that relates to the packaging or labeling of a cosmetic means any specific requirement relating to the same aspect of such cosmetic as a requirement specifically applicable to that particular cosmetic or class of cosmetics under this Act for packaging or labeling, including any State requirement relating to public information or any other form of public communication.

''(d) NO EFFECT ON PRODUCT LIABILITY LAW.—Nothing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.

''(e) STATE INITIATIVE.—This section shall not apply to a State requirement adopted by a State public initiative or referendum enacted prior to September 1, 1997.''.

SEC. 808. INFORMATION PROGRAM ON CLINICAL TRIALS FOR SERIOUS OR LIFE-THREATENING DISEASES.

(a) IN GENERAL.—Section 402 of the Public Health Service Act (42 U.S.C. 282) is amended—

(1) by redesignating subsections (j) and (k) as subsections (k) and (l), respectively; and

(2) by inserting after subsection (i), the following:

''(j)(1) The Secretary, acting through the Director of the National Institutes of Health and subject to the availability of appropriations, shall establish, maintain, and operate a program with respect to information on research relating to the treatment, detection, and prevention of serious or life-threatening diseases and conditions. The program shall, with respect to the agencies of the Department of Health and Human Services, be integrated and coordinated, and, to the extent practicable, coordinated with other data banks containing similar information.

''(2)(A) After consultation with the Commissioner of Food and Drugs, the directors of the appropriate agencies of the National Institutes of Health (including the National Library of Medicine), and the Director of the Centers for Disease Control and Prevention, the Secretary shall, in carrying out paragraph (1), establish a data bank of information on clinical trials for drugs, and biologicals, for serious or life-threatening diseases and conditions.

''(B) In carrying out subparagraph (A), the Secretary shall collect, catalog, store, and disseminate the information described in such subparagraph. The Secretary shall disseminate such information through information systems, which shall include toll-free telephone communications, available to individuals with serious or life-threatening diseases and conditions, to other members of the public, to health care providers, and to researchers.

''(3) The data bank shall include the following:

''(A) A registry of clinical trials (whether federally or privately funded) of experimental treatments for serious or life-threatening diseases and conditions under regulations promulgated pursuant to sections 505 and 520 of the Federal Food, Drug, and Cosmetic Act that provides a description of the purpose of each experimental drug or biological protocol, either with the consent of the protocol sponsor, or when a trial to test efficacy begins. Information provided shall consist of eligibility criteria, a description of the location of trial sites, and a point of contact for those wanting to enroll in the trial, and shall be in a form that can be readily understood by members of the public. Such information must be forwarded to the data bank by the sponsor of the trial not later than 21 days after the approval by the Food and Drug Administration.

''(B) Information pertaining to experimental treatments for serious or life-threatening diseases and conditions that may be available—

''(i) under a treatment investigational new drug application that has been submitted to the Food and Drug Administration pursuant to part 312 of title 21, Code of Federal Regulations; or

''(ii) as a Group C cancer drug.

The data bank may also include information pertaining to the results of clinical trials of such treatments, with the consent of the sponsor, including information concerning potential toxicities or adverse effects associated with the use or administration of such experimental treatments.

''(4) The data bank shall not include information relating to an investigation if the sponsor has provided a detailed certification to the Secretary that disclosure of such information would substantially interfere with the timely enrollment of subjects in the investigation, unless the Secretary, after the receipt of the certification, provides the sponsor with a detailed written determination that finds that such disclosure would not substantially interfere with such enrollment.

''(5) For the purpose of carrying out this subsection, there are authorized to be appropriated such sums as may be necessary. Fees collected under section 736 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h) shall not be authorized or appropriated for use in carrying out this subsection.''.

(b) COLLABORATION AND REPORT.—

(1) IN GENERAL.—The Secretary of Health and Human Services, the Director of the National Institutes of Health, and the Commissioner of Food and Drugs shall collaborate to determine the feasibility of including device investigations within the scope of the registry requirements set forth in subsection (j) of section 402 of the Public Health Service Act.

(2) REPORT.—Not later than 2 years after the date of enactment of this section, the Secretary of Health and Human Services shall prepare and submit to the Committee on Labor and Human Resources of the Senate and the Committee on Commerce of the House of Representatives a report that shall consider, among other things—

(A) the public health need, if any, for inclusion of device investigations within the scope of the registry requirements set forth in subsection (j) of section 402 of the Public Health Service Act; and

(B) the adverse impact, if any, on device innovation and research in the United States if information relating to such device investigation is required to be publicly disclosed.

SEC. 809. APPLICATION OF FEDERAL LAW TO THE PRACTICE OF PHARMACY COMPOUNDING.

Section 503 (21 U.S.C. 353) is amended by adding at the end the following:

''(h)(1) Sections 501(a)(2)(B), 502(f)(1), 502(l), 505, and 507 shall not apply to a drug product if—

''(A) the drug product is compounded for an identified individual patient, based on a medical need for a compounded product—

''(i) by a licensed pharmacist in a State licensed pharmacy or a Federal facility, or a licensed physician, on the prescription order of a licensed physician or other licensed practitioner authorized by State law to prescribe drugs; or

''(ii) by a licensed pharmacist or licensed physician in limited quantities, prior to the receipt of a valid prescription order for the identified individual patient, and is compounded based on a history of the licensed pharmacist or licensed physician receiving valid prescription orders for the compounding of the drug product that have been generated solely within an established relationship between the licensed pharmacist, or licensed physician, and—

''(I) the individual patient for whom the prescription order will be provided; or

''(II) the physician or other licensed practitioner who will write such prescription order; and

''(B) the licensed pharmacist or licensed physician—

''(i) compounds the drug product using bulk drug substances—

''(I) that—

''(aa) comply with the standards of an applicable United States Pharmacopeia or National Formulary monograph; or

''(bb) in a case in which such a monograph does not exist, are drug substances that are covered by regulations issued by the Secretary under paragraph (3);

''(II) that are manufactured by an establishment that is registered under section 510 (including a foreign establishment that is registered under section 510(i)); and

''(III) that are accompanied by valid certificates of analysis for each bulk drug substance;

''(ii) compounds the drug product using ingredients (other than bulk drug substances) that comply with the standards of an applicable United States Pharmacopeia or National Formulary monograph and the United States Pharmacopeia chapter on pharmacy compounding;

''(iii) only advertises or promotes the compounding service provided by the licensed pharmacist or licensed physician and does not advertise or promote the compounding of any particular drug, class of drug, or type of drug;

''(iv) does not compound a drug product that appears on a list published by the Secretary in the Federal Register of drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective;

''(v) does not compound a drug product that is identified by the Secretary in regulation as presenting demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product; and

''(vi) does not distribute compounded drugs outside of the State in which the drugs are compounded, unless the principal State agency of jurisdiction that regulates the practice of pharmacy in such State has entered into a memorandum of understanding with the Secretary regarding the regulation of drugs that are compounded in the State and are distributed outside of the State, that provides for appropriate investigation by the State agency of complaints relating to compounded products distributed outside of the State.

''(2)(A) The Secretary shall, after consultation with the National Association of Boards of Pharmacy, develop a standard memorandum of understanding for use by States in complying with paragraph (1)(B)(vi).

''(B) Paragraph (1)(B)(vi) shall not apply to a licensed pharmacist or licensed physician, who does not distribute inordinate amounts of compounded products outside of the State, until—

''(i) the date that is 180 days after the development of the standard memorandum of understanding; or

''(ii) the date on which the State agency enters into a memorandum of understanding under paragraph (1)(B)(vi),

whichever occurs first.

''(3) The Secretary, after consultation with the United States Pharmacopeia Convention Incorporated, shall promulgate regulations limiting compounding under paragraph (1)(B)(i)(I)(bb) to drug substances that are components of drug products approved by the Secretary and to other drug substances as the Secretary may identify.

''(4) The provisions of paragraph (1) shall not apply—

''(A) to compounded positron emission tomography drugs as defined in section 201(ii); or

''(B) to radiopharmaceuticals.

''(5) In this subsection, the term 'compound' does not include to mix, reconstitute, or perform another similar act, in accordance with directions contained in approved drug labeling provided by a drug manufacturer and other drug manufacturer directions consistent with that labeling.''.

SEC. 810. REPORTS OF POSTMARKETING APPROVAL STUDIES.

(a) IN GENERAL.—Chapter V (21 U.S.C. 351 et seq.), as amended by section 613(a), is further amended by adding at the end the following:

''SEC. 562. REPORTS OF POSTMARKETING STUDIES.

''(a) SUBMISSION.—

''(1) IN GENERAL.—A sponsor of a drug that has entered into an agreement with the Secretary to conduct a postmarketing study of a drug shall submit to the Secretary, within 1 year after the approval of such drug and annually thereafter until the study is completed or terminated, a report of the progress of the study or the reasons for the failure of the sponsor to conduct the study. The report shall be submitted in such form as prescribed by the Secretary in regulations issued by the Secretary.

''(2) AGREEMENTS PRIOR TO EFFECTIVE DATE.—An agreement entered into between the Secretary and a sponsor of a drug, prior to the date of enactment of this section, to conduct a postmarketing study of a drug shall be subject to the requirements of paragraph (1). An initial report for such an agreement shall be submitted within 6 months after the date of the issuance of the regulations under paragraph (1).

''(b) CONSIDERATION OF INFORMATION AS PUBLIC INFORMATION.—Any information pertaining to a report described in paragraph (1) shall be considered to be public information to the extent that the information is necessary—

''(1) to identify the sponsor; and

''(2) to establish the status of a study described in subsection (a) and the reasons, if any, for any failure to carry out the study.

''(c) STATUS OF STUDIES AND REPORTS.—The Secretary shall annually develop and publish in the Federal Register a report that provides a status of the postmarketing studies—

''(1) that sponsors have entered into agreements to conduct; and

''(2) for which reports have been submitted under subsection (a)(1).''.

(b) REPORT TO CONGRESSIONAL COMMITTEES.—Not later than October 1, 2001, the Secretary shall prepare and submit to the Committee on Labor and Human Resources of the Senate and the Committee on Commerce of the House of Representatives a report containing—

(1) a summary of the reports submitted under section 562 of the Federal Food, Drug, and Cosmetic Act; and

(2) an evaluation of—

(A) the performance of the sponsors in fulfilling the agreements with respect to the conduct of postmarketing studies described in such section of such Act;

(B) the timeliness of the Secretary's review of the postmarketing studies; and

(C) any legislative recommendations respecting postmarketing studies.

SEC. 811. INFORMATION EXCHANGE.

(a) IN GENERAL.—Chapter VII (2 U.S.C. 371 et seq.), as amended by section 807, is further amended by adding at the end the following:

''Subchapter G—Dissemination of Treatment Information

''SEC. 771. DISSEMINATION OF TREATMENT INFORMATION ON DRUGS, BIOLOGICAL PRODUCTS, AND DEVICES.

''(a) DISSEMINATION OF TREATMENT INFORMATION.—

''(1) IN GENERAL.—Notwithstanding sections 301(d), 502(f), 505, and 507 and section 351 of the Public Health Service Act (42 U.S.C. 262), and subject to the requirements of paragraphs (2) through (6) and subsection (b), a manufacturer may disseminate to a health care practitioner, a pharmacy benefit manager, a health maintenance organization or

other managed health care organization, or a health care insurer or governmental agency, written information concerning the safety, effectiveness, or benefit (whether or not such information is contained in the official labeling) of a drug, biological product, or device for which—

''(A) an approval of an application filed under section 505(b), 505(j), or 515, a clearance in accordance with section 510(k), an approval in accordance with section 507, or a biologics license issued under section 351 of the Public Health Service Act, is in effect; and

''(B) if the use is not described in the approved labeling of the product, the manufacturer has submitted to the Secretary a certification that a supplemental application for that use will be submitted to the Secretary pursuant to paragraph (3) or the manufacturer has received an exemption under paragraph (3)(C).

''(2) AUTHORIZED INFORMATION.—A manufacturer may disseminate the written information under paragraph (1) only if the information—

''(A) is in the form of an unabridged—

''(i) reprint or copy of a peer-reviewed article from a scientific or medical journal (as defined in subsection (c)(5)) of a clinical investigation, with respect to a drug, biological product or device, that would be considered to be scientifically sound by experts qualified by scientific training or experience to evaluate the safety or effectiveness of the drug, biological product, or device that is the subject of such clinical investigation; or

''(ii) reference textbook (as defined in subsection (c)(4)) that includes information about a clinical investigation with respect to a drug, biological product, or device, that would be considered to be scientifically sound by experts qualified by scientific training or experience to evaluate the safety or effectiveness of the drug, biological product, or device that is the subject of such clinical investigation; and

''(B) is not false, not misleading, and would not pose a significant risk to the public health.

''(3) COMMITMENT TO FILE A SUPPLEMENTAL APPLICATION; INCENTIVES FOR RESEARCH.—

''(A) IN GENERAL.—A manufacturer may disseminate information about a use not described in the approved labeling of a drug, biological product, or device pursuant to paragraph (1) only if—

''(i) the manufacturer has submitted to the Secretary a certification that the studies needed to file a supplemental application for such use have been completed and such supplement will be filed within 6 months after the date of the initial dissemination of information under paragraph (1); or

''(ii)(I) the manufacturer has submitted to the Secretary a proposed protocol and schedule for conducting the studies needed to submit a supplemental application for such use and has certified that the supplement will be submitted within 36 months after the date of the initial dissemination of information under paragraph (1); and

''(II) the Secretary has determined that the protocol for conducting such studies is adequate and that the schedule for completing such studies is reasonable.

''(B) EXTENSION.—

''(i) LONGER PERIOD OF TIME.—The Secretary may grant a longer period of time for a manufacturer to submit a supplemental application pursuant to subparagraph (A) if the Secretary determines that the studies needed to submit a supplemental application cannot be completed and submitted within 36 months.

''(ii) EXTENSION OF 3-YEAR PERIOD.—The Secretary may extend the time within which a manufacturer must submit a supplemental application pursuant to subparagraph (A) if the manufacturer demonstrates that the manufacturer has acted with due diligence to conduct the studies in a timely manner. Such extension shall not exceed a period of 24 months.

''(C) EXEMPTIONS.—A manufacturer may file a request for an exemption from the requirements set forth in subparagraph (A). Such request shall be submitted in the form and manner prescribed by the Secretary and shall demonstrate that—

''(i) due to the size of the patient population or the lack of potential benefit to the sponsor, the cost of obtaining clinical information and submitting a supplemental application is economically prohibitive; or

''(ii) it would be unethical to conduct the studies necessary to obtain adequate evidence for approval of a supplemental application.

The Secretary shall act on a request for an exemption under this subparagraph within 60 days after the receipt of the request. If the Secretary fails to act within 60 days, the manufacturer may begin to disseminate information pursuant to paragraph (1) without complying with subparagraph (A). If the Secretary subsequently denies the request for an exemption, the manufacturer either shall cease dissemination or shall comply with the requirements of subparagraph (A) within 60 days after such denial. If the manufacturer ceases dissemination pursuant to this subparagraph solely on the basis that the manufacturer does not comply with subparagraph (A), the Secretary may take appropriate corrective action, but may not order the manufacturer to take corrective action.

''(D) REPORT.—A manufacturer who submits a certification to the Secretary under subparagraph (A) shall provide the Secretary periodic reports that describe the status of the studies being conducted to obtain adequate evidence for approval of a supplemental application.

''(4) INFORMATION ON NEW USES.—

''(A) IN GENERAL.—If the information being disseminated under paragraph (1) meets the requirements of this section, a manufacturer may disseminate information under paragraph (1) concerning the new use of a drug, biological product, or device (described in paragraph (1)) 60 calendar days after the manufacturer has submitted to the Secretary—

''(i) a copy of the information; and

''(ii) any clinical trial information the manufacturer has relating to the safety or efficacy of the new use, any reports of clinical experience pertinent to the safety of the new use, and a summary of such information.

If any of the information required to be provided under clause (ii) has already been provided to the Secretary, the manufacturer may meet the requirements of clause (ii) by providing any such information obtained by the manufacturer since the manufacturer's last submission to the Secretary and a summary that identifies the information previously provided.

''(B) ADDITIONAL INFORMATION.—If the Secretary determines that the information submitted by a manufacturer under subparagraph (A)(i) with respect to a new use of a drug, biological product, or device fails to provide data, analyses, or other written matter, that is objective and balanced, the Secretary may require the manufacturer to disseminate along with the information described in subparagraph (A)—

''(i) additional information with respect to the new use of the drug, biological product, or device that—

''(I) is in the form of an article described in paragraph (2)(A); and

''(II) provides data, analyses, or other written matter, that is scientifically sound;

''(ii) additional objective and scientifically sound information that pertains to the safety or efficacy of the use and is necessary to provide objectivity and balance, including any information that the manufacturer has submitted to the Secretary, or where appropriate, a summary of such information, or any other information that the Secretary has authority to make available to the public;

''(iii) an objective statement prescribed by the Secretary based on information described in clause (i) or (ii), provided the manufacturer has access to the data that forms the basis of such statement unless the Secretary is prohibited from making such data available to the manufacturer; and

''(iv) a statement that describes any previous public announcements by the Secretary relevant to the new use.

''(5) NEW INFORMATION.—If a manufacturer that is disseminating information pursuant to paragraph (1) becomes aware of new information relating to the safety or efficacy of a new use of a drug, biological product, or device for which information was disseminated under paragraph (1), the manufacturer shall notify the Secretary with respect to the new information. If the Secretary determines that the new information demonstrates that a drug, biological product, or device may not be effective or may present a significant risk to public health, the Secretary shall, in consultation with the manufacturer, take such appropriate action as the Secretary determines necessary to ensure public health and safety. The Secretary may limit the types of new information that must be submitted under this paragraph.

''(6) CESSATION OF DISSEMINATION; CORRECTIVE ACTION.—The Secretary may order a manufacturer to cease the dissemination of all information being disseminated pursuant to paragraph (1) if—

''(A) the Secretary finds that a supplemental application does not contain adequate information for approval for the use that is the subject of the information;

''(B) the Secretary determines, after an informal hearing, that the manufacturer is not acting with due diligence to complete the studies necessary to file a supplemental application for the use that is the subject of the information being disseminated; or

''(C) the Secretary determines that the information being disseminated does not comply with the requirements set forth in this section, after providing notice, an opportunity for a meeting, and for minor violations of this section (if there has been substantial compliance with this section), an opportunity to correct such information.

If the Secretary orders cessation of dissemination pursuant to this paragraph, the Secretary may order the manufacturer to take appropriate corrective action.

''(7) SPONSORED RESEARCH.—If a manufacturer has sponsored research that results in information as described in paragraph (2)(A), another manufacturer may not distribute the information under this section, unless such manufacturer is required by the Secretary to distribute the information.

''(b) DISCLOSURE STATEMENT.—In order to afford a full and fair evaluation of the information described in subsection (a), a manufacturer disseminating the information shall include along with the information—

''(1) a prominently displayed statement that discloses—

''(A) that the information concerns a use of a drug, biological product, or device or other attribute of a drug, biological product, or device that has not been approved by the Food and Drug Administration;

''(B) if applicable, that the information is being disseminated at the expense of the manufacturer;

''(C) if applicable, the name of any authors of the information who are employees of, or consultants to, or have received compensation from, the manufacturer, or who have a significant financial interest in the manufacturer;

''(D) the official labeling for the drug, biological product, or device and all updates with respect to the labeling;

''(E) if applicable, a statement that there are products or treatments that have been approved for the use that is the subject of the information being disseminated pursuant to subsection (a)(1); and

''(F) the identification of any person that has provided funding for the conduct of a study relating to a new use of a drug, biological product, or device for which such information is being disseminated; and

''(2) a bibliography of other articles from a scientific reference textbook or scientific or medical journal that have been previously published about the new use of a drug, biological product, or device covered by the information disseminated (unless the information already includes such bibliography).

''(c) DEFINITIONS.—As used in this section:

''(1) HEALTH CARE PRACTITIONER.—The term 'health care practitioner' means a medical provider that is licensed to prescribe a drug or biological product, or to prescribe or use a device, for the treatment of a disease or other medical condition.

''(2) MANUFACTURER.—The term 'manufacturer' includes a person who manufactures, distributes, or markets a drug, biological product, or device.

''(3) NEW USE.—The term 'new use' used with respect to a drug, biological product, or device means a use of a drug, biological product, or device not included in the approved labeling of such drug, biological product, or device.

''(4) REFERENCE TEXTBOOK.—The term 'reference textbook' means a reference publication that—

''(A) has not been written, edited, excerpted, or published specifically for, or at the request of a manufacturer of a drug, biological product, or device;

''(B) has not been edited or significantly influenced by a manufacturer of a drug, biological product, or device;

''(C) is not solely distributed through a manufacturer of a drug, biological product, or device but is generally available in bookstores or other distribution channels where medical textbooks are sold;

''(D) does not focus on any particular drug, biological product, or device of a manufacturer that disseminates information under subsection (a), and does not have a primary focus on new uses of drugs, biological products, or devices that are marketed or under investigation by a manufacturer supporting the dissemination of information; and

''(E) presents materials that are not false or misleading.

''(5) SCIENTIFIC OR MEDICAL JOURNAL.—The term 'scientific or medical journal' means a scientific or medical publication—

''(A) that is published by an organization—

''(i) that has an editorial board;

''(ii) that utilizes experts, who have demonstrated expertise in the subject of an article under review by the organization and who are independent of the organization, to review and objectively select, reject, or provide comments about proposed articles; and

''(iii) that has a publicly stated policy, to which the organization adheres, of full disclosure of any conflict of interest or biases for all authors or contributors involved with the journal or organization;

''(B) whose articles are peer-reviewed and published in accordance with the regular peer-review procedures of the organization;

''(C) that is generally recognized to be of national scope and reputation;

''(D) that is indexed in the Index Medicus of the National Library of Medicine of the National Institutes of Health;

''(E) that presents materials that are not false or misleading; and

''(F) that is not in the form of a special supplement that has been funded in whole or in part by 1 or more manufacturers.

''(d) CONSTRUCTION.—Nothing in this section shall be construed as prohibiting a manufacturer from disseminating information in response to an unsolicited request from a health care practitioner.

''(e) STUDIES AND REPORTS.—

''(1) GENERAL ACCOUNTING OFFICE.—

''(A) IN GENERAL.—The Comptroller General of the United States shall conduct a study to determine the impact of this section on the resources of the Department of Health and Human Services.

''(B) REPORT.—Not later than January 1, 2002, the Comptroller General of the United States shall prepare and submit to the Committee on Labor and Human Resources of the Senate and the Committee on Commerce of the House of Representatives a report of the results of the study.

''(2) DEPARTMENT OF HEALTH AND HUMAN SERVICES.—

''(A) IN GENERAL.—In order to assist Congress in determining whether the provisions of this section should be extended beyond the termination date specified in section 811(e) of the Food and Drug Administration Modernization and Accountability Act of 1997, the Secretary of Health and Human Services shall, in accordance with subparagraph (B), arrange for the conduct of a study of the scientific issues raised as a result of the enactment of this section, including issues relating to—

''(i) the effectiveness of this section with respect to the provision of useful scientific information to health care practitioners;

''(ii) the quality of the information being disseminated pursuant to the provisions of this section;

''(iii) the quality and usefulness of the information provided, in accordance with this section, by the Secretary or by the manufacturer at the request of the Secretary; and

''(iv) the impact of this section on research in the area of new uses, indications, or dosages, particularly the impact on pediatric indications and rare diseases.

''(3) PROCEDURE FOR STUDY.—

''(A) IN GENERAL.—The Secretary shall request the Institute of Medicine of the National Academy of Sciences to conduct the study required by paragraph (2), and to prepare and submit the report required by subparagraph (B), under an arrangement by which the actual expenses incurred by the Institute of Medicine in conducting the study and preparing the report will be paid by the Secretary. If the Institute of Medicine is unwilling to conduct the study under such an arrangement, the Secretary shall enter into a similar arrangement with another appropriate nonprofit private group or association under which the group or association will conduct the study and prepare and submit the report.

''(B) REPORT.—Not later than September 30, 2005, the Institute of Medicine, the group, or association, as appropriate, shall prepare and submit to the Committee on Labor and Human Resources of the Senate, the Committee on Commerce of the House of Representatives, and the Secretary a report of the results of the study required by paragraph (2). The Secretary, after the receipt of the report, shall make the report available to the public.

''(4) AUTHORIZATION OF APPROPRIATION.—There are authorized to be appropriated such sums as are necessary to carry out this subsection.

''SEC. 772. ESTABLISHMENT OF LIST OF ARTICLES AND TEXTBOOKS DISSEMINATED AND LIST OF PROVIDERS THAT RECEIVED ARTICLES AND REFERENCE TEXTBOOKS.

''(a) IN GENERAL.—A manufacturer that disseminates information in the form of articles or reference textbooks under section 771 shall prepare and submit to the Secretary biannually—

''(1) a list containing the titles of the articles and reference textbooks relating to the new use of drugs, biological products, and devices that were disseminated by the manufacturer to a person described in section 771(a)(1) for the 6-month period preceding the date on which the manufacturer submits the list to the Secretary; and

''(2) a list that identifies the categories of providers (as described in section 771(a)(1)) that received the articles and reference textbooks for the 6-month period described in paragraph (1).

''(b) RECORDS.—A manufacturer that disseminates information under section 771 shall keep records that identify the recipients of articles and textbooks provided pursuant to section 771. Such records are to be used by the manufacturer when, pursuant to section 771(a)(6), such manufacturer is required to take corrective action and shall be made available to the Secretary, upon request, for purposes of ensuring or taking corrective action pursuant to paragraph (3), (5), or (6) of section 771(a).

''SEC. 773. CONSTRUCTION.

''(a) DISSEMINATION OF INFORMATION ON DRUGS OR DEVICES NOT EVIDENCE OF INTENDED USE.—Notwithstanding subsection (a), (f), or (o) of section 502, or any other provision of law, the dissemination of information relating to a new use of a drug or device, in accordance with section 771, shall not be construed by the Secretary as evidence of a new intended use of the drug or device that is different from the intended use of the drug or device set forth in the official labeling of the drug or device. Such dissemination shall not be considered by the Secretary as labeling, adulteration, or misbranding of the drug or device.

''(b) PATENT PROTECTION.—Nothing in section 771 shall affect patent rights in any manner.

''(c) AUTHORIZATION FOR DISSEMINATION OF ARTICLES AND FEES FOR REPRINTS OF ARTICLES.—Nothing in section 771 shall be construed as prohibiting an entity that publishes a scientific journal (as defined in section 771(c)(5)) from requiring authorization from the entity to disseminate an article published by such entity and from charging fees for the purchase of reprints of published articles from such entity.''.

(b) PROHIBITED ACT.—Section 301 (21 U.S.C. 331), as amended by section 205(b), is further amended by adding at the end the following:

''(y) The dissemination of information pursuant to section 771 by a manufacturer who fails to comply with the requirements of such section.''.

(c) REGULATIONS.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall promulgate regulations to implement the amendments made by this section.

(d) EFFECTIVE DATE.—The amendments made by this section shall take effect 1 year after the date of enactment of this Act, or upon the Secretary's issuance of final regulations pursuant to subsection (c), whichever is sooner.

(e) TERMINATION OF EFFECTIVENESS.—The amendments made by this section cease to be effective September 30, 2006, or 7 years after the date on which the Secretary promulgates the regulations described in subsection (c), whichever is later.

SEC. 812. REAUTHORIZATION OF CLINICAL PHARMACOLOGY PROGRAM.

Section 2 of Public Law 102–222 (105 Stat. 1677) is amended—

(1) in subsection (a), by striking ''a grant'' and all that follows through ''Such grant'' and inserting the following: ''grants for a pilot program for the training of individuals in clinical pharmacology at appropriate medical schools. Such grants''; and

(2) in subsection (b), by striking ''to carry out this section'' and inserting '', and for fiscal years 1998 through 2002 $3,000,000 for each fiscal year, to carry out this section''.

SEC. 813. MONOGRAPH FOR SUNBURN PRODUCTS.

Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services shall issue a final monograph for over-the-counter sunburn products for prevention or treatment of sunburn.

SEC. 814. SAFETY REPORT DISCLAIMERS.

Chapter IX (21 U.S.C. 391 et seq.), as amended by section 804, is further amended by adding at the end the following:

''SEC. 908. SAFETY REPORT DISCLAIMERS.

''With respect to any entity that submits or is required to submit a safety report or other information in connection with the safety of a product (including a product which is a food, drug, new drug, device, dietary supplement, or cosmetic) under this Act (and any release by the Secretary of that report or information), such report or information shall not be construed to necessarily reflect a conclusion by the entity or the Secretary that the report or information constitutes an admission that the product involved caused or contributed to an adverse experience, or otherwise caused or contributed to a death, serious injury, serious illness, or malfunction. Such an entity need not admit, and may deny, that the report or information submitted by the entity constitutes an admission that the product involved caused or contributed to an adverse experience or caused or contributed to a death, serious injury, serious illness, or malfunction.''.

MOTION OFFERED BY MR. BLILEY

Mr. BLILEY. Mr. Speaker, I offer a motion.

The SPEAKER pro tempore. The Clerk will report the motion.

The Clerk read as follows:

Mr. BLILEY moves to strike out all after the enacting clause, and insert in lieu thereof the text of H.R. 1411, as passed by the House.

The motion was agreed to.

The Senate bill was ordered to be read a third time, was read the third time, and passed.

The title of the Senate bill was amended so as to read: ''A bill to amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to facilitate the development and approval of new drugs and biological products, and for other purposes.''

A motion to reconsider was laid on the table.

A similar House bill (H.R. 1411) was laid on the table.

NATIONAL MONUMENT FAIRNESS ACT OF 1997

The SPEAKER pro tempore. Pursuant to House Resolution 256 and rule XXIII, the Chair declares the House in the Committee of the Whole House on the State of the Union for the further consideration of the bill, H.R. 1127.

□ 1132

IN THE COMMITTEE OF THE WHOLE

Accordingly the House resolved itself into the Committee of the Whole House on the State of the Union for the further consideration of the bill (H.R. 1127) to amend the Antiquities Act to require an Act of Congress and the concurrence of the Governor and State legislature for the establishment by the President of national monuments in excess of 5,000 acres, with Mr. SNOWBARGER in the chair.

The Clerk read the title of the bill.

The CHAIRMAN. When the Committee of the Whole rose on Monday, October 6, 1997, the demand for a recorded vote on the amendment offered by the gentleman from Utah [Mr. HANSEN] printed in section 3 of House Resolution 256 had been postponed.

SEQUENTIAL VOTES POSTPONED IN COMMITTEE OF THE WHOLE

The CHAIRMAN. Pursuant to House Resolution 256, proceedings will now resume on those amendments on which further proceedings were postponed in the following order: Amendment No. 2 offered by the gentleman from Minnesota [Mr. VENTO] and amendment No. 6 offered by the gentleman from Utah [Mr. HANSEN].

The Chair will reduce to 5 minutes the time for any electronic vote after the first such vote in this series.

AMENDMENT NO. 5 OFFERED BY MR. VENTO

The CHAIRMAN. The unfinished business is the demand for a recorded vote on the amendment offered by the gentleman from Minnesota [Mr. VENTO] on which further proceedings were postponed, and on which the noes prevailed by voice vote.

The Clerk will redesignate the amendment.

The text of the amendment is as follows:

Amendment No. 5 offered by Mr. VENTO:

Page 3, line 14, strike ''unless and until'' and insert ''until 1 year after''.

Page 3, beginning on line 16, insert a period after ''Congress'' and strike all that follows through the period on line 18 and insert in lieu thereof: ''During the period of review, Federal lands within the proclamation area are hereby withdrawn from all forms of entry, appropriation, or disposal under the public land laws, from location, entry, or patent under the mining laws, and from disposition under all mineral and geothermal leasing laws.''

RECORDED VOTE

The CHAIRMAN. A recorded vote has been demanded.

A recorded vote was ordered.

The vote was taken by electronic device, and there were—ayes 201, noes 224, not voting 8, as follows:

[Roll No. 493]

AYES—201

Abercrombie	Gutierrez	Morella
Ackerman	Hall (OH)	Nadler
Allen	Hamilton	Neal
Andrews	Harman	Obey
Baldacci	Hastings (FL)	Olver
Barcia	Hefner	Owens
Barrett (WI)	Hinchey	Pallone
Becerra	Hinojosa	Pascrell
Bentsen	Hooley	Pastor
Berman	Houghton	Payne
Blagojevich	Hoyer	Pelosi
Blumenauer	Jackson (IL)	Pomeroy
Bonior	Jackson-Lee (TX)	Porter
Borski	Jefferson	Poshard
Boucher	John	Price (NC)
Brown (CA)	Johnson (CT)	Rahall
Brown (FL)	Johnson (WI)	Ramstad
Brown (OH)	Johnson, E. B.	Rangel
Capps	Kanjorski	Reyes
Cardin	Kaptur	Rivers
Carson	Kelly	Rodriguez
Castle	Kennedy (MA)	Roemer
Clay	Kennedy (RI)	Rothman
Clement	Kennelly	Roukema
Clyburn	Kildee	Roybal-Allard
Conyers	Kilpatrick	Rush
Costello	Kind (WI)	Sabo
Coyne	King (NY)	Sanchez
Cramer	Kleczka	Sanders
Cummings	Kucinich	Sandlin
Davis (FL)	Lampson	Sawyer
Davis (IL)	Lantos	Saxton
Davis (VA)	Lazio	Schumer
DeFazio	Leach	Scott
DeGette	Levin	Serrano
Delahunt	Lewis (GA)	Shays
DeLauro	Lipinski	Sherman
Dellums	LoBiondo	Skaggs
Deutsch	Lofgren	Skelton
Dicks	Lowey	Slaughter
Dingell	Luther	Smith (NJ)
Dixon	Maloney (CT)	Smith, Adam
Doggett	Maloney (NY)	Snyder
Dooley	Manton	Spratt
Engel	Markey	Stabenow
English	Martinez	Stark
Eshoo	Mascara	Stokes
Etheridge	Matsui	Strickland
Evans	McCarthy (MO)	Stupak
Farr	McCarthy (NY)	Tanner
Fattah	McDermott	Tauscher
Fawell	McGovern	Taylor (MS)
Fazio	McHale	Thurman
Filner	McIntyre	Tierney
Flake	McKinney	Torres
Foglietta	McNulty	Towns
Forbes	Meehan	Velazquez
Ford	Meek	Vento
Fox	Menendez	Visclosky
Frank (MA)	Millender-McDonald	Waters
Franks (NJ)	Miller (CA)	Watt (NC)
Frost	Minge	Waxman
Furse	Mink	Wexler
Gejdenson	Moakley	Wise
Gephardt	Mollohan	Woolsey
Gilman	Moran (VA)	Wynn
Gordon		Yates
Green		

NOES—224

Aderholt	Brady	Cubin
Archer	Bryant	Cunningham
Armey	Bunning	Danner
Bachus	Burr	Deal
Baesler	Burton	DeLay
Baker	Buyer	Diaz-Balart
Ballenger	Callahan	Dickey
Barr	Calvert	Doolittle
Barrett (NE)	Camp	Doyle
Bartlett	Campbell	Dreier
Barton	Canady	Duncan
Bass	Cannon	Dunn
Bateman	Chabot	Edwards
Bereuter	Chambliss	Ehlers
Berry	Chenoweth	Ehrlich
Bilbray	Christensen	Emerson
Bilirakis	Coble	Ensign
Bishop	Coburn	Everett
Bliley	Collins	Ewing
Blunt	Combest	Foley
Boehlert	Condit	Fowler
Boehner	Cook	Frelinghuysen
Bonilla	Cooksey	Gallegly
Bono	Cox	Ganske
Boswell	Crane	Gekas
Boyd	Crapo	Gibbons