

Union Calendar No. 180

105TH CONGRESS
1ST Session

H. R. 1411

[Report No. 105-310]

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.

OCTOBER 7, 1997

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

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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.

IN THE HOUSE OF REPRESENTATIVES

APRIL 23, 1997

Mr. BURR of North Carolina (for himself, Mr. GREENWOOD, Mr. BARTON of Texas, Mr. KLUG, Mr. COBURN, and Mr. DEAL of Georgia) introduced the following bill; which was referred to the Committee on Commerce

OCTOBER 7, 1997

Additional sponsors: Mr. THOMAS, Mr. UPTON, Mr. SOLOMON, Mr. HASTERT, Mr. CANNON, Mr. DOOLEY of California, Ms. MCCARTHY of Missouri, Mr. PRICE of North Carolina, Mr. BLILEY, Mr. INGLIS of South Carolina, and Mr. MCHALE

OCTOBER 7, 1997

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

[Strike out all after the enacting clause and insert the part printed in *italic*]

[For text of introduced bill, see copy of bill as introduced on April 23, 1997]

A BILL

To amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to facilitate the develop-

ment and approval of new drugs and biological products,
and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*
3 **SECTION 1. SHORT TITLE; REFERENCES; TABLE OF CON-**
4 **TENTS.**

5 (a) *SHORT TITLE.*—*This Act may be cited as the “Pre-*
6 *scription Drug User Fee Reauthorization and Drug Regu-*
7 *latory Modernization Act of 1997”.*

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

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

- Sec. 1. Short title; references; table of contents.*
- Sec. 2. Fees relating to drugs.*
- Sec. 3. Pediatric studies of drugs.*
- Sec. 4. Expediting study and approval of fast track drugs.*
- Sec. 5. Expanded access to investigational therapies.*
- Sec. 6. Information program on clinical trials for serious or life-threatening diseases.*
- Sec. 7. Dissemination of information on new uses.*
- Sec. 8. Studies and reports.*
- Sec. 9. Approval of supplemental applications for approved products.*
- Sec. 10. Health care economic information.*
- Sec. 11. Clinical investigations.*
- Sec. 12. Manufacturing changes for drugs.*
- Sec. 13. Streamlining clinical research on drugs.*
- Sec. 14. Data requirements for drugs.*
- Sec. 15. Content and review of applications.*
- Sec. 16. Scientific advisory panels.*
- Sec. 17. Dispute resolution.*

Sec. 18. Informal agency statements.
Sec. 19. Positron emission tomography.
Sec. 20. Requirements for radiopharmaceuticals.
Sec. 21. Modernization of regulation.
Sec. 22. Pilot and small scale manufacture.
Sec. 23. Insulin and antibiotics.
Sec. 24. FDA mission and annual report.
Sec. 25. Information system.
Sec. 26. Education and training.
Sec. 27. Centers for education and research on drugs.
Sec. 28. Harmonization.
Sec. 29. Environmental impact review.
Sec. 30. National uniformity.
Sec. 31. FDA study of mercury compounds in drugs and food.
Sec. 32. Notification of discontinuance of a life saving product.

1 SEC. 2. FEES RELATING TO DRUGS.

2 (a) *FINDINGS.*—Congress finds that—

3 (1) *prompt approval of safe and effective new*
 4 *drugs and other therapies is critical to the improve-*
 5 *ment of the public health so that patients may enjoy*
 6 *the benefits provided by these therapies to treat and*
 7 *prevent illness and disease;*

8 (2) *the public health will be served by making*
 9 *additional funds available for the purpose of aug-*
 10 *menting the resources of the Food and Drug Adminis-*
 11 *tration that are devoted to the process for review of*
 12 *human drug applications;*

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

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

1 (B) carried out by the Food and Drug Ad-
 2 ministration with new commitments to imple-
 3 ment more ambitious and comprehensive im-
 4 provements in regulatory processes of the Food
 5 and Drug Administration; and

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

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

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

20 (A) by striking “Service Act, and” and in-
 21 serting “Service Act,”; and

22 (B) by striking “September 1, 1992.” and
 23 inserting the following: “September 1, 1992, does
 24 not include an application for a licensure of a
 25 biological product for further manufacturing use

1 *only, and does not include an application or*
2 *supplement submitted by a State or Federal Gov-*
3 *ernment entity for a drug that is not distributed*
4 *commercially. Such term does include an appli-*
5 *cation for licensure, as described in subpara-*
6 *graph (D), of a large volume biological product*
7 *intended for single dose injection for intravenous*
8 *use or infusion.”;*

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

10 *(A) by striking “Service Act, and” and in-*
11 *serting “Service Act,”; and*

12 *(B) by striking “September 1, 1992.” and*
13 *inserting the following: “September 1, 1992, does*
14 *not include a biological product that is licensed*
15 *for further manufacturing use only, and does not*
16 *include a drug that is not distributed commer-*
17 *cially and is the subject of an application or*
18 *supplement submitted by a State or Federal Gov-*
19 *ernment entity. Such term does include a large*
20 *volume biological product intended for single*
21 *dose injection for intravenous use or infusion.”;*

22 *(3) in paragraph (4), by striking “without” and*
23 *inserting “without substantial”;*

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

1 “(5) The term ‘prescription drug establishment’
 2 means a foreign or domestic place of business which
 3 is at one general physical location consisting of one
 4 or more buildings all of which are within 5 miles of
 5 each other and at which one or more prescription
 6 drug products are manufactured in final dosage
 7 form.”.

8 (5) in paragraph (7)(A)—

9 (A) by striking “employees under contract”
 10 and all that follows through “Administration,”
 11 the second time it occurs and inserting “contrac-
 12 tors of the Food and Drug Administration,”; and

13 (B) by striking “and committees,” and in-
 14 serting “and committees and to contracts with
 15 such contractors,”;

16 (6) in paragraph (8)—

17 (A) in subparagraph (A)—

18 (i) by striking “August of” and insert-
 19 ing “April of”; and

20 (ii) by striking “August 1992” and in-
 21 serting “April 1997”;

22 (B) in subparagraph (B), by striking
 23 “1992” and inserting “1997”; and

24 (C) by striking the second sentence; and

25 (7) by adding at the end the following:

1 “(9) *The term ‘affiliate’ means a business entity*
 2 *that has a relationship with a second business entity*
 3 *if, directly or indirectly—*

4 “(A) *one business entity controls, or has the*
 5 *power to control, the other business entity; or*

6 “(B) *a third party controls, or has power to*
 7 *control, both of the business entities.”.*

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

9 (1) *TYPES OF FEES.—Section 736(a) (21 U.S.C.*
 10 *379h(a)) is amended—*

11 (A) *by striking “Beginning in fiscal year*
 12 *1993” and inserting “Beginning in fiscal year*
 13 *1998”;*

14 (B) *in paragraph (1)—*

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

17 “(B) *PAYMENT.—The fee required by sub-*
 18 *paragraph (A) shall be due upon submission of*
 19 *the application or supplement.”;*

20 (ii) *in subparagraph (D)—*

21 (I) *in the subparagraph heading,*
 22 *by striking “NOT ACCEPTED” and in-*
 23 *serting “REFUSED”;*

24 (II) *by striking “50 percent” and*
 25 *inserting “75 percent”;*

1 (III) by striking “subparagraph
2 (B)(i)” and inserting “subparagraph
3 (B)”; and

4 (IV) by striking “not accepted”
5 and inserting “refused”; and

6 (iii) by adding at the end the follow-
7 ing:

8 “(E) *EXCEPTION FOR DESIGNATED ORPHAN*
9 *DRUG OR INDICATION.*—A human drug applica-
10 tion for a prescription drug product that has
11 been designated as a drug for a rare disease or
12 condition pursuant to section 526 shall not be
13 subject to a fee under subparagraph (A), unless
14 the human drug application includes indications
15 for other than rare diseases or conditions. A sup-
16 plement proposing to include a new indication
17 for a rare disease or condition in a human drug
18 application shall not be subject to a fee under
19 subparagraph (A), if the drug has been des-
20 ignated pursuant to section 526 as a drug for a
21 rare disease or condition with regard to the indi-
22 cation proposed in such supplement.

23 “(F) *EXCEPTION FOR SUPPLEMENTS FOR*
24 *PEDIATRIC INDICATIONS.*—A supplement to a
25 human drug application for an indication for

1 *use in pediatric populations shall not be assessed*
 2 *a fee under subparagraph (A).*

3 *“(G) REFUND OF FEE IF APPLICATION*
 4 *WITHDRAWN.—If an application or supplement*
 5 *is withdrawn after the application or supple-*
 6 *ment is filed, the Secretary may waive and re-*
 7 *fund the fee or a portion of the fee if no substan-*
 8 *tial work was performed on the application or*
 9 *supplement after the application or supplement*
 10 *was filed. The Secretary shall have the sole dis-*
 11 *cretion to waive and refund a fee or a portion*
 12 *of the fee under this subparagraph. A determina-*
 13 *tion by the Secretary concerning a waiver or re-*
 14 *fund under this paragraph shall not be*
 15 *reviewable.”;*

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

18 *“(2) PRESCRIPTION DRUG ESTABLISHMENT*
 19 *FEE.—*

20 *“(A) IN GENERAL.—Except as provided in*
 21 *subparagraph (B), each person that is named as*
 22 *the applicant in a human drug application, and*
 23 *after September 1, 1992, had pending before the*
 24 *Secretary a human drug application or supple-*
 25 *ment, shall be assessed an annual fee established*

1 *in subsection (b) for each prescription drug es-*
2 *tabishment listed in its approved human drug*
3 *application as an establishment that manufac-*
4 *tures the prescription drug product named in the*
5 *application. The annual establishment fee shall*
6 *be assessed in each fiscal year in which the pre-*
7 *scription drug product named in the application*
8 *is assessed a fee under paragraph (3) unless the*
9 *prescription drug establishment listed in the ap-*
10 *plication does not engage in the manufacture of*
11 *the prescription drug product during the fiscal*
12 *year. The establishment fee shall be payable on*
13 *or before January 31 of each year. Each such es-*
14 *tabishment shall be assessed only one fee per es-*
15 *tabishment, notwithstanding the number of pre-*
16 *scription drug products manufactured at the es-*
17 *tabishment. In the event an establishment is*
18 *listed in a human drug application by more*
19 *than 1 applicant, the establishment fee for the*
20 *fiscal year shall be divided equally and assessed*
21 *among the applicants whose prescription drug*
22 *products are manufactured by the establishment*
23 *during the fiscal year and assessed product fees*
24 *under paragraph (3).*

1 “(B) *EXCEPTION.*—If, during the fiscal
2 year, an applicant initiates or causes to be initi-
3 ated the manufacture of a prescription drug
4 product at an establishment listed in its human
5 drug application—

6 “(i) that did not manufacture the
7 product in the previous fiscal year; and

8 “(ii) for which the full establishment
9 fee has been assessed in the fiscal year at a
10 time before manufacture of the prescription
11 drug product was begun;
12 the applicant will not be assessed a share of the
13 establishment fee for the fiscal year in which the
14 manufacture of the product began.”.

15 (D) in paragraph (3)—

16 (i) in subparagraph (A)—

17 (I) in clause (i), by striking “is
18 listed” and inserting “has been submit-
19 ted for listing”; and

20 (II) by striking “Such fee shall be
21 paid” and all that follows through
22 “section 510.” and inserting the follow-
23 ing: “Such fee shall be payable for the
24 fiscal year in which the product is first
25 submitted for listing under section 510,

1 or for relisting under section 510 if the
 2 product has been withdrawn from list-
 3 ing and relisted. After such fee is paid
 4 for that fiscal year, such fee shall be
 5 payable on or before January 31 of
 6 each year. Such fee shall be paid only
 7 once for each product for a fiscal year
 8 in which the fee is payable.”; and

9 (ii) in subparagraph (B), by striking
 10 “505(j).” and inserting the following:
 11 “505(j), under an abbreviated application
 12 filed under section 507, or under an abbrev-
 13 iated new drug application pursuant to
 14 regulations in effect prior to the implemen-
 15 tation of the Drug Price Competition and
 16 Patent Term Restoration Act of 1984.”.

17 (2) *FEE AMOUNTS.*—Section 736(b) (21 U.S.C.
 18 379h(b)) is amended to read as follows:

19 “(b) *FEE AMOUNTS.*—Except as provided in sub-
 20 sections (c), (d), (f), and (g), the fees required under sub-
 21 section (a) shall be determined and assessed as follows:

22 “(1) *APPLICATION AND SUPPLEMENT FEES.*—

23 “(A) *FULL FEES.*—The application fee
 24 under subsection (a)(1)(A)(i) shall be \$250,704
 25 in fiscal year 1998, \$256,338 in each of fiscal

1 years 1999 and 2000, \$267,606 in fiscal year
2 2001, and \$258,451 in fiscal year 2002.

3 “(B) *OTHER FEES.*—The fee under sub-
4 section (a)(1)(A)(ii) shall be \$125,352 in fiscal
5 year 1998, \$128,169 in each of fiscal years 1999
6 and 2000, \$133,803 in fiscal year 2001, and
7 \$129,226 in fiscal year 2002.

8 “(2) *FEE REVENUES FOR ESTABLISHMENT*
9 *FEES.*—The total fee revenues to be collected in estab-
10 lishment fees under subsection (a)(2) shall be
11 \$35,600,000 in fiscal year 1998, \$36,400,000 in each
12 of fiscal years 1999 and 2000, \$38,000,000 in fiscal
13 year 2001, and \$36,700,000 in fiscal year 2002.

14 “(3) *TOTAL FEE REVENUES FOR PRODUCT*
15 *FEES.*—The total fee revenues to be collected in prod-
16 uct fees under subsection (a)(3) in a fiscal year shall
17 be equal to the total fee revenues collected in establish-
18 ment fees under subsection (a)(2) in that fiscal year.”.

19 (3) *INCREASES AND ADJUSTMENTS.*—Section
20 736(c) (21 U.S.C. 379h(c)) is amended—

21 (A) in the subsection heading, by striking

22 “*INCREASES AND*”;

23 (B) in paragraph (1)—

24 (i) by striking “(1) *REVENUE*” and all
25 that follows through “increased by the Sec-

1 retary” and inserting the following: “(1) IN-
 2 FLATION ADJUSTMENT.—The fees and total
 3 fee revenues established in subsection (b)
 4 shall be adjusted by the Secretary”;

5 (ii) in subparagraph (A), by striking
 6 “increase” and inserting “change”;

7 (iii) in subparagraph (B), by striking
 8 “increase” and inserting “change”; and

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

11 “The adjustment made each fiscal year by this sub-
 12 section will be added on a compounded basis to the
 13 sum of all adjustments made each fiscal year after fis-
 14 cal year 1997 under this subsection.”;

15 (C) in paragraph (2), by striking “October
 16 1, 1992,” and all that follows through “such
 17 schedule.” and inserting the following: “Septem-
 18 ber 30, 1997, adjust the establishment and prod-
 19 uct fees described in subsection (b) for the fiscal
 20 year in which the adjustment occurs so that the
 21 revenues collected from each of the categories of
 22 fees described in paragraphs (2) and (3) of sub-
 23 section (b) shall be set to be equal to the revenues
 24 collected from the category of application and

1 *supplement fees described in paragraph (1) of*
 2 *subsection (b).”; and*

3 *(D) in paragraph (3), by striking “para-*
 4 *graph (2)” and inserting “this subsection”.*

5 *(4) FEE WAIVER OR REDUCTION.—Section*
 6 *736(d) (21 U.S.C. 379h(d)) is amended—*

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

10 *(B) by striking “The Secretary shall grant*
 11 *a” and all that follows through “finds that—”*
 12 *and inserting the following:*

13 *“(1) IN GENERAL.—The Secretary shall grant a*
 14 *waiver from or a reduction of one or more fees as-*
 15 *essed under subsection (a) where the Secretary finds*
 16 *that—”;*

17 *(C) in subparagraph (C) (as so redesignated*
 18 *by subparagraph (A)), by striking “, or” and in-*
 19 *serting a comma;*

20 *(D) in subparagraph (D) (as so redesign-*
 21 *ated by subparagraph (A)), by striking the pe-*
 22 *riod and inserting “, or”;*

23 *(E) by inserting after subparagraph (D) (as*
 24 *so redesignated by subparagraph (A)) the follow-*
 25 *ing:*

1 “(E) the applicant is a small business sub-
2 mitting its first human drug application to the
3 Secretary for review.”; and

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

7 “(2) *USE OF STANDARD COSTS.*—In making the
8 finding in paragraph (1)(C), the Secretary may use
9 standard costs.

10 “(3) *RULES RELATING TO SMALL BUSINESSES.*—

11 “(A) *DEFINITION.*—In paragraph (1)(E),
12 the term ‘small business’ means an entity that
13 has fewer than 500 employees, including employ-
14 ees of affiliates.

15 “(B) *WAIVER OF APPLICATION FEE.*—The
16 Secretary shall waive under paragraph (1)(E)
17 the application fee for the first human drug ap-
18 plication that a small business or its affiliate
19 submits to the Secretary for review. After a small
20 business or its affiliate is granted such a waiver,
21 the small business or its affiliate shall pay—

22 “(i) application fees for all subsequent
23 human drug applications submitted to the
24 Secretary for review in the same manner as

1 *an entity that does not qualify as a small*
 2 *business; and*

3 “(ii) *all supplement fees for all supple-*
 4 *ments to human drug applications submit-*
 5 *ted to the Secretary for review in the same*
 6 *manner as an entity that does not qualify*
 7 *as a small business.”.*

8 (5) *ASSESSMENT OF FEES.*—Section 736(f)(1)
 9 (21 U.S.C. 379h(f)(1)) *is amended—*

10 (A) *by striking “fiscal year 1993” and in-*
 11 *serting “fiscal year 1997”; and*

12 (B) *by striking “fiscal year 1992” and in-*
 13 *serting “fiscal year 1997 (excluding the amount*
 14 *of fees appropriated for such fiscal year)”.*

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

17 (A) *in paragraph (1), by adding at the end*
 18 *the following: “Such sums as may be necessary*
 19 *may be transferred from the Food and Drug Ad-*
 20 *ministration salaries and expenses appropria-*
 21 *tion account without fiscal year limitation to*
 22 *such appropriation account for salaries and ex-*
 23 *penses with such fiscal year limitation. The sums*
 24 *transferred shall be available solely for the proc-*

ess 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 reve-
nues made under this section and changes in the total
amounts collected by application, supplement, estab-
lishment, and product fees.

1 “(4) *OFFSET*.—Any amount of fees collected for
 2 a fiscal year which exceeds the amount of fees speci-
 3 fied in appropriation Acts for such fiscal year shall
 4 be credited to the appropriation account of the Food
 5 and Drug Administration as provided in paragraph
 6 (1), and shall be subtracted from the amount of fees
 7 that would otherwise be authorized to be collected
 8 under appropriation Acts for a subsequent fiscal
 9 year.”.

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

13 (A) by redesignating subsection (i) as sub-
 14 section (j); and

15 (B) by inserting after subsection (h) the fol-
 16 lowing:

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

24 (8) *SPECIAL RULE FOR WAIVER, REFUNDS, AND*
 25 *EXCEPTIONS*.—Any requests for waivers, refunds, or

1 *exceptions for fees assessed prior to the date of enact-*
2 *ment of this Act shall be submitted in writing to the*
3 *Secretary of Health and Human Services within 1*
4 *year after the date of enactment of this Act.*

5 *(d) ANNUAL REPORTS.—*

6 *(1) PERFORMANCE REPORT.—Beginning with*
7 *fiscal year 1998, not later than 60 days after the end*
8 *of each fiscal year during which fees are collected*
9 *under part 2 of subchapter C of chapter VII of the*
10 *Federal Food, Drug, and Cosmetic Act (21 U.S.C.*
11 *379g et seq.), the Secretary of Health and Human*
12 *Services shall prepare and submit to the Committee*
13 *on Commerce of the House of Representatives and the*
14 *Committee on Labor and Human Resources of the*
15 *Senate a report concerning the progress of the Food*
16 *and Drug Administration in achieving the goals iden-*
17 *tified in the letter described in subsection (a)(4) dur-*
18 *ing such fiscal year and the future plans of the Food*
19 *and Drug Administration for meeting the goals.*

20 *(2) FISCAL REPORT.—Beginning with fiscal year*
21 *1998, not later than 120 days after the end of each*
22 *fiscal year during which fees are collected under the*
23 *part described in subsection (a), the Secretary of*
24 *Health and Human Services shall prepare and sub-*
25 *mit to the Committee on Commerce of the House of*

1 *Representatives and the Committee on Labor and*
 2 *Human Resources of the Senate a report on the im-*
 3 *plementation of the authority for such fees during*
 4 *such fiscal year and the use, by the Food and Drug*
 5 *Administration, of the fees collected during such fiscal*
 6 *year for which the report is made.*

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

9 *(f) TERMINATION OF EFFECTIVENESS.—The amend-*
 10 *ments made by subsections (b) and (c) cease to be effective*
 11 *October 1, 2002, and subsection (d) ceases to be effective*
 12 *120 days after such date.*

13 **SEC. 3. PEDIATRIC STUDIES OF DRUGS.**

14 *Chapter V (21 U.S.C. 351 et seq.) is amended by in-*
 15 *serting after section 505 the following:*

16 *“PEDIATRIC STUDIES OF DRUGS*

17 *“SEC. 505A. (a) MARKET EXCLUSIVITY FOR NEW*
 18 *DRUGS.—If, prior to approval of an application that is*
 19 *submitted under section 505(b)(1), the Secretary determines*
 20 *that information relating to the use of a drug in the pedi-*
 21 *atric population may produce health benefits in that popu-*
 22 *lation, the Secretary makes a written request for pediatric*
 23 *studies (which shall include a timeframe for completing*
 24 *such studies), and such studies are completed within any*
 25 *such timeframe and the reports thereof submitted in accord-*

1 *ance with subsection (d)(2) or accepted in accordance with*
 2 *subsection (d)(3)—*

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

12 “(B) *the period of market exclusivity under sub-*
 13 *sections (c)(3)(D)(iii) and (iv) and (j)(4)(D)(iii) and*
 14 *(iv) of section 505 shall be three years and six months*
 15 *rather than three years; and*

16 “(2)(A) *if the drug is the subject of—*

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

23 “(ii) *a listed patent for which a certifi-*
 24 *cation has been submitted under subsections*
 25 *(b)(2)(A)(iii) or (j)(2)(A)(vii)(III) of section 505,*

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

6 *“(B) if the drug is the subject of a listed patent*
 7 *for which a certification has been sub-*
 8 *mitted under subsection (b)(2)(A)(iv) or*
 9 *(j)(2)(A)(vii)(IV) of section 505, and in the patent in-*
 10 *fringement litigation resulting from the certification*
 11 *the court determines that the patent is valid and*
 12 *would be infringed, the period during which an appli-*
 13 *cation may not be approved under section 505(c)(3)*
 14 *or section 505(j)(4)(B) shall be extended by a period*
 15 *of six months after the date the patent expires (in-*
 16 *cluding any patent extensions).*

17 *“(b) SECRETARY TO DEVELOP LIST OF DRUGS FOR*
 18 *WHICH ADDITIONAL PEDIATRIC INFORMATION MAY BE*
 19 *BENEFICIAL.—Not later than 180 days after the date of en-*
 20 *actment of this section, the Secretary, after consultation*
 21 *with experts in pediatric research shall develop, prioritize,*
 22 *and publish an initial list of approved drugs for which ad-*
 23 *ditional pediatric information may produce health benefits*
 24 *in the pediatric population. The Secretary shall annually*
 25 *update the list.*

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

11 “(1)(A) *the period during which an application*
12 *may not be submitted under subsection (c)(3)(D)(ii)*
13 *or (j)(4)(D)(ii) of section 505 shall be five years and*
14 *six months rather than five years, and the references*
15 *in subsections (c)(3)(D)(ii) and (j)(4)(D)(ii) of sec-*
16 *tion 505 to four years, to forty-eight months, and to*
17 *seven and one-half years shall be deemed to be four*
18 *and one-half years, fifty-four months, and eight years,*
19 *respectively; or*

20 “(B) *the period of market exclusivity under sub-*
21 *sections (c)(3)(D)(iii) and (iv) and (j)(4)(D)(iii) and*
22 *(iv) of section 505 shall be three years and six months*
23 *rather than three years; and*

24 “(2)(A) *if the drug is the subject of—*

1 “(i) a listed patent for which a certification
2 has been submitted under subsection (b)(2)(A)(ii)
3 or (j)(2)(A)(vii)(II) of section 505 and for which
4 pediatric studies were submitted prior to the ex-
5 piration of the patent (including any patent ex-
6 tensions); or

7 “(ii) a listed patent for which a certifi-
8 cation has been submitted under subsection
9 (b)(2)(A)(iii) or (j)(2)(A)(vii)(III) of section 505,
10 the period during which an application may not be
11 approved under section 505(c)(3) or section
12 505(j)(4)(B) shall be extended by a period of six
13 months after the date the patent expires (including
14 any patent extensions); or

15 “(B) if the drug is the subject of a listed patent
16 for which a certification has been submitted under
17 subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section
18 505, and in the patent infringement litigation result-
19 ing from the certification the court determines that
20 the patent is valid and would be infringed, the period
21 during which an application may not be approved
22 under section 505(c)(3) or section 505(j)(4)(B) shall
23 be extended by a period of six months after the date
24 the patent expires (including any patent extensions).

25 “(d) CONDUCT OF PEDIATRIC STUDIES.—

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

4 “(A) *the sponsor of an application for an*
5 *investigational new drug under section 505(i);*

6 “(B) *the sponsor of an application for a*
7 *drug under section 505(b)(1); or*

8 “(C) *the holder of an approved application*
9 *for a drug under section 505(b)(1),*
10 *agree with the sponsor or holder for the conduct of pe-*
11 *diatric studies for such drug.*

12 “(2) *WRITTEN PROTOCOLS TO MEET THE STUD-*
13 *IES REQUIREMENT.*—*If the sponsor or holder and the*
14 *Secretary agree upon written protocols for the studies,*
15 *the studies requirement of subsection (a) or (c) is sat-*
16 *isfied upon the completion of the studies and submis-*
17 *sion of the reports thereof in accordance with the*
18 *original written request and the written agreement re-*
19 *ferred to in paragraph (1). Not later than 60 days*
20 *after the submission of the report of the studies, the*
21 *Secretary shall determine if such studies were or were*
22 *not conducted in accordance with the original written*
23 *request and the written agreement and reported in ac-*
24 *cordance with the requirements of the Secretary for*
25 *filing and so notify the sponsor or holder.*

1 “(3) *OTHER METHODS TO MEET THE STUDIES*
2 *REQUIREMENT.*—*If the sponsor or holder and the Sec-*
3 *retary have not agreed in writing on the protocols for*
4 *the studies, the studies requirement of subsection (a)*
5 *or (c) is satisfied when such studies have been com-*
6 *pleted and the reports accepted by the Secretary. Not*
7 *later than 90 days after the submission of the reports*
8 *of the studies, the Secretary shall accept or reject such*
9 *reports and so notify the sponsor or holder. The Sec-*
10 *retary’s only responsibility in accepting or rejecting*
11 *the reports shall be to determine, within the 90 days,*
12 *whether the studies fairly respond to the written re-*
13 *quest, whether such studies have been conducted in ac-*
14 *cordance with commonly accepted scientific principles*
15 *and protocols, and whether such studies have been re-*
16 *ported in accordance with the requirements of the*
17 *Secretary for filing.*

18 “(e) *DELAY OF EFFECTIVE DATE FOR CERTAIN APPLI-*
19 *CATIONS; PERIOD OF MARKET EXCLUSIVITY.*—*If the Sec-*
20 *retary determines that the acceptance or approval of an ap-*
21 *plication under section 505(b)(2) or 505(j) for a drug may*
22 *occur after submission of reports of pediatric studies under*
23 *this section, which were submitted prior to the expiration*
24 *of the patent (including any patent extension) or market*
25 *exclusivity protection, but before the Secretary has deter-*

1 *mined whether the requirements of subsection (d) have been*
 2 *satisfied, the Secretary shall delay the acceptance or ap-*
 3 *proval under section 505(b)(2) or 505(j), respectively, until*
 4 *the determination under subsection (d) is made, but such*
 5 *delay shall not exceed 90 days. In the event that require-*
 6 *ments of this section are satisfied, the applicable period of*
 7 *market exclusivity referred to in subsection (a) or (c) shall*
 8 *be deemed to have been running during the period of delay.*

9 “(f) *NOTICE OF DETERMINATIONS ON STUDIES RE-*
 10 *QUIREMENT.*—*The Secretary shall publish a notice of any*
 11 *determination that the requirements of subsection (d) have*
 12 *been met and that submissions and approvals under section*
 13 *505(b)(2) or (j) for a drug will be subject to the provisions*
 14 *of this section.*

15 “(g) *DEFINITIONS.*—*As used in this section, the term*
 16 *‘pediatric studies’ or ‘studies’ means at least one clinical*
 17 *investigation (that, at the Secretary’s discretion, may in-*
 18 *clude pharmacokinetic studies) in pediatric age groups in*
 19 *which a drug is anticipated to be used.*

20 “(h) *LIMITATION.*—*The holder of an approved applica-*
 21 *tion for a new drug that has already received six months*
 22 *of market exclusivity under subsection (a) or (c) may, if*
 23 *otherwise eligible, obtain six months of market exclusivity*
 24 *under subsection (c)(1)(B) for a supplemental application,*

1 *except that the holder is not eligible for exclusivity under*
 2 *subsection (c)(2).*

3 “(i) *RELATIONSHIP TO REGULATIONS.—Notwith-*
 4 *standing any other provision of law, if any pediatric study*
 5 *is required pursuant to regulations promulgated by the Sec-*
 6 *retary, such study shall be deemed to satisfy the requirement*
 7 *for market exclusivity pursuant to this section.*

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

14 “(1) *the effectiveness of the program in improv-*
 15 *ing information about important pediatric uses for*
 16 *approved drugs;*

17 “(2) *the adequacy of the incentive provided*
 18 *under this section;*

19 “(3) *the economic impact of the program on tax-*
 20 *payers and consumers, including the impact of the*
 21 *lack of lower cost generic drugs on lower income pa-*
 22 *tients; and*

23 “(4) *any suggestions for modification that the*
 24 *Secretary deems appropriate.”.*

1 **SEC. 4. EXPEDITING STUDY AND APPROVAL OF FAST TRACK**
 2 **DRUGS.**

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

5 “SUBCHAPTER D—FAST TRACK PRODUCTS

6 “SEC. 741. FAST TRACK PRODUCTS.

7 “(a) *DESIGNATION OF DRUG AS A FAST TRACK PROD-*
 8 *UCT.*—

9 “(1) *IN GENERAL.*—The Secretary shall facilitate
 10 the development and expedite the review of new drugs
 11 that are intended for the treatment of serious or life-
 12 threatening conditions and that demonstrate the po-
 13 tential to address unmet medical needs for such con-
 14 ditions. In this section, such products shall be known
 15 as ‘fast track products’.

16 “(2) *REQUEST FOR DESIGNATION.*—The sponsor
 17 of a drug may request the Secretary to designate the
 18 drug as a fast track product. A request for the des-
 19 ignation may be made concurrently with, or at any
 20 time after, submission of an application for the inves-
 21 tigation of the drug under section 505(i) or section
 22 351(a)(4) of the Public Health Service Act.

23 “(3) *DESIGNATION.*—Within 30 calendar days
 24 after the receipt of a request under paragraph (2), the
 25 Secretary shall determine whether the drug that is the
 26 subject of the request meets the criteria described in

1 *paragraph (1). If the Secretary finds that the drug*
2 *meets the criteria, the Secretary shall designate the*
3 *drug as a fast track product and shall take such ac-*
4 *tions as are appropriate to expedite the development*
5 *and review of the application for approval of such*
6 *product.*

7 “(b) *APPROVAL OF APPLICATION FOR A FAST TRACK*
8 *PRODUCT.—*

9 “(1) *IN GENERAL.—The Secretary may approve*
10 *an application for approval of a fast track product*
11 *under section 505(b) or section 351 of the Public*
12 *Health Service Act (21 U.S.C. 262) upon a deter-*
13 *mination that the product has an effect on a clinical*
14 *endpoint or a surrogate endpoint that is reasonably*
15 *likely to predict clinical benefit.*

16 “(2) *LIMITATION.—Approval of a fast track*
17 *product under this subsection may be subject to the*
18 *requirements—*

19 “(A) *that the sponsor conduct appropriate*
20 *post-approval studies to validate the surrogate*
21 *endpoint or otherwise confirm the effect on the*
22 *clinical endpoint; and*

23 “(B) *that the sponsor submit copies of all*
24 *promotional materials related to the fast track*
25 *product during the preapproval review period*

1 *and, following approval and for such period*
2 *thereafter as the Secretary deems appropriate, at*
3 *least 30 days prior to dissemination of the mate-*
4 *rials.*

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

10 “(A) *the sponsor fails to conduct any re-*
11 *quired post-approval study of the fast track drug*
12 *with due diligence;*

13 “(B) *a post-approval study of the fast track*
14 *product fails to verify clinical benefit of the*
15 *product;*

16 “(C) *other evidence demonstrates that the*
17 *fast track product is not safe or effective under*
18 *the conditions of use; or*

19 “(D) *the sponsor disseminates false or mis-*
20 *leading promotional materials with respect to*
21 *the product.*

22 “(c) *REVIEW OF INCOMPLETE APPLICATIONS FOR AP-*
23 *PROVAL OF A FAST TRACK PRODUCT.—*

24 “(1) *IN GENERAL.—If the Secretary determines,*
25 *after preliminary evaluation of clinical data submit-*

1 *ted by the sponsor, that a fast track product may be*
2 *effective the Secretary shall evaluate for filing, and*
3 *may commence review of portions of, an application*
4 *for the approval of the product before the sponsor sub-*
5 *mits a complete application. The Secretary shall com-*
6 *mence such review only if the applicant (A) provides*
7 *a schedule for submission of information necessary to*
8 *make the application complete, and (B) pays any fee*
9 *that may be required under section 736.*

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

19 *“(d) AWARENESS EFFORTS.—The Secretary shall—*
20 *“(1) develop and disseminate to physicians, pa-*
21 *tient organizations, pharmaceutical and biotechnology*
22 *companies, and other appropriate persons a descrip-*
23 *tion of the provisions applicable to fast track products*
24 *established under this section; and*

1 “(2) *establish a program to encourage the devel-*
 2 *opment of surrogate endpoints that are reasonably*
 3 *likely to predict clinical benefit for serious or life-*
 4 *threatening conditions for which there exist signifi-*
 5 *cant unmet medical needs.”.*

6 **(b) GUIDANCE.**—*Within 1 year after the date of enact-*
 7 *ment of this Act, the Secretary shall issue guidance for fast*
 8 *track products (as defined in section 741(a)(1) of the Fed-*
 9 *eral Food, Drug, and Cosmetic Act) that describes the poli-*
 10 *cies and procedures that pertain to section 741 of such Act.*

11 **SEC. 5. EXPANDED ACCESS TO INVESTIGATIONAL THERA-**
 12 **PIES.**

13 *Chapter V (21 U.S.C. 351 et seq.) is amended by add-*
 14 *ing at the end the following:*

15 **“SUBCHAPTER D—UNAPPROVED THERAPIES AND**
 16 **DIAGNOSTICS**

17 **“SEC. 551. EXPANDED ACCESS TO UNAPPROVED THERAPIES**
 18 **AND DIAGNOSTICS.**

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

1 “(b) *INDIVIDUAL PATIENT ACCESS TO INVESTIGA-*
2 *TIONAL PRODUCTS INTENDED FOR SERIOUS DISEASES.—*
3 *Any person, acting through a physician licensed in accord-*
4 *ance with State law, may request from a manufacturer or*
5 *distributor, and any manufacturer or distributor may pro-*
6 *vide to such physician after compliance with the provisions*
7 *of this subsection, an investigational drug (as defined in*
8 *regulations prescribed by the Secretary) for the diagnosis*
9 *or treatment of a serious disease or condition if—*

10 “(1) *the licensed physician determines that the*
11 *person has no comparable or satisfactory alternative*
12 *therapy available to diagnose or treat the disease or*
13 *condition involved, and that the risk to the person*
14 *from the investigational drug is not greater than the*
15 *risk from the disease or condition;*

16 “(2) *the Secretary determines that there is suffi-*
17 *cient evidence of safety and effectiveness to support*
18 *the use of the investigational drug in the case de-*
19 *scribed in paragraph (1);*

20 “(3) *the Secretary determines that provision of*
21 *the investigational drug will not interfere with the*
22 *initiation, conduct, or completion of clinical inves-*
23 *tigations to support marketing approval; and*

24 “(4) *the sponsor, or clinical investigator, of the*
25 *investigational drug submits to the Secretary a clini-*

1 *cal protocol consistent with the provisions of section*
2 *505(i) and any regulations promulgated under section*
3 *505(i) describing the use of investigational drugs in*
4 *a single patient or a small group of patients.*

5 *“(c) TREATMENT INDs.—Upon submission by a spon-*
6 *sor or a physician of a protocol intended to provide wide-*
7 *spread access to an investigational drug for eligible pa-*
8 *tients, the Secretary shall permit such investigational drug*
9 *to be made available for expanded access under a treatment*
10 *investigational new drug application if the Secretary deter-*
11 *mines that—*

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

16 *“(2) there is no comparable or satisfactory alter-*
17 *native therapy available to diagnose or treat that*
18 *stage of disease or condition in the population of pa-*
19 *tients to which the investigational drug is intended to*
20 *be administered;*

21 *“(3)(A) the investigational drug is under inves-*
22 *tigation in a controlled clinical trial for the use de-*
23 *scribed in paragraph (1) under an effective investiga-*
24 *tional new drug application; or*

1 “(B) all clinical trials necessary for approval of
2 that use of the investigational drug have been com-
3 pleted;

4 “(4) the sponsor of the controlled clinical trials
5 is actively pursuing marketing approval of the inves-
6 tigational drug for the use described in paragraph (1)
7 with due diligence;

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

11 “(6) in the case of serious diseases, there is suffi-
12 cient evidence of safety and effectiveness to support
13 the use described in paragraph (1); and

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

20 A protocol submitted under this subsection shall be subject
21 to the provisions of section 505(i) and regulations promul-
22 gated under section 505(i). The Secretary may inform na-
23 tional, State, and local medical associations and societies,
24 voluntary health associations, and other appropriate per-
25 sons about the availability of an investigational drug under

1 *expanded access protocols submitted under this subsection.*
 2 *The information provided by the Secretary, in accordance*
 3 *with the preceding sentence, shall be of the same type of*
 4 *information that is required by section 402(j)(3) of the Pub-*
 5 *lic Health Service Act.*

6 “(d) *TERMINATION.*—*The Secretary may, at any time,*
 7 *with respect to a sponsor, physician, manufacturer, or dis-*
 8 *tributor described in this section, terminate expanded access*
 9 *provided under this section for an investigational drug if*
 10 *the requirements under this section are no longer met.”.*

11 **SEC. 6. INFORMATION PROGRAM ON CLINICAL TRIALS FOR**
 12 **SERIOUS OR LIFE-THREATENING DISEASES.**

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

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

17 (2) *by inserting after subsection (i), the follow-*
 18 *ing:*

19 “(j)(1) *The Secretary, acting through the Director of*
 20 *the National Institutes of Health, shall establish, maintain,*
 21 *and operate a program with respect to information on re-*
 22 *search relating to the treatment, detection, and prevention*
 23 *of serious or life-threatening diseases and conditions. The*
 24 *program shall, with respect to the agencies of the Depart-*
 25 *ment of Health and Human Services, be integrated and co-*

1 *ordinated, and, to the extent practicable, coordinated with*
2 *other data banks containing similar information.*

3 “(2)(A) *After consultation with the Commissioner of*
4 *Food and Drugs, the directors of the appropriate agencies*
5 *of the National Institutes of Health (including the National*
6 *Library of Medicine), and the Director of the Centers for*
7 *Disease Control and Prevention, the Secretary shall, in car-*
8 *rying out paragraph (1), establish a data bank of informa-*
9 *tion on clinical trials for drugs for serious or life-threaten-*
10 *ing diseases and conditions.*

11 “(B) *In carrying out subparagraph (A), the Secretary*
12 *shall collect, catalog, store, and disseminate the information*
13 *described in such subparagraph. The Secretary shall dis-*
14 *seminate such information through information systems,*
15 *which shall include toll-free telephone communications,*
16 *available to individuals with serious or life-threatening dis-*
17 *eases and conditions, to other members of the public, to*
18 *health care providers, and to researchers.*

19 “(3) *The data bank shall include the following:*

20 “(A) *A registry of clinical trials (whether feder-*
21 *ally or privately funded) of experimental treatments*
22 *for serious or life-threatening diseases and conditions*
23 *under regulations promulgated pursuant to sections*
24 *505 of the Federal Food, Drug, and Cosmetic Act that*
25 *provides a description of the purpose of each experi-*

1 *mental drug, either with the consent of the protocol*
2 *sponsor, or when a trial to test effectiveness begins.*
3 *Information provided shall consist of eligibility cri-*
4 *teria, a description of the location of trial sites, and*
5 *a point of contact for those wanting to enroll in the*
6 *trial, and shall be in a form that can be readily un-*
7 *derstood by members of the public. Such information*
8 *must be forwarded to the data bank by the sponsor*
9 *of the trial not later than 21 days after trials to test*
10 *clinical effectiveness have begun.*

11 *“(B) Information pertaining to experimental*
12 *treatments for serious or life-threatening diseases and*
13 *conditions that may be available—*

14 *“(i) under a treatment investigational new*
15 *drug application that has been submitted to the*
16 *Food and Drug Administration under section*
17 *551(c) of the Federal Food, Drug, and Cosmetic*
18 *Act; or*

19 *“(ii) as a Group C cancer drug (as defined*
20 *by the National Cancer Institute).*

21 *The data bank may also include information pertain-*
22 *ing to the results of clinical trials of such treatments,*
23 *with the consent of the sponsor, including information*
24 *concerning potential toxicities or adverse effects asso-*

1 *ciated with the use or administration of such experi-*
 2 *mental treatments.*

3 *“(4) The data bank shall not include information re-*
 4 *lating to an investigation if the sponsor has provided a de-*
 5 *tailed certification to the Secretary that disclosure of such*
 6 *information would substantially interfere with the timely*
 7 *enrollment of subjects in the investigation, unless the Sec-*
 8 *retary, after the receipt of the certification, provides the*
 9 *sponsor with a detailed written determination that such*
 10 *disclosure would not substantially interfere with such en-*
 11 *rollment.*

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

17 *(b) COLLABORATION AND REPORT.—*

18 *(1) IN GENERAL.—The Secretary of Health and*
 19 *Human Services, the Director of the National Insti-*
 20 *tutes of Health, and the Commissioner of Food and*
 21 *Drugs shall collaborate to determine the feasibility of*
 22 *including device investigations within the scope of the*
 23 *registry requirements set forth in section 402(j) of the*
 24 *Public Health Service Act.*

1 (2) *REPORT.*—Not later than 2 years after the
2 date of enactment of this section, the Secretary of
3 Health and Human Services shall prepare and sub-
4 mit to the Committee on Labor and Human Re-
5 sources of the Senate and the Committee on Commerce
6 of the House of Representatives a report—

7 (A) of the public health need, if any, for in-
8 clusion of device investigations within the scope
9 of the registry requirements set forth in section
10 402(j) of the Public Health Service Act;

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

15 (C) on such other issues relating to such sec-
16 tion 402(j) as the Secretary may deem appro-
17 priate.

18 **SEC. 7. DISSEMINATION OF INFORMATION ON NEW USES.**

19 (a) *IN GENERAL.*—Chapter VII (21 U.S.C. 371 et
20 seq.), as amended by section 4, is amended by adding at
21 the end the following:

5 “(a) *IN GENERAL.*—Notwithstanding sections 301(d),
6 502(f), and 505 and section 351 of the Public Health Serv-
7 ice Act (42 U.S.C. 262), a manufacturer may disseminate
8 to—

9 “(1) a health care practitioner,
10 “(2) a pharmacy benefit manager,
11 “(3) a health insurance issuer,
12 “(4) a group health plan, or
13 “(5) a Federal or State governmental agency,
14 written information concerning the safety, effectiveness, or
15 benefit of a use not described in the approved labeling of
16 a drug if the manufacturer meets the requirements of sub-
17 section (b).

18 “(b) *SPECIFIC REQUIREMENTS.*—A manufacturer may
19 disseminate information about a new use of a drug under
20 subsection (a) only if—

21 “(1) there is in effect for such drug an applica-
22 tion filed under section 505(b) or a biologics license
23 issued under section 351 of the Public Health Service
24 Act;

1 “(2) the information meets the requirements of
2 section 746;

3 “(3) the information to be disseminated is not
4 derived from clinical research conducted by another
5 manufacturer or if it was derived from research con-
6 ducted by another manufacturer, the manufacturer
7 disseminating the information has the permission of
8 such other manufacturer to make the dissemination;

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

11 “(A) a copy of the information dissemi-
12 nated; and

13 “(B) any clinical trial information the
14 manufacturer has relating to the safety or effec-
15 tiveness of the new use, any reports of clinical
16 experience pertinent to the safety of the new use,
17 and a summary of such information;

18 “(5) the manufacturer has complied with the re-
19 quirements of section 748 (relating to certification
20 that the manufacturer will submit a supplemental ap-
21 plication with respect to such use);

22 “(6) the manufacturer agrees to include along
23 with the information disseminated under this sub-
24 section—

1 “(A) a prominently displayed statement
2 that discloses—

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

6 “(ii) if applicable, that the informa-
7 tion is being disseminated at the expense of
8 the manufacturer;

9 “(iii) if applicable, the name of any
10 authors of the information who are employ-
11 ees of, consultants to, or have received com-
12 pensation from, the manufacturer, or who
13 have a significant financial interest in the
14 manufacturer;

15 “(iv) the official labeling for the drug
16 and all updates with respect to the labeling;

17 “(v) if applicable, a statement that
18 there are products or treatments that have
19 been approved for the use that is the subject
20 of the information being disseminated pur-
21 suant to subsection (a)(1); and

22 “(vi) the identification of any person
23 that has provided funding for the conduct of
24 a study relating to the new use of a drug

1 *for which such information is being dis-*
2 *seminated; and*

3 “(B) a bibliography of other articles from a
4 scientific reference publication or scientific or
5 medical journal that have been previously pub-
6 lished about the such use of the drug covered by
7 the information disseminated (unless the infor-
8 mation already includes such bibliography).

9 “(c) *ADDITIONAL INFORMATION.*—If the Secretary de-
10 termines, after providing notice of such determination and
11 an opportunity for a meeting with respect to such deter-
12 mination, that the information submitted by a manufac-
13 turer under subsection (b)(3)(B), with respect to the use of
14 a drug for which the manufacturer is disseminating infor-
15 mation, fails to provide data, analyses, or other written
16 matter that is objective and balanced, the Secretary may
17 require the manufacturer to disseminate—

18 “(1) additional objective and scientifically sound
19 information that pertains to the safety or effectiveness
20 of the use and is necessary to provide objectivity and
21 balance, including any information that the manufac-
22 turer has submitted to the Secretary or, where appro-
23 priate, a summary of such information or any other
24 information that the Secretary has authority to make
25 available to the public; and

1 “(2) an objective statement of the Secretary,
2 *based on data or other scientifically sound informa-*
3 *tion available to the Secretary, that bears on the safe-*
4 *ty or effectiveness of the new use of the drug.*

5 **“SEC. 746. INFORMATION AUTHORIZED TO BE DISSEMI-**
6 **NATED.**

7 “(a) *AUTHORIZED INFORMATION.—A manufacturer*
8 *may disseminate the information on the new use of a drug*
9 *under section 745 only if the information—*

10 “(1) *is in the form of an unabridged—*

11 “(A) *reprint or copy of an article, peer-re-*
12 *viewed by experts qualified by scientific training*
13 *or experience to evaluate the safety or effective-*
14 *ness of the drug, which was published in a sci-*
15 *entific or medical journal (as defined in section*
16 *750(6)), which is about a clinical investigation*
17 *with respect to the drug, and which would be*
18 *considered to be scientifically sound by such ex-*
19 *perts; or*

20 “(B) *reference publication, described in sub-*
21 *section (b), that includes information about a*
22 *clinical investigation with respect to the drug*
23 *that would be considered to be scientifically*
24 *sound by experts qualified by scientific training*
25 *or experience to evaluate the safety or effective-*

1 *ness of the drug that is the subject of such a clin-*
2 *ical investigation; and*

3 “(2) *is not false or misleading and would not*
4 *pose a significant risk to the public health.*

5 “(b) *REFERENCE PUBLICATION.—A reference publica-*
6 *tion referred to in subsection (a)(1)(B) is a publication*
7 *that—*

8 “(1) *has not been written, edited, excerpted, or*
9 *published specifically for, or at the request of, a man-*
10 *ufacturer of a drug;*

11 “(2) *has not been edited or significantly influ-*
12 *enced by a such a manufacturer;*

13 “(3) *is not solely distributed through such a*
14 *manufacturer but is generally available in bookstores*
15 *or other distribution channels where medical textbooks*
16 *are sold;*

17 “(4) *does not focus on any particular drug of a*
18 *manufacturer that disseminates information under*
19 *section 745 and does not have a primary focus on*
20 *new uses of drugs that are marketed or under inves-*
21 *tigation by a manufacturer supporting the dissemina-*
22 *tion of information; and*

23 “(5) *presents materials that are not false or mis-*
24 *leading.*

1 **“SEC. 747. ESTABLISHMENT OF LIST OF ARTICLES AND PUB-**
2 **LICATIONS DISSEMINATED AND LIST OF PRO-**
3 **VIDERS THAT RECEIVED ARTICLES AND REF-**
4 **ERENCE PUBLICATIONS.**

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

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

14 “(2) a list that identifies the categories of provid-
15 ers (as described in section 745(a)) that received the
16 articles and reference publications for the 6-month pe-
17 riod described in paragraph (1).

18 “(b) *RECORDS.*—A manufacturer that disseminates
19 information under section 745 shall keep records that may
20 be used by the manufacturer when, pursuant to section 749,
21 such manufacturer is required to take corrective action and
22 shall be made available to the Secretary, upon request, for
23 purposes of ensuring or taking corrective action pursuant
24 to such section. Such records, at the Secretary’s discretion,
25 may identify the recipient of information provided pursu-
26 ant to section 745 or the categories of such recipients.

1 **“SEC. 748. REQUIREMENT REGARDING SUBMISSION OF SUP-**
2 **PLEMENTAL APPLICATION FOR NEW USE; EX-**
3 **EMPTION FROM REQUIREMENT.**

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

6 “(1) *the manufacturer meets the condition de-*
7 *scribed in subsection (b) or in subsection (c); or*

8 “(2) *there is in effect for the manufacturer an ex-*
9 *emption under subsection (d) from the requirement of*
10 *paragraph (1).*

11 “(b) *SUPPLEMENTAL APPLICATION; CONDITION IN*
12 *CASE OF COMPLETED STUDIES.*—For purposes of sub-
13 section (a)(1), a manufacturer may disseminate informa-
14 tion on a new use if the manufacturer has submitted to
15 the Secretary an application containing a certification
16 that—

17 “(1) *the studies needed for the submission of a*
18 *supplemental application for the new use have been*
19 *completed; and*

20 “(2) *the supplemental application will be sub-*
21 *mitted to the Secretary not later than 6 months after*
22 *the date of the initial dissemination of information*
23 *under section 745.*

24 “(c) *SUPPLEMENTAL APPLICATION; CONDITION IN*
25 *CASE OF PLANNED STUDIES.*—

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

4 “(A) the manufacturer has submitted to the
5 Secretary an application containing—

6 “(i) a proposed protocol and schedule
7 for conducting the studies needed for the
8 submission of a supplemental application
9 for the new use; and

10 “(ii) a certification that the supple-
11 mental application will be submitted to the
12 Secretary not later than 36 months after the
13 date of the initial dissemination of informa-
14 tion under section 745 (or, as applicable,
15 not later than such date as the Secretary
16 may specify pursuant to an extension under
17 this paragraph or paragraph (3)); and

18 “(B) the Secretary has determined that the
19 proposed protocol is adequate and that the sched-
20 ule for completing such studies is reasonable.

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

1 “(2) *PROGRESS REPORTS ON STUDIES.*—A man-
 2 ufacturer that submits to the Secretary an applica-
 3 tion under paragraph (1) shall submit to the Sec-
 4 retary periodic reports describing the status of the
 5 studies involved.

6 “(3) *EXTENSION OF TIME REGARDING PLANNED*
 7 *STUDIES.*—The period of 36 months authorized in
 8 paragraph (1)(A)(ii) for the completion of studies
 9 may be extended by the Secretary if the manufacturer
 10 involved submits to the Secretary a written request
 11 for the extension and the Secretary determines that
 12 the manufacturer has acted with due diligence to con-
 13 duct the studies in a timely manner. Such extension
 14 may not provide more than 24 additional months.

15 “(d) *EXEMPTION FROM REQUIREMENT OF SUPPLE-*
 16 *MENTAL APPLICATION.*—

17 “(1) *IN GENERAL.*—For purposes of subsection
 18 (a)(2), a manufacturer may disseminate information
 19 on a new use if—

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

23 “(B)(i) the Secretary has approved the ap-
 24 plication in accordance with paragraph (2); or

1 “(ii) the application is deemed under para-
2 graph (3)(A) to have been approved (unless such
3 approval is terminated pursuant to paragraph
4 (3)(B)).

5 “(2) CONDITIONS FOR APPROVAL.—The Sec-
6 retary may approve an application under paragraph
7 (1) for an exemption only if the Secretary determines
8 that—

9 “(A) it would be economically prohibitive
10 with respect to such drug for the manufacturer
11 to incur the costs necessary for the submission of
12 a supplemental application for reasons, as de-
13 fined by the Secretary, such as the lack of avail-
14 ability under law of any period during which
15 the manufacturer would have exclusive market-
16 ing rights with respect to the new use involved
17 or that the population expected to benefit from
18 approval of the supplemental application is
19 small; or

20 “(B) it would be unethical to conduct the
21 studies necessary for the supplemental applica-
22 tion for a reason such as the new use involved
23 is the standard of medical care for a health con-
24 dition.

1 “(3) *TIME FOR CONSIDERATION OF APPLICATION;*
2 *DEEMED APPROVAL.*—

3 “(A) *IN GENERAL.*—*The Secretary shall ap-*
4 *prove or deny an application under paragraph*
5 *(1) for an exemption not later than 60 days after*
6 *the receipt of the application. If the Secretary*
7 *does not comply with the preceding sentence, the*
8 *application is deemed to be approved.*

9 “(B) *TERMINATION OF DEEMED AP-*
10 *PROVAL.*—*If pursuant to a deemed approval*
11 *under subparagraph (A) a manufacturer dis-*
12 *seminates written information under section 745*
13 *on a new use, the Secretary may at any time*
14 *terminate such approval and under section*
15 *749(b)(3) order the manufacturer to cease dis-*
16 *seminating the information.*

17 “(e) *REQUIREMENTS REGARDING APPLICATIONS.*—
18 *Applications under this section shall be submitted in the*
19 *form and manner prescribed by the Secretary.*

20 “(f) *TRANSITION RULE.*—*For purposes of this section,*
21 *in any case in which a manufacturer has submitted to the*
22 *Secretary a supplemental application for which action by*
23 *the Secretary is pending as of the date of the enactment*
24 *of the Prescription Drug User Fee Reauthorization and*
25 *Drug and Biological Products Regulatory Modernization*

1 *Act of 1997, the application is deemed to be a supplemental*
 2 *application submitted under subsection (b).*

3 **“SEC. 749. CORRECTIVE ACTIONS; CESSATION OF DISSEMI-**
 4 **NATION.**

5 *“(a) POSTDISSEMINATION DATA REGARDING SAFETY*
 6 *AND EFFECTIVENESS.—*

7 *“(1) CORRECTIVE ACTIONS.—With respect to*
 8 *data received by the Secretary after the dissemination*
 9 *of information under section 745 by a manufacturer*
 10 *has begun (whether received pursuant to paragraph*
 11 *(2) or otherwise), if the Secretary determines that the*
 12 *data indicate that the new use involved may not be*
 13 *effective or may present a significant risk to public*
 14 *health, the Secretary shall, in consultation with the*
 15 *manufacturer, take such action regarding the dissemi-*
 16 *nation of the information as the Secretary determines*
 17 *to be appropriate for the protection of the public*
 18 *health, which may include ordering that the manufac-*
 19 *turer cease the dissemination of the information.*

20 *“(2) RESPONSIBILITIES OF MANUFACTURERS TO*
 21 *SUBMIT DATA.—After a manufacturer disseminates*
 22 *information pursuant to section 745, the manufac-*
 23 *turer shall submit to the Secretary a notification of*
 24 *any additional knowledge of the manufacturer on*
 25 *clinical research or other data that relate to the safety*

1 *or effectiveness of the new use involved. If the manu-*
 2 *facturer is in possession of the data, the notification*
 3 *shall include the data. The Secretary shall by regula-*
 4 *tion establish the scope of the responsibilities of man-*
 5 *ufacturers under this paragraph, including such lim-*
 6 *its on the responsibilities as the Secretary determines*
 7 *to be appropriate.*

8 *“(b) CESSATION OF DISSEMINATION.—*

9 *“(1) FAILURE OF MANUFACTURER TO COMPLY*
 10 *WITH REQUIREMENTS.—The Secretary may order a*
 11 *manufacturer to cease the dissemination of informa-*
 12 *tion pursuant to section 745 if the Secretary deter-*
 13 *mines that the information being disseminated does*
 14 *not comply with the requirements established in this*
 15 *subchapter. Such an order may be issued only after*
 16 *the Secretary has provided notice to the manufacturer*
 17 *of the intent of the Secretary to issue the order and*
 18 *has provided an opportunity for a meeting with re-*
 19 *spect to such intent unless paragraph (2)(B) applies.*
 20 *If the failure of the manufacturer constitutes a minor*
 21 *violation of this subchapter, the Secretary shall delay*
 22 *issuing the order and provide to the manufacturer an*
 23 *opportunity to correct the violation.*

24 *“(2) SUPPLEMENTAL APPLICATIONS.—The Sec-*
 25 *retary may order a manufacturer to cease the dis-*

1 *semination of information pursuant to section 745 if*
2 *the Secretary determines that—*

3 *“(A) in the case of a manufacturer to which*
4 *section 748(b) applies, the Secretary determines*
5 *that the supplemental application received under*
6 *such section does not contain adequate informa-*
7 *tion for approval of the new use with respect to*
8 *which the application was submitted; or*

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

14 *“(3) TERMINATION OF DEEMED APPROVAL OF*
15 *EXEMPTION REGARDING SUPPLEMENTAL APPLICA-*
16 *TIONS.—If under section 748(d)(3) the Secretary ter-*
17 *minates a deemed approval of an exemption, the Sec-*
18 *retary may order the manufacturer involved to cease*
19 *disseminating the information. A manufacturer shall*
20 *comply with an order under the preceding sentence*
21 *not later than 60 days after the receipt of the order.*

22 *“(c) CORRECTIVE ACTIONS BY MANUFACTURERS.—*

23 *“(1) IN GENERAL.—In any case in which under*
24 *this section the Secretary orders a manufacturer to*
25 *cease disseminating information, the Secretary may*

1 *order the manufacturer to take action to correct the*
 2 *information that has been disseminated, except as*
 3 *provided in paragraph (2).*

4 *“(2) TERMINATION OF DEEMED APPROVAL OF*
 5 *EXEMPTION REGARDING SUPPLEMENTAL APPLICA-*
 6 *TIONS.—In the case of an order under subsection*
 7 *(b)(3) to cease disseminating information, the Sec-*
 8 *retary may not order the manufacturer involved to*
 9 *take action to correct the information that has been*
 10 *disseminated unless the Secretary determines that the*
 11 *new use described in the information would pose a*
 12 *significant risk to the public health.*

13 **“SEC. 750. DEFINITIONS.**

14 *“For purposes of this subchapter:*

15 *“(1) The term ‘health care practitioner’ means a*
 16 *physician, or other individual who is a provider of*
 17 *health care, who is licensed under the law of a State*
 18 *to prescribe drugs.*

19 *“(2) The terms ‘health insurance issuer’ and*
 20 *‘group health plan’ have the meaning given such*
 21 *terms under section 2791 of the Public Health Service*
 22 *Act.*

23 *“(3) The term ‘manufacturer’ means a person*
 24 *who manufactures a drug, or who is licensed by such*
 25 *person to distribute or market the drug.*

1 “(4) The term ‘new use’, with respect to a drug,
2 means a use that is not included in the approved la-
3 beling of the drug.

4 “(5) The term ‘pharmacy benefit manager’
5 means an organization that—

6 “(A) manages pharmaceutical costs
7 through—

8 “(i) pharmacy benefit administration,
9 including claims processing adjudication,
10 pharmacy networks, mail service, and data
11 reporting;

12 “(ii) formulary management and con-
13 tracting, including evaluating drugs for for-
14 mulary status, negotiations of contracts
15 with manufacturers, and disbursement of
16 rebates; and

17 “(iii) utilization management, includ-
18 ing communicating and enforcing therapy
19 guidelines and drug use principles to physi-
20 cians, pharmacists, and patients; and

21 “(B) serves 2 principal types of customers
22 which are—

23 “(i) employers, both private- and pub-
24 lic-sector, who use either self-funded health
25 benefits through a third party administra-

1 *tor's insurance carrier or use traditional*
2 *indemnity coverage, using providers from a*
3 *preferred provider network or in a fee-for-*
4 *service capacity; and*

5 *“(ii) health maintenance organiza-*
6 *tions.*

7 *“(6) The term ‘scientific or medical journal’*
8 *means a scientific or medical publication—*

9 *“(A) that is published by an organization—*

10 *“(i) that has an editorial board;*

11 *“(ii) that utilizes experts, who have*
12 *demonstrated expertise in the subject of an*
13 *article under review by the organization*
14 *and who are independent of the organiza-*
15 *tion, to review and objectively select, reject,*
16 *or provide comments about proposed arti-*
17 *cles; and*

18 *“(iii) that has a publicly stated policy,*
19 *to which the organization adheres, of full*
20 *disclosure of any conflict of interest or bi-*
21 *ases for all authors or contributors involved*
22 *with the journal or organization;*

23 *“(B) whose articles are peer-reviewed and*
24 *published in accordance with the regular peer-re-*
25 *view procedures of the organization;*

1 “(C) that is generally recognized to be of
2 national scope and reputation;

3 “(D) that is indexed in the *Index Medicus*
4 of the National Library of Medicine of the Na-
5 tional Institutes of Health; and

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

9 **“SEC. 751. RULES OF CONSTRUCTION.**

10 “(a) *UNSOLICITED REQUEST*.—Nothing in section 745
11 shall be construed as prohibiting a manufacturer from dis-
12 seminating information in response to an unsolicited re-
13 quest from a health care practitioner.

14 “(b) *DISSEMINATION OF INFORMATION ON DRUGS NOT*
15 *EVIDENCE OF INTENDED USE*.—Notwithstanding sub-
16 section (a), (f), or (o) of section 502, or any other provision
17 of law, the dissemination of information relating to a new
18 use of a drug, in accordance with section 745, shall not
19 be construed by the Secretary as evidence of a new intended
20 use of the drug that is different from the intended use of
21 the drug set forth in the official labeling of the drug. Such
22 dissemination shall not be considered by the Secretary as
23 labeling, adulteration, or misbranding of the drug.

24 “(c) *PATENT PROTECTION*.—Nothing in section 745
25 shall affect patent rights in any manner.

1 “(d) *AUTHORIZATION FOR DISSEMINATION OF ARTI-*
 2 *CLES AND FEES FOR REPRINTS OF ARTICLES.*—*Nothing in*
 3 *section 745 shall be construed as prohibiting an entity that*
 4 *publishes a scientific journal (as defined in section 750(6))*
 5 *from requiring authorization from the entity to disseminate*
 6 *an article published by such entity or charging fees for the*
 7 *purchase of reprints of published articles from such entity.”.*

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

10 “(x) *The dissemination of information in violation of*
 11 *section 745.”.*

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

16 (d) *EFFECTIVE DATE.*—*The amendments made by this*
 17 *section shall take effect 1 year after the date of enactment*
 18 *of this Act, or upon the Secretary’s issuance of final regula-*
 19 *tions pursuant to subsection (c), whichever is sooner.*

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

1 **SEC. 8. STUDIES AND REPORTS.**

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

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

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

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

13 (B) *the quality of the information being dis-*
14 *seminated pursuant to such amendments;*

15 (C) *the quality and usefulness of the infor-*
16 *mation provided, in accordance with such*
17 *amendments, by the Secretary or by a manufac-*
18 *turer at the request of the Secretary; and*

19 (D) *the impact of such amendments on re-*
20 *search in the area of new uses of drugs, indica-*
21 *tions for new uses, or dosages of drugs for new*
22 *uses, particularly the impact on pediatric indi-*
23 *cations and rare diseases.*

24 (b) *REPORT.*—*Not later than January 1, 2002, the*
25 *Comptroller General of the United States shall prepare and*
26 *submit to the Committee on Labor and Human Resources*

1 *of the Senate and the Committee on Commerce of the House*
2 *of Representatives a report of the results of the study under*
3 *subsection (a).*

4 **SEC. 9. APPROVAL OF SUPPLEMENTAL APPLICATIONS FOR**
5 **APPROVED PRODUCTS.**

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

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

19 (1) *clarify circumstances in which published*
20 *matter may be the basis for approval of a supple-*
21 *mental application;*

22 (2) *specify data requirements that will avoid du-*
23 *plication of previously submitted data by recognizing*
24 *the availability of data previously submitted in sup-*
25 *port of an original application; and*

1 (3) *define supplemental applications that are eli-*
2 *gible for priority review.*

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

7 (1) *encouraging the prompt review of supple-*
8 *mental applications for approved articles; and*

9 (2) *working with sponsors to facilitate the devel-*
10 *opment and submission of data to support supple-*
11 *mental applications.*

12 (d) *COLLABORATION.—The Secretary shall implement*
13 *programs and policies that will foster collaboration between*
14 *the Food and Drug Administration, the National Institutes*
15 *of Health, professional medical and scientific societies, and*
16 *other persons, to identify published and unpublished studies*
17 *that may support a supplemental application, and to en-*
18 *courage sponsors to make supplemental applications or con-*
19 *duct further research in support of a supplemental applica-*
20 *tion based, in whole or in part, on such studies.*

21 **SEC. 10. HEALTH CARE ECONOMIC INFORMATION.**

22 *Section 502(a) (21 U.S.C. 352(a)) is amended by add-*
23 *ing at the end the following: “Health care economic infor-*
24 *mation provided to a formulary committee, or other similar*
25 *entity, in the course of the committee or the entity carrying*

1 *out its responsibilities for the selection of drugs for managed*
 2 *care or other similar organizations, shall not be considered*
 3 *to be false or misleading if the health care economic infor-*
 4 *mation directly relates to an indication approved under*
 5 *section 505 or 507 or section 351(a) of the Public Health*
 6 *Service Act (42 U.S.C. 262(a)) for such drug and is based*
 7 *on competent and reliable scientific evidence. The require-*
 8 *ments set forth in section 505(a), 507, or section 351(a) of*
 9 *the Public Health Service Act (42 U.S.C. 262(a)) shall not*
 10 *apply to health care economic information provided to such*
 11 *a committee or entity in accordance with this paragraph.*
 12 *Information that is relevant to the substantiation of the*
 13 *health care economic information presented pursuant to*
 14 *this paragraph shall be made available to the Secretary*
 15 *upon request. In this paragraph, the term ‘health care eco-*
 16 *nomic information’ means any analysis that identifies,*
 17 *measures, or compares the economic consequences, including*
 18 *the costs of the represented health outcomes, of the use of*
 19 *a drug to the use of another drug, to another health care*
 20 *intervention, or to no intervention.”.*

21 **SEC. 11. CLINICAL INVESTIGATIONS.**

22 (a) **CLARIFICATION OF THE NUMBER OF REQUIRED**
 23 **CLINICAL INVESTIGATIONS FOR APPROVAL.**—Section
 24 505(d) (21 U.S.C. 355(d)) is amended by adding at the end
 25 the following: “If the Secretary determines, based on rel-

1 *evant science, that data from one adequate and well-con-*
 2 *trolled clinical investigation and confirmatory evidence (ob-*
 3 *tained prior to or after such investigation) are sufficient*
 4 *to establish effectiveness, the Secretary may consider such*
 5 *data and evidence to constitute substantial evidence for pur-*
 6 *poses of the preceding sentence.”.*

7 (b) *WOMEN AND MINORITIES.*—Section 505(b)(1) (21
 8 *U.S.C. 355(b)(1)) is amended by adding at the end the fol-*
 9 *lowing: “The Secretary shall, in consultation with the Di-*
 10 *rector of the National Institutes of Health, review and de-*
 11 *velop guidance, as appropriate, on the inclusion of women*
 12 *and minorities in clinical trials required by clause (A).”.*

13 **SEC. 12. MANUFACTURING CHANGES FOR DRUGS.**

14 (a) *IN GENERAL.*—Chapter VII (21 U.S.C. 371 *et*
 15 *seq.*), as amended by section 7, is amended by adding at
 16 *the end the following subchapter:*

17 “SUBCHAPTER F—MANUFACTURING CHANGES

18 **“SEC. 755. MANUFACTURING CHANGES.**

19 “(a) *IN GENERAL.*—With respect to a drug for which
 20 *there is in effect an approved application under section 505*
 21 *or 512 or a license under section 351 of the Public Health*
 22 *Service Act, a change from the manufacturing process ap-*
 23 *proved pursuant to such application or license may be*
 24 *made, and the drug as made with the change may be dis-*
 25 *tributed, if—*

1 “(1) the holder of the approved application or li-
2 cense (referred to in this section as a ‘holder’) has
3 validated the effects of the change in accordance with
4 subsection (b); and

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

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

11 “(b) *VALIDATION OF EFFECTS OF CHANGES.*—For
12 purposes of subsection (a)(1), a drug made with a manufac-
13 turing change (whether a major manufacturing change or
14 otherwise) may be distributed only if, before distribution
15 of the drug as so made, the holder involved validates the
16 effects of the change on the identity, strength, quality, pu-
17 rity, and potency of the drug as the identity, strength, qual-
18 ity, purity, and potency may relate to the safety, bioequiva-
19 lence, bioavailability, or effectiveness of the drug.

20 “(c) *MAJOR MANUFACTURING CHANGES.*—

21 “(1) *REQUIREMENT OF SUPPLEMENTAL APPLICA-*
22 *TION.*—For purposes of subsection (a)(2)(A), a drug
23 made with a major manufacturing change may be
24 distributed only if, before the distribution of the drug
25 as so made, the holder involved submits to the Sec-

1 *retary a supplemental application for such change*
 2 *and the Secretary approves the application. The ap-*
 3 *plication shall contain such information as the Sec-*
 4 *retary determines to be appropriate, and shall include*
 5 *the information developed under subsection (b) by the*
 6 *holder in validating the effects of the change.*

7 *“(2) CHANGES QUALIFYING AS MAJOR*
 8 *CHANGES.—For purposes of subsection (a)(2)(A), a*
 9 *major manufacturing change is a manufacturing*
 10 *change that—*

11 *“(A) is determined by the Secretary to have*
 12 *substantial potential to adversely affect the iden-*
 13 *tity, strength, quality, purity, or potency of the*
 14 *drug as they may relate to the safety, bioequiva-*
 15 *lence, bioavailability, or effectiveness of a drug;*
 16 *and*

17 *“(B)(i) is made in the qualitative or quan-*
 18 *titative formulation of the drug involved or in*
 19 *the specifications in the approved application or*
 20 *license referred to in subsection (a) for the drug*
 21 *(unless exempted by the Secretary from the re-*
 22 *quirements of this subsection);*

23 *“(ii) is determined by the Secretary by reg-*
 24 *ulation or guidance to require completion of an*
 25 *appropriate clinical study demonstrating equiva-*

1 *lence of the drug to the drug as manufactured*
2 *without the change; or*

3 *“(iii) is determined by the Secretary by reg-*
4 *ulation or guidance to have a substantial poten-*
5 *tial to adversely affect the safety or effectiveness*
6 *of the drug.*

7 *“(d) OTHER MANUFACTURING CHANGES.—*

8 *“(1) IN GENERAL.—For purposes of subsection*
9 *(a)(2)(B), the Secretary may regulate drugs made*
10 *with manufacturing changes that are not major man-*
11 *ufacturing changes as follows:*

12 *“(A) The Secretary may authorize holders*
13 *to distribute such drugs without prior approval*
14 *by the Secretary.*

15 *“(B) The Secretary may require that, prior*
16 *to the distribution of such drugs, holders submit*
17 *to the Secretary supplemental applications for*
18 *such changes.*

19 *“(C) The Secretary may establish categories*
20 *of such changes and designate categories to which*
21 *subparagraph (A) applies and categories to*
22 *which subparagraph (B) applies.*

23 *“(2) CHANGES NOT REQUIRING SUPPLEMENTAL*
24 *APPLICATION.—*

1 “(A) *SUBMISSION OF REPORT.*—A holder
2 *making a manufacturing change to which para-*
3 *graph (1)(A) applies shall submit to the Sec-*
4 *retary a report on the change, which shall con-*
5 *tain such information as the Secretary deter-*
6 *mines to be appropriate, and which shall include*
7 *the information developed under subsection (b)*
8 *by the holder in validating the effects of the*
9 *change. The report shall be submitted by such*
10 *date as the Secretary may specify.*

11 “(B) *AUTHORITY REGARDING ANNUAL RE-*
12 *PORTS.*—In the case of a holder that during a
13 *single year makes more than one manufacturing*
14 *change to which paragraph (1)(A) applies, the*
15 *Secretary may in carrying out subparagraph*
16 *(A) authorize the holder to comply with such*
17 *subparagraph by submitting a single report for*
18 *the year that provides the information required*
19 *in such subparagraph for all the changes made*
20 *by the holder during the year.*

21 “(3) *CHANGES REQUIRING SUPPLEMENTAL AP-*
22 *PLICATION.*—

23 “(A) *SUBMISSION OF SUPPLEMENTAL AP-*
24 *PLICATION.*—The supplemental application re-
25 *quired under paragraph (1)(B) for a manufac-*

1 *turing change shall contain such information as*
2 *the Secretary determines to be appropriate,*
3 *which shall include the information developed*
4 *under subsection (b) by the holder in validating*
5 *the effects of the change.*

6 *“(B) AUTHORITY FOR DISTRIBUTION.—In*
7 *the case of a manufacturing change to which*
8 *paragraph (1)(B) applies:*

9 *“(i) The holder involved may com-*
10 *mence distribution of the drug involved 30*
11 *days after the Secretary receives the supple-*
12 *mental application under such paragraph,*
13 *unless the Secretary notifies the holder with-*
14 *in such 30-day period that prior approval*
15 *of the application is required before dis-*
16 *tribution may be commenced.*

17 *“(ii) The Secretary may designate a*
18 *category of such changes for the purpose of*
19 *providing that, in the case of a change that*
20 *is in such category, the holder involved may*
21 *commence distribution of the drug involved*
22 *upon the receipt by the Secretary of a sup-*
23 *plemental application for the change.*

24 *“(iii) If the Secretary disapproves the*
25 *supplemental application, the Secretary*

1 *may order the manufacturer to cease the*
 2 *distribution of the drugs that have been*
 3 *made with the manufacturing change.”.*

4 *(b) TRANSITION RULE.—The amendment made by sub-*
 5 *section (a) takes effect upon the effective date of regulations*
 6 *promulgated by the Secretary of Health and Human Serv-*
 7 *ices to implement such amendment, or upon the expiration*
 8 *of the 24-month period beginning on the date of the enact-*
 9 *ment of this Act, whichever occurs first.*

10 **SEC. 13. STREAMLINING CLINICAL RESEARCH ON DRUGS.**

11 *Section 505(i) (21 U.S.C. 355(i)) is amended by add-*
 12 *ing “(1)” before “The Secretary”, by redesignating para-*
 13 *graphs (1), (2), and (3) as subparagraphs (A), (B), and*
 14 *(C), respectively, by striking the last two sentences, and by*
 15 *adding the following new paragraphs:*

16 *“(2) Subject to paragraph (3), a clinical investigation*
 17 *of a new drug may begin 30 days after the Secretary has*
 18 *received from the manufacturer or sponsor of the investiga-*
 19 *tion a submission containing such information about the*
 20 *drug and the clinical investigation, including—*

21 *“(A) information on design of the investigation*
 22 *and adequate reports of basic information, certified*
 23 *by the applicant to be accurate reports, necessary to*
 24 *assess the safety of the drug for use in clinical inves-*
 25 *tigation; and*

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

5 “(3)(A) At any time, the Secretary may prohibit the
6 sponsor of an investigation from conducting the investiga-
7 tion (referred to in this paragraph as a ‘clinical hold’) if
8 the Secretary makes a determination described in subpara-
9 graph (B). The Secretary shall specify the basis for the clin-
10 ical hold, including the specific information available to the
11 Secretary which served as the basis for such clinical hold,
12 and confirm such determination in writing.

13 “(B) For purposes of subparagraph (A), a determina-
14 tion described in this subparagraph with respect to a clini-
15 cal hold is that—

16 “(i) the drug involved represents an unreason-
17 able risk to the safety of the persons who are the sub-
18 ject of the clinical investigation, taking into account
19 the qualifications of the clinical investigators, infor-
20 mation about the drug, the design of the clinical in-
21 vestigation, the condition for which the drug is to be
22 investigated, and the health status of the subjects in-
23 volved; or

24 “(ii) the clinical hold should be issued for such
25 other reasons as the Secretary may by regulation es-

1 *tablish (including reasons established by regulation*
2 *before the date of the enactment of the Prescription*
3 *Drug User Fee Reauthorization and Drug Regulatory*
4 *Modernization Act of 1997).*

5 *Such regulations shall provide that such exemption shall*
6 *be conditioned upon the manufacturer, or the sponsor of the*
7 *investigation, requiring that experts using such drugs for*
8 *investigational purposes certify to such manufacturer or*
9 *sponsor that they will inform any human beings to whom*
10 *such drugs, or any controls used in connection therewith,*
11 *are being administered, or their representatives, that such*
12 *drugs are being used for investigational purposes and will*
13 *obtain the consent of such human beings or their representa-*
14 *tives, except where they deem it not feasible or, in their pro-*
15 *fessional judgment, contrary to the best interests of such*
16 *human beings. Nothing in this subsection shall be construed*
17 *to require any clinical investigator to submit directly to*
18 *the Secretary reports on the investigational use of drugs.*

19 *“(C) Any request to the Secretary from the sponsor of*
20 *an investigation that a clinical hold be removed shall re-*
21 *ceive a decision, in writing and specifying the reasons*
22 *therefor, within 30 days after receipt of such request. Any*
23 *such request shall include sufficient information to support*
24 *the removal of such clinical hold.”.*

1 **SEC. 14. DATA REQUIREMENTS FOR DRUGS.**

2 *Within 12 months after the date of enactment of this*
3 *Act, the Secretary of the Health and Human Services, act-*
4 *ing through the Commissioner of Food and Drugs, shall*
5 *issue guidance that describes, for certain types of studies,*
6 *when abbreviated study reports may be submitted, in lieu*
7 *of full reports, with a new drug application under section*
8 *505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.*
9 *355) and with a biologics license application under section*
10 *351 of the Public Health Service Act (42 U.S.C. 262). Such*
11 *guidance shall describe the kinds of studies for which abbre-*
12 *viated reports are appropriate and the appropriate abbre-*
13 *viated report formats.*

14 **SEC. 15. CONTENT AND REVIEW OF APPLICATIONS.**

15 *(a) SECTION 505(b).—Section 505(b) (21 U.S.C.*
16 *355(b)) is amended by adding at the end the following:*

17 *“(4)(A) The Secretary shall issue guidance for the re-*
18 *view of applications submitted under paragraph (1) relat-*
19 *ing to promptness, technical excellence, lack of bias and con-*
20 *flict of interest, and knowledge of regulatory and scientific*
21 *standards which shall apply equally to all individuals who*
22 *review such applications.*

23 *“(B) The Secretary shall meet with a sponsor of an*
24 *investigation or an applicant for approval under this sec-*
25 *tion or section 351 of the Public Health Service Act if the*
26 *sponsor or applicant makes a reasonable request for a meet-*

1 *ing, for the purpose of reaching agreement on the design*
2 *and size of clinical trials. Minutes of any such meeting shall*
3 *be prepared by the Secretary and made available to the*
4 *sponsor or applicant upon request.*

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

11 *“(i) with the written agreement of the sponsor or*
12 *applicant; or*

13 *“(ii) pursuant to a decision, made in accordance*
14 *with subparagraph (D) by the director of the division*
15 *in which the drug is reviewed, that a substantial sci-*
16 *entific issue essential to determining the safety or ef-*
17 *fectiveness of the drug has been identified after the*
18 *testing has begun.*

19 *“(D) A decision under subparagraph (C)(ii) by the di-*
20 *rector shall be in writing and the Secretary shall provide*
21 *to the sponsor or applicant an opportunity for a meeting*
22 *at which the director and the sponsor or applicant will be*
23 *present and at which the director documents the scientific*
24 *issue involved.*

1 “(E) *The written decisions of the reviewing division*
 2 *shall be binding upon, and may not directly or indirectly*
 3 *be changed by, the field or compliance division personnel*
 4 *unless such field or compliance division personnel dem-*
 5 *onstrate to the reviewing division why such decision should*
 6 *be modified. For purposes of this paragraph, the reviewing*
 7 *division is the division responsible for the review of an ap-*
 8 *plication for approval of a drug (including all scientific*
 9 *and medical matters, chemistry, manufacturing, and con-*
 10 *trols).*

11 “(F) *No action by the reviewing division may be de-*
 12 *layed because of the unavailability of information from or*
 13 *action by field personnel unless the reviewing division de-*
 14 *termines that a delay is necessary to assure the marketing*
 15 *of a safe and effective drug.”.*

16 (b) *SECTION 505(j).*—

17 (1) *AMENDMENT.*—*Section 505(j) (21 U.S.C*
 18 *355(j)) is amended by redesignating paragraphs (3)*
 19 *through (8) as paragraphs (4) through (9), respec-*
 20 *tively, and by adding after paragraph (2) the follow-*
 21 *ing:*

22 “(3)(A) *The Secretary shall issue guidance for the re-*
 23 *view of applications submitted under paragraph (1) relat-*
 24 *ing to promptness, technical excellence, lack of bias and con-*
 25 *flict of interest, and knowledge of regulatory and scientific*

1 *standards which shall apply equally to all individuals who*
2 *review such applications.*

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

10 “(C) *Agreements regarding the parameters of design*
11 *and size of bioavailability and bioequivalence trials of a*
12 *drug under this subsection that are reached between the Sec-*
13 *retary and a sponsor or applicant shall be reduced to writ-*
14 *ing and made part of the administrative record by the Sec-*
15 *retary. Such agreement shall not be changed after the test-*
16 *ing begins, except—*

17 “(i) *with the written agreement of the sponsor or*
18 *applicant; or*

19 “(ii) *pursuant to a decision, made in accordance*
20 *with subparagraph (D) by the director of the division*
21 *in which the drug is reviewed, that a substantial sci-*
22 *entific issue essential to determining the safety or ef-*
23 *fectiveness of the drug has been identified after the*
24 *testing has begun.*

1 “(D) A decision under subparagraph (C)(ii) by the di-
2 rector shall be in writing and the Secretary shall provide
3 to the sponsor or applicant an opportunity for a meeting
4 at which the director and the sponsor or applicant will be
5 present and at which the director documents the scientific
6 issue involved.

7 “(E) The written decisions of the reviewing division
8 shall be binding upon, and may not directly or indirectly
9 be changed by, the field or compliance office personnel un-
10 less such field or compliance office personnel demonstrate
11 to the reviewing division why such decision should be modi-
12 fied. For purposes of this paragraph, the reviewing division
13 is the division responsible for the review of an application
14 under this subsection (including scientific matters, chem-
15 istry, manufacturing, and controls).

16 “(F) No action by the reviewing division may at any
17 time be delayed because of the unavailability of information
18 from or action by field personnel unless the reviewing divi-
19 sion determines that a delay is necessary to assure the mar-
20 keting of a safe and effective drug.”.

21 (2) CONFORMING AMENDMENTS.—Section 505(j)
22 (21 U.S.C. 355(j)), as amended by paragraph (1), is
23 amended—

24 (A) in paragraph (2)(A)(i), by striking
25 “(6)” and inserting “(7)”;

1 (B) in paragraph (4), by striking “(4)” and
2 inserting “(5)”;

3 (C) in paragraph (4)(I), by striking “(5)”
4 and inserting “(6)”;

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

7 **SEC. 16. SCIENTIFIC ADVISORY PANELS.**

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

10 “(n)(1) For the purpose of providing expert scientific
11 advice and recommendations to the Secretary regarding a
12 clinical investigation of a drug or the approval for market-
13 ing of a drug under section 505 or section 351 of the Public
14 Health Service Act, the Secretary shall establish panels of
15 experts or use panels of experts established before the date
16 of the enactment of this subsection, or both.

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

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

24 “(A) members who are qualified by training and
25 experience to evaluate the safety and effectiveness of

1 *the drugs to be referred to the panel and who, to the*
2 *extent feasible, possess skill and experience in the de-*
3 *velopment, manufacture, or utilization of such drugs;*

4 *“(B) members with diverse expertise in such*
5 *fields as clinical and administrative medicine, phar-*
6 *macy, pharmacology, pharmacoeconomics, biological*
7 *and physical sciences, and other related professions;*

8 *“(C) a representative of consumer interests and*
9 *a representative of interests of the drug manufactur-*
10 *ing industry not directly affected by the matter to be*
11 *brought before the panel; and*

12 *“(D) 2 or more members who are specialists or*
13 *have other expertise in the particular disease or con-*
14 *dition for which the drug under review is proposed to*
15 *be indicated.*

16 *Scientific, trade, and consumer organizations shall be af-*
17 *forded an opportunity to nominate individuals for appoint-*
18 *ment to the panels. No individual who is in the regular*
19 *full-time employ of the United States and engaged in the*
20 *administration of this Act may be a voting member of any*
21 *panel. The Secretary shall designate one of the members of*
22 *each panel to serve as chairman thereof.*

23 *“(4) Each member of a panel shall publicly disclose*
24 *all conflicts of interest that member may have with the work*
25 *to be undertaken by the panel. No member of a panel may*

1 *vote on any matter where the member or the immediate*
2 *family of such member could gain financially from the ad-*
3 *vice given to the Secretary. The Secretary may grant a*
4 *waiver of any conflict of interest upon public disclosure of*
5 *such conflict of interest if such waiver is necessary to afford*
6 *the panel essential expertise, except that the Secretary may*
7 *not grant a waiver for a member of a panel when the mem-*
8 *ber's own scientific work is involved.*

9 “(5) *The Secretary shall provide education and train-*
10 *ing to each new panel member before such member partici-*
11 *pates in a panel's activities, including education regarding*
12 *requirements under this Act and related regulations of the*
13 *Secretary, and the administrative processes and procedures*
14 *related to panel meetings.*

15 “(6) *Panel members (other than officers or employees*
16 *of the United States), while attending meetings or con-*
17 *ferences of a panel or otherwise engaged in its business,*
18 *shall be entitled to receive compensation for each day so*
19 *engaged, including traveltime, at rates to be fixed by the*
20 *Secretary, but not to exceed the daily equivalent of the rate*
21 *in effect for positions classified above grade GS-15 of the*
22 *General Schedule. While serving away from their homes or*
23 *regular places of business, panel members may be allowed*
24 *travel expenses (including per diem in lieu of subsistence)*
25 *as authorized by section 5703 of title 5, United States Code,*

1 *for persons in the Government service employed intermit-*
 2 *tently.*

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

9 “(8) *Within 60 days after a scientific advisory panel*
 10 *makes recommendations on any matter under its review,*
 11 *the Food and Drug Administration official responsible for*
 12 *the matter shall review the conclusions and recommenda-*
 13 *tions of the panel, and notify the affected persons of the*
 14 *final decision on the matter, or of the reasons that no such*
 15 *decision has been reached. Each such final decision shall*
 16 *be documented including the rationale for the decision.*

17 “(9) *A scientific advisory panel under this subsection*
 18 *shall not be subject to the annual chartering and annual*
 19 *report requirements of the Federal Advisory Committee*
 20 *Act.”.*

21 **SEC. 17. DISPUTE RESOLUTION.**

22 *Chapter V (21 U.S.C. 351 et seq.), as amended by sec-*
 23 *tion 3, is amended by inserting after section 505A the fol-*
 24 *lowing:*

1 “DISPUTE RESOLUTION

2 “SEC. 506. *If, regarding an obligation under this Act,*
3 *there is a scientific controversy between the Secretary and*
4 *a person who is a sponsor, applicant, or manufacturer and*
5 *no specific provision of this Act or regulation promulgated*
6 *under this Act provides a right of review of the matter in*
7 *controversy, the Secretary shall, by regulation, establish a*
8 *procedure under which such sponsor, applicant, or manu-*
9 *facturer may request a review of such controversy by an*
10 *appropriate scientific advisory panel under section 505(n).*
11 *Such review shall take place in a timely manner. The Sec-*
12 *retary shall promulgate such regulations within 180 days*
13 *of the date of the enactment of the Prescription Drug User*
14 *Fee Reauthorization and Medical Device Regulatory Mod-*
15 *ernization Act of 1997.”.*

16 **SEC. 18. INFORMAL AGENCY STATEMENTS.**

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

19 “(h)(1)(A) *The Secretary shall develop guidance docu-*
20 *ments with public participation and ensure that the exist-*
21 *ence of such documents and the documents themselves are*
22 *made available to the public both in written form and*
23 *through electronic means. Such documents shall not create*
24 *or confer any rights for or on any person, although they*

1 *present the views of the Secretary on matters under the ju-*
2 *risdiction of the Food and Drug Administration.*

3 “(B) *Although guidance documents shall not be bind-*
4 *ing on the Secretary, the Secretary shall ensure that em-*
5 *ployees of the Food and Drug Administration do not deviate*
6 *from such guidances without appropriate justification and*
7 *supervisory concurrence.*

8 “(C) *For guidance documents that set forth initial in-*
9 *terpretations of statute or regulation, changes in interpreta-*
10 *tion or policy that are of more than a minor nature, com-*
11 *plex scientific issues, or highly controversial issues, the Sec-*
12 *retary shall ensure public participation prior to implemen-*
13 *tation of any guidance documents, unless the Secretary de-*
14 *termines that for reasons of the public health need, such*
15 *prior public participation is not feasible. In such cases, the*
16 *Secretary shall provide for public comment upon implemen-*
17 *tation, and take such comment into account.*

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

21 “(2) *In developing guidance documents, the Secretary*
22 *shall ensure uniform nomenclature and uniform internal*
23 *procedures for approval of such documents. The Secretary*
24 *shall ensure that guidance documents and revisions of such*

1 *documents are properly dated and indicate the nonbinding*
 2 *nature of the documents.*

3 “(3) *The Secretary, through the Food and Drug Ad-*
 4 *ministration, shall maintain electronically and publish pe-*
 5 *riodically in the Federal Register a list of guidance docu-*
 6 *ments. Such list shall be updated quarterly. All such docu-*
 7 *ments shall be made available to the public.*

8 “(4) *The Secretary shall report to the Committee on*
 9 *Commerce of the House of Representatives and the Commit-*
 10 *tee on Labor and Human Resources of the Senate no later*
 11 *than July 1, 2000, on the implementation of these prac-*
 12 *tices.*”.

13 **SEC. 19. POSITRON EMISSION TOMOGRAPHY.**

14 (a) *REGULATION OF COMPOUNDED POSITRON EMIS-*
 15 *SION TOMOGRAPHY DRUGS.—*

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

18 “(ii) *The term ‘compounded positron emission tomog-*
 19 *raphy drug’—*

20 “(1) *means a drug that—*

21 “(A) *exhibits spontaneous disintegration of*
 22 *unstable nuclei by the emission of positrons and*
 23 *is used for the purpose of providing dual photon*
 24 *positron emission tomographic diagnostic im-*
 25 *ages; and*

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

8 “(2) includes any nonradioactive reagent, rea-
 9 gent kit, ingredient, nuclide generator, accelerator,
 10 target material, electronic synthesizer, or other appa-
 11 ratus or computer program to be used in the prepara-
 12 tion of such a drug.”.

13 (b) ADULTERATION.—

14 (1) IN GENERAL.—Section 501(a)(2) (21 U.S.C.
 15 351(a)(2)) is amended by striking “; or (3)” and in-
 16 serting the following: “; or (C) if it is a compounded
 17 positron emission tomography drug and the methods
 18 used in, or the facilities and controls used for, its
 19 compounding, processing, packing, or holding do not
 20 conform to or are not operated or administered in
 21 conformity with the positron emission tomography
 22 compounding standards and the official monographs
 23 of the United States Pharmacopeia to assure that
 24 such drug meets the requirements of this Act as to
 25 safety and has the identity and strength, and meets

1 *the quality and purity characteristics, that it*
 2 *purports or is represented to possess; or (3)’’.*

3 (2) *SUNSET.—Section 501(a)(2)(C) of the Fed-*
 4 *eral Food, Drug, and Cosmetic Act (21 U.S.C.*
 5 *351(a)(2)(C)) shall not apply 4 years after the date*
 6 *of enactment of this Act or 2 years after the date on*
 7 *which the Secretary of Health and Human Services*
 8 *establishes the requirements described in subsection*
 9 *(c)(1)(B), whichever is later.*

10 (c) *REQUIREMENTS FOR REVIEW OF APPROVAL PRO-*
 11 *CEDURES AND CURRENT GOOD MANUFACTURING PRAC-*
 12 *TICES FOR POSITRON EMISSION TOMOGRAPHY.—*

13 (1) *PROCEDURES AND REQUIREMENTS.—*

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

21 (i) *appropriate procedures for the ap-*
 22 *proval of compounded positron emission to-*
 23 *mography drugs pursuant to section 505 of*
 24 *the Federal Food, Drug, and Cosmetic Act*
 25 *(21 U.S.C. 355); and*

1 (ii) appropriate current good manufac-
2 turing practice requirements for such drugs.

3 (B) CONSIDERATIONS AND CONSULTA-
4 TION.—In establishing the procedures and re-
5 quirements required by subparagraph (A), the
6 Secretary of Health and Human Services shall
7 take due account of any relevant differences be-
8 tween not-for-profit institutions that compound
9 the drugs for their patients and commercial
10 manufacturers of the drugs. Prior to establishing
11 the procedures and requirements, the Secretary of
12 Health and Human Services shall consult with
13 patient advocacy groups, professional associa-
14 tions, manufacturers, and physicians and sci-
15 entists licensed to make or use compounded
16 positron emission tomography drugs.

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

19 (A) IN GENERAL.—Except as provided in
20 subparagraph (B), the Secretary of Health and
21 Human Services shall not require the submission
22 of new drug applications or abbreviated new
23 drug applications under subsection (b) or (j) of
24 section 505 (21 U.S.C. 355), for compounded
25 positron emission tomography drugs that are not

1 *adulterated drugs described in section*
2 *501(a)(2)(C) of the Federal Food, Drug, and*
3 *Cosmetic Act (21 U.S.C. 351(a)(2)(C)) (as*
4 *amended by subsection (b)), for a period of 4*
5 *years after the date of enactment of this Act, or*
6 *for 2 years after the date on which the Secretary*
7 *establishes procedures and requirements under*
8 *paragraph (1), whichever is later.*

9 *(B) EXCEPTION.—Nothing in this Act shall*
10 *prohibit the voluntary submission of such appli-*
11 *cations or the review of such applications by the*
12 *Secretary of Health and Human Services. Noth-*
13 *ing in this Act shall constitute an exemption for*
14 *a compounded positron emission tomography*
15 *drug from the requirements of regulations issued*
16 *under section 505(i) of the Federal Food, Drug,*
17 *and Cosmetic Act (21 U.S.C. 355(i)) for such*
18 *drugs.*

19 *(d) REVOCATION OF CERTAIN INCONSISTENT DOCU-*
20 *MENTS.—Within 30 days after the date of enactment of this*
21 *Act, the Secretary of Health and Human Services shall pub-*
22 *lish in the Federal Register a notice terminating the appli-*
23 *cation of the following notices and rule, to the extent the*
24 *notices and rule relate to compounded positron emission to-*
25 *mography drugs:*

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

5 (2) *A notice entitled “Guidance for Industry:*
 6 *Current Good Manufacturing Practices for Positron*
 7 *Emission Tomographic (PET) Drug Products; Avail-*
 8 *ability”, published in the Federal Register on April*
 9 *22, 1997.*

10 (3) *A final rule entitled “Current Good Manu-*
 11 *facturing Practice for Finished Pharmaceuticals;*
 12 *Positron Emission Tomography”, published in the*
 13 *Federal Register on April 22, 1997.*

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

18 **SEC. 20. REQUIREMENTS FOR RADIOPHARMACEUTICALS.**

19 (a) *REQUIREMENTS.—*

20 (1) *REGULATIONS.—*

21 (A) *PROPOSED REGULATIONS.—Not later*
 22 *than 180 days after the date of enactment of this*
 23 *Act, the Secretary of Health and Human Serv-*
 24 *ices, after consultation with patient advocacy*
 25 *groups, associations, physicians licensed to use*

1 *radiopharmaceuticals, and the regulated indus-*
2 *try, shall issue proposed regulations governing*
3 *the approval of radiopharmaceuticals designed*
4 *for diagnosis and monitoring of diseases and*
5 *conditions. The regulations shall provide that the*
6 *determination of the safety and effectiveness of*
7 *such a radiopharmaceutical under section 505 of*
8 *the Federal Food, Drug, and Cosmetic Act (21*
9 *U.S.C. 355) or section 351 of the Public Health*
10 *Service Act (42 U.S.C. 262) shall include consid-*
11 *eration of the proposed use of the*
12 *radiopharmaceutical in the practice of medicine,*
13 *the pharmacological and toxicological activity of*
14 *the radiopharmaceutical (including any carrier*
15 *or ligand component of the*
16 *radiopharmaceutical), and the estimated ab-*
17 *sorbed radiation dose of the*
18 *radiopharmaceutical.*

19 *(B) FINAL REGULATIONS.—Not later than*
20 *18 months after the date of enactment of this*
21 *Act, the Secretary shall promulgate final regula-*
22 *tions governing the approval of the*
23 *radiopharmaceuticals.*

24 *(2) SPECIAL RULE.—In the case of a*
25 *radiopharmaceutical intended to be used for diag-*

1 *nostic or monitoring purposes, the indications for*
2 *which such radiopharmaceutical is approved for mar-*
3 *keting may, in appropriate cases, refer to manifesta-*
4 *tions of disease (such as biochemical, physiological,*
5 *anatomic, or pathological processes) common to, or*
6 *present in, one or more disease states.*

7 (b) *DEFINITION.—In this section, the term*
8 *“radiopharmaceutical” means—*

9 (1) *an article—*

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

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

16 (2) *any nonradioactive reagent kit or nuclide*
17 *generator that is intended to be used in the prepara-*
18 *tion of any such article.*

19 **SEC. 21. MODERNIZATION OF REGULATION.**

20 (a) *LICENSES.—*

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

1 “(a)(1) No person shall introduce or deliver for intro-
2 duction into interstate commerce any biological product un-
3 less—

4 “(A) a biologics license is in effect for the biologi-
5 cal product; and

6 “(B) each package of the biological product is
7 plainly marked with—

8 “(i) the proper name of the biological prod-
9 uct contained in the package;

10 “(ii) the name, address, and applicable li-
11 cense number of the manufacturer of the biologi-
12 cal product; and

13 “(iii) the expiration date of the biological
14 product.

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

18 “(B) The Secretary shall approve a biologics license
19 application—

20 “(i) on the basis of a demonstration that—

21 “(I) the biological product that is the sub-
22 ject of the application is safe, pure, and potent;
23 and

24 “(II) the facility in which the biological
25 product is manufactured, processed, packed, or

1 *held meets standards designed to assure that the*
 2 *biological product continues to be safe, pure, and*
 3 *potent; and*

4 “(ii) if the applicant (or other appropriate per-
 5 son) consents to the inspection of the facility that is
 6 the subject of the application, in accordance with sub-
 7 section (c).

8 “(3) The Secretary shall prescribe requirements under
 9 which a biological product undergoing investigation shall
 10 be exempt from the requirements of paragraph (1).”.

11 (2) *ELIMINATION OF EXISTING LICENSE RE-*
 12 *QUIREMENT.—Section 351(d) of the Public Health*
 13 *Service Act (42 U.S.C. 262(d)) is amended—*

14 (A) by striking “(d)(1)” and all that follows
 15 through “of this section.”;

16 (B) in paragraph (2)—

17 (i) by striking “(2)(A) Upon” and in-
 18 serting “(d)(1) Upon” and

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

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

23 (i) by striking “subparagraph (A)”
 24 and inserting “paragraph (1)”; and

1 (ii) by striking “this subparagraph”
2 each place it appears and inserting “this
3 paragraph”.

4 (b) *LABELING*.—Section 351(b) of the Public Health
5 Service Act (42 U.S.C. 262(b)) is amended to read as fol-
6 lows:

7 “(b) No person shall falsely label or mark any package
8 or container of any biological product or alter any label
9 or mark on the package or container of the biological prod-
10 uct so as to falsify the label or mark.”.

11 (c) *INSPECTION*.—Section 351(c) of the Public Health
12 Service Act (42 U.S.C. 262(c)) is amended by striking
13 “virus, serum,” and all that follows and inserting “biologi-
14 cal product.”.

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

18 “(i) In this section, the term ‘biological product’ means
19 a virus, therapeutic serum, toxin, antitoxin, vaccine, blood,
20 blood component or derivative, allergenic product, or analo-
21 gous product, or arsphenamine or derivative of arsphen-
22 amine (or any other trivalent organic arsenic compound),
23 applicable to the prevention, treatment, or cure of a disease
24 or condition of human beings.”.

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

3 (1) in subparagraph (A)—

4 (A) by striking “section 351(a)” and insert-
5 ing “section 351(i)”; and

6 (B) by striking “262(a)” and inserting
7 “262(i)”; and

8 (2) in subparagraph (B)(iii), by striking “prod-
9 uct or establishment license under subsection (a) or
10 (d)” and inserting “biologics license application
11 under subsection (a)”.

12 (f) *SPECIAL RULE.*—The Secretary of Health and
13 Human Services shall take measures to minimize dif-
14 ferences in the review and approval of products required
15 to have approved biologics license applications under sec-
16 tion 351 of the Public Health Service Act (42 U.S.C. 262)
17 and products required to have approved new drug applica-
18 tions under section 505(b)(1) of the Federal Food, Drug,
19 and Cosmetic Act (21 U.S.C. 355(b)(1)).

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

23 “(3) *EXAMINATIONS AND PROCEDURES.*—The ex-
24 aminations and procedures identified in paragraph
25 (2) are laboratory examinations and procedures

1 *which have been approved by the Food and Drug Ad-*
 2 *ministration for home use or which, as determined by*
 3 *the Secretary, are simple laboratory examinations*
 4 *and procedures which have an insignificant risk of an*
 5 *erroneous result, including those which—*

6 “(A) *employ methodologies that are so sim-*
 7 *ple and accurate as to render the likelihood of er-*
 8 *roneous results by the user negligible, or*

9 “(B) *the Secretary has determined pose no*
 10 *reasonable risk of harm to the patient if per-*
 11 *formed incorrectly.”.*

12 **SEC. 22. PILOT AND SMALL SCALE MANUFACTURE.**

13 (a) *HUMAN DRUGS.—Section 505(c) (21 U.S.C.*
 14 *355(c)) is amended by adding at the end thereof the follow-*
 15 *ing:*

16 “(4) *A drug manufactured in a pilot or other small*
 17 *facility may be used to demonstrate the safety and effective-*
 18 *ness of the drug and to obtain approval prior to scaling*
 19 *up to a larger facility, unless the Secretary makes a deter-*
 20 *mination that a full scale production facility is necessary*
 21 *to ensure the safety or effectiveness of the drug.”.*

22 (b) *ANIMAL DRUGS.—Section 512(c) (21 U.S.C.*
 23 *360b(c)) is amended by adding at the end the following:*

24 “(4) *A drug manufactured in a pilot or other small*
 25 *facility may be used to demonstrate the safety and effective-*

ness 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. 23. 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

1 *end of subparagraph (B), by striking “; or” at*
 2 *the end of subparagraph (C) and inserting a pe-*
 3 *riod, and by striking subparagraph (D).*

4 ***(b) CERTIFICATION OF ANTIBIOTICS.—***

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

7 ***(2) CONFORMING AMENDMENTS.—***

8 ***(A)*** *Section 201(aa) (21 U.S.C. 321(aa)) is*
 9 *amended by striking out “or 507”, section*
 10 *201(dd) (21 U.S.C. 321(dd)) is amended by*
 11 *striking “507,”, and section 201(ff)(3)(A) (21*
 12 *U.S.C. 321(ff)(3)(A)) is amended by striking “,*
 13 *certified as an antibiotic under section 507,”.*

14 ***(B)*** *Section 301(e) (21 U.S.C. 331(e)) is*
 15 *amended by striking “507(d) or (g),”.*

16 ***(C)*** *Section 306(d)(4)(B)(ii) (21 U.S.C.*
 17 *335a(d)(4)(B)(ii)) is amended by striking “or*
 18 *507”.*

19 ***(D)*** *Section 502 (21 U.S.C. 352) is amend-*
 20 *ed by striking subsection (l).*

21 ***(E)*** *Section 520(l) (21 U.S.C. 360j(l)) is*
 22 *amended by striking paragraph (4) and by strik-*
 23 *ing “or Antibiotic Drugs” in the subsection*
 24 *heading.*

1 (F) Section 525(a) (21 U.S.C. 360aa(a)) is
2 amended by inserting “or” at the end of para-
3 graph (1), by striking paragraph (2), and by re-
4 designating paragraph (3) as paragraph (2).

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

8 (H) Section 526(a)(1) (21 U.S.C. 360bb) is
9 amended by striking “the submission of an ap-
10 plication for certification of the drug under sec-
11 tion 507,” by inserting “or” at the end of sub-
12 paragraph (A), by striking subparagraph (B),
13 and by redesignating subparagraph (C) as sub-
14 paragraph (B).

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

17 (i) in paragraph (1), by striking “, a
18 certificate was issued for the drug under
19 section 507,”; and

20 (ii) in paragraph (2) by striking “, a
21 certificate has not been issued for the drug
22 under section 507,” and by striking “, ap-
23 proval of an application for certification
24 under section 507,”.

1 (J) Section 527(a) (21 U.S.C. 360cc(a)) is
2 amended by inserting “or” at the end of para-
3 graph (1), by striking paragraph (2), by redesign-
4 ating paragraph (3) as paragraph (2), and by
5 striking “, issue another certificate under section
6 507,”.

7 (K) Section 527(b) (21 U.S.C. 360cc(b)) is
8 amended by striking “, if a certification is is-
9 sued under section 507 for such a drug, or”, “of
10 the issuance of the certification under section
11 507,” and “issue another certification under sec-
12 tion 507, or”.

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

15 (M) Section 735(1) (21 U.S.C. 379g(1)(C))
16 is amended by inserting “or” at the end of sub-
17 paragraph (B), by striking subparagraph (C),
18 and by redesignating subparagraph (D) as sub-
19 paragraph (C).

20 (N) Subparagraphs (A)(ii) and (B) of sec-
21 tions 5(b)(1) of the Orphan Drug Act (21 U.S.C.
22 360ee(b)(1)(A), 360ee(b)(1)(B)) are each amend-
23 ed by striking “or 507”.

1 (O) Section 45C(b)(2)(A)(ii)(II) of the In-
2 ternal Revenue Code of 1986 is amended by
3 striking “or 507”.

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

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

9 “(i) Insulin and antibiotics may be exported without
10 regard to the requirements in this section if the insulin and
11 antibiotics meet the requirements of section 801(e)(1).”.

12 (d) APPLICATION.—An antibiotic drug which was cer-
13 tified or exempted from certification under section 507 of
14 the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357)
15 before the date of the enactment of this Act shall, after such
16 date, be considered to be a drug for which an application
17 was filed under section 505(b) of such Act (21 U.S.C.
18 355(b)), and approved for safety and effectiveness under sec-
19 tion 505(c) of such Act (21 U.S.C. 355(c)), except that if
20 such antibiotic drug was approved under an abbreviated
21 application under such section 507, such drug shall be con-
22 sidered to have been approved under section 505(j) of such
23 Act.

24 (e) EFFECT.—In the application of section 505 of the
25 Federal Food, Drug, and Cosmetic Act after the date of en-

1 *actment of this Act to a drug that contains an active ingre-*
 2 *dient (including any ester or salt of the active ingredient)*
 3 *that was an antibiotic drug within the meaning of section*
 4 *507 of such Act and was the subject of an approved or pend-*
 5 *ing application for marketing approval (exemption from*
 6 *certification) before the date of the enactment of such Act,*
 7 *none of the patent or market exclusivity provisions of sec-*
 8 *tion 505 shall apply to such a drug.*

9 **SEC. 24. FDA MISSION AND ANNUAL REPORT.**

10 *(a) MISSION.—Section 903 (21 U.S.C. 393) is amend-*
 11 *ed by redesignating subsections (b) and (c) as subsections*
 12 *(c) and (d), respectively, and by adding after subsection (a)*
 13 *the following:*

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

20 *“(1) foods are safe, wholesome, sanitary, and*
 21 *properly labeled;*

22 *“(2) human and veterinary drugs are safe and*
 23 *effective;*

24 *“(3) there is reasonable assurance of safety and*
 25 *effectiveness of devices intended for human use;*

1 “(4) cosmetics are safe and properly labeled; and
 2 “(5) public health and safety are protected from
 3 *electronic product radiation.*

4 *The Food and Drug Administration shall participate with*
 5 *other countries to reduce the burden of regulation, har-*
 6 *monize regulatory requirements, and achieve appropriate*
 7 *reciprocal arrangements.”.*

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

11 “(e) *ANNUAL REPORT.*—*The Secretary shall, simulta-*
 12 *neously with the submission each year of the budget for the*
 13 *Food and Drug Administration, submit to the Committee*
 14 *on Commerce of the House of Representatives and the Com-*
 15 *mittee on Labor and Human Resources of the Senate an*
 16 *annual report which shall—*

17 “(1) *review the performance of the Food and*
 18 *Drug Administration in meeting its mission and the*
 19 *development of Food and Drug Administration poli-*
 20 *cies to implement such mission;*

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

1 “(3) describe the staffing and resources of the
2 *Food and Drug Administration; and*

3 “(4)(A) list each bilateral and multinational
4 *meeting held by the Food and Drug Administration*
5 *to address methods and approaches to reduce the bur-*
6 *den of regulation, to harmonize regulation, and to*
7 *seek appropriate reciprocal arrangements, (B) de-*
8 *scribe the goals, activities, and accomplishments of the*
9 *Food and Drug Administration in such meetings, and*
10 *(C) list issues that the Food and Drug Administra-*
11 *tion is considering or has presented for each such*
12 *meeting.”.*

13 **SEC. 25. INFORMATION SYSTEM.**

14 *Chapter IX is amended by adding at the end the fol-*
15 *lowing section:*

16 **“SEC. 906. INFORMATION SYSTEM.**

17 *“The Secretary shall establish and maintain an infor-*
18 *mation system to track the status and progress of each ap-*
19 *plication or submission (including a petition, notification,*
20 *or other similar form of request) submitted to the Food and*
21 *Drug Administration requesting agency action.”.*

22 **SEC. 26. EDUCATION AND TRAINING.**

23 *Chapter IX, as amended by section 25, is amended by*
24 *adding at the end the following sections:*

1 **“SEC. 907. EDUCATION.**

2 *“The Secretary shall conduct training and education*
 3 *programs for the employees of the Food and Drug Adminis-*
 4 *tration relating to the regulatory responsibilities and poli-*
 5 *cies established by this Act, including programs for sci-*
 6 *entific training and training in administrative process and*
 7 *procedure and integrity issues.”.*

8 **SEC. 27. CENTERS FOR EDUCATION AND RESEARCH ON**
 9 **DRUGS.**

10 *Chapter IX, as amended by section 26, is amended by*
 11 *adding at the end the following section:*

12 **“SEC. 908. DEMONSTRATION PROGRAM REGARDING CEN-**
 13 **TERS FOR EDUCATION AND RESEARCH ON**
 14 **DRUGS.**

15 *“(a) IN GENERAL.—The Secretary, acting through the*
 16 *Commissioner of Food and Drugs, shall establish a dem-*
 17 *onstration program for the purpose of making one or more*
 18 *grants for the establishment and operation of one or more*
 19 *centers to carry out the activities specified in subsection (b).*

20 *“(b) REQUIRED ACTIVITIES.—The activities referred to*
 21 *in subsection (a) are the following:*

22 *“(1) The conduct of state-of-the-art clinical and*
 23 *laboratory research for the following purposes:*

24 *“(A) To increase awareness of new uses of*
 25 *drugs and the unforeseen risks of new uses of*
 26 *drugs.*

1 “(B) *To provide objective clinical informa-*
2 *tion to the following entities:*

3 “(i) *Health care practitioners or other*
4 *providers of health care goods or services.*

5 “(ii) *Pharmacy benefit managers.*

6 “(iii) *Health maintenance organiza-*
7 *tions or other managed health care organi-*
8 *zations.*

9 “(iv) *Health care insurers or govern-*
10 *mental agencies.*

11 “(C) *To improve the quality of health care*
12 *while reducing the cost of health care through the*
13 *prevention of adverse effects of drugs and the*
14 *consequences of such effects, such as unnecessary*
15 *hospitalizations.*

16 “(2) *The conduct of research on the comparative*
17 *effectiveness and safety of drugs.*

18 “(3) *Such other activities as the Secretary deter-*
19 *mines to be appropriate, except that the grant may*
20 *not be expended to assist the Secretary in the review*
21 *of new drugs.*

22 “(c) *APPLICATION FOR GRANT.—A grant under sub-*
23 *section (a) may be made only if an application for the*
24 *grant is submitted to the Secretary and the application is*
25 *in such form, is made in such manner, and contains such*

1 *agreements, assurances, and information as the Secretary*
2 *determines to be necessary to carry out this section.*

3 “(d) *PEER REVIEW.—A grant under subsection (a)*
4 *may be made only if the application for the grant has un-*
5 *dergone appropriate technical and scientific peer review.*

6 “(e) *AUTHORIZATION OF APPROPRIATIONS.—For the*
7 *purpose of carrying out this section, there are authorized*
8 *to be appropriated \$2,000,000 for fiscal year 1998, and*
9 *\$3,000,000 for fiscal year 1999.”.*

10 **SEC. 28. HARMONIZATION.**

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

13 “(c) *The Secretary shall participate in meetings with*
14 *representatives of other countries to discuss methods and*
15 *approaches to reduce the burden of regulation and har-*
16 *monize regulatory requirements if the Secretary determines*
17 *that such harmonization continues consumer protections*
18 *consistent with the purposes of this Act. The Secretary shall*
19 *report to the Committee on Commerce of the House of Rep-*
20 *resentatives and the Committee on Labor and Human Re-*
21 *sources of the Senate at least 60 days before executing any*
22 *bilateral or multilateral agreement under subsection (b).”.*

23 **SEC. 29. ENVIRONMENTAL IMPACT REVIEW.**

24 *Chapter VII, as amended by section 12, is amended*
25 *by adding at the end the following:*

1 “SUBCHAPTER G—ENVIRONMENTAL IMPACT REVIEW

2 **“SEC. 761. ENVIRONMENTAL IMPACT REVIEW.**

3 *“Notwithstanding any other provision of law, an envi-*
 4 *ronmental impact statement prepared in accordance with*
 5 *the regulations published at part 25 of 21 C.F.R. (as in*
 6 *effect on August 31, 1997) in connection with an action*
 7 *carried out under (or a recommendation or report relating*
 8 *to) this Act, shall be considered to meet the requirements*
 9 *for a detailed statement under section 102(2)(C) of the Na-*
 10 *tional Environmental Policy Act.”.*

11 **SEC. 30. NATIONAL UNIFORMITY.**

12 *(a) NONPRESCRIPTION DRUGS.—Chapter VII (21*
 13 *U.S.C. 371 et seq.), as amended by section 29, is further*
 14 *amended by adding at the end the following:*

15 “SUBCHAPTER H—NATIONAL UNIFORMITY FOR NON-
 16 PRESCRIPTION DRUGS FOR HUMAN USE AND PRE-
 17 EMPTION FOR LABELING OR PACKAGING OF COSMET-
 18 ICS

19 **“SEC. 771. NATIONAL UNIFORMITY FOR NONPRESCRIPTION**
 20 **DRUGS FOR HUMAN USE.**

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

1 “(1) that relates to the regulation of a drug in-
2 tended for human use that is not subject to the re-
3 quirements of section 503(b)(1); and

4 “(2) that is different from or in addition to, or
5 that is otherwise not identical with, a requirement
6 under this Act, the Poison Prevention Packaging Act
7 of 1970 (15 U.S.C. 1471 et seq.), or the Fair Packag-
8 ing and Labeling Act (15 U.S.C. 1451 et seq.).

9 “(b) EXEMPTION.—Upon application of a State or po-
10 litical subdivision thereof, the Secretary may by regulation,
11 after notice and opportunity for written and oral presen-
12 tation of views, exempt from subsection (a), under such con-
13 ditions as may be prescribed in such regulation, a State
14 or political subdivision requirement that—

15 “(1) protects an important public interest that
16 would otherwise be unprotected;

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

20 “(3) would not unduly burden interstate com-
21 merce.

22 “(c) SCOPE.—

23 “(1) IN GENERAL.—This section shall not apply
24 to—

1 “(A) any State or political subdivision re-
2 quirement that relates to the practice of phar-
3 macy; or

4 “(B) any State or political subdivision re-
5 quirement that a drug be dispensed only upon
6 the prescription of a practitioner licensed by law
7 to administer such drug.

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

14 “(d) EXCEPTIONS.—

15 “(1) IN GENERAL.—In the case of a drug de-
16 scribed in subsection (a)(1) that is not the subject of
17 an application approved under section 505 or 507 or
18 a final regulation promulgated by the Secretary es-
19 tablishing conditions under which the drug is gen-
20 erally recognized as safe and effective and not mis-
21 branded, subsection (a) shall apply only with respect
22 to a requirement of a State or political subdivision of
23 a State that relates to the same subject as, but is dif-
24 ferent from or in addition to, or that is otherwise not
25 identical with—

1 “(A) a regulation in effect with respect to
2 the drug pursuant to a statute described in sub-
3 section (a)(2); or

4 “(B) any other requirement in effect with
5 respect to the drug pursuant to an amendment
6 to such a statute made on or after the date of en-
7 actment of this section.

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

11 “(e) *NO EFFECT ON PRODUCT LIABILITY LAW.*—Noth-
12 ing in this section shall be construed to modify or otherwise
13 affect any action or the liability of any person under the
14 product liability law of any State.

15 “(f) *STATE ENFORCEMENT AUTHORITY.*—Nothing in
16 this section shall prevent a State or political subdivision
17 thereof from enforcing, under any relevant civil or other en-
18 forcement authority, a requirement that is identical to a
19 requirement of this Act.”.

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

24 (c) *MISBRANDING.*—Paragraph (1) of section 502(e)
25 (21 U.S.C. 352(e)(1)) is amended to read as follows:

1 “(1)(A) If it is a drug, unless its label bears, to the
2 exclusion of any other nonproprietary name (except the ap-
3 plicable systematic chemical name or the chemical for-
4 mula)—

5 “(i) the established name (as defined in subpara-
6 graph (3)) of the drug, if there is such a name;

7 “(ii) the established name and quantity or, if
8 deemed appropriate by the Secretary, the proportion
9 of each active ingredient, including the quantity,
10 kind, and proportion of any alcohol, and also includ-
11 ing whether active or not the established name and
12 quantity or if deemed appropriate by the Secretary,
13 the proportion of any bromides, ether, chloroform, ac-
14 etanilide, acetophenetidin, amidopyrine, antipyrine,
15 atropine, hyoscine, hyoscyamine, arsenic, digitalis,
16 digitalis glucosides, mercury, ouabain, strophanthin,
17 strychnine, thyroid, or any derivative or preparation
18 of any such substances, contained therein, except that
19 the requirement for stating the quantity of the active
20 ingredients, other than the quantity of those specifi-
21 cally named in this subclause, shall not apply to non-
22 prescription drugs not intended for human use; and
23 “(iii) the established name of each inactive in-
24 gredient listed in alphabetical order on the outside
25 container of the retail package and, if deemed appro-

1 *priate by the Secretary, on the immediate container,*
2 *as prescribed in regulation promulgated by the Sec-*
3 *retary, but nothing in this clause shall be deemed to*
4 *require that any trade secret be divulged, except that*
5 *the requirements of this subclause with respect to al-*
6 *phabetical order shall apply only to nonprescription*
7 *drugs that are not also cosmetics and this subclause*
8 *shall not apply to nonprescription drugs not intended*
9 *for human use.*

10 *“(B) For any prescription drug the established name*
11 *of such drug or ingredient, as the case may be, on such*
12 *label (and on any labeling on which a name for such drug*
13 *or ingredient is used) shall be printed prominently and in*
14 *type at least half as large as that used thereon for any pro-*
15 *prietary name or designation for such drug or ingredient,*
16 *except that to the extent that compliance with the require-*
17 *ments of clause (A)(ii) or (iii) or this subparagraph is im-*
18 *practicable, exemptions shall be established by regulations*
19 *promulgated by the Secretary.”.*

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

1 **“SEC. 772. PREEMPTION FOR LABELING OR PACKAGING OF**
2 **COSMETICS.**

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

13 “(b) *EXEMPTION.*—*Upon application of a State or po-*
14 *litical subdivision thereof, the Secretary may by regulation*
15 *after notice and opportunity for written and oral presen-*
16 *tation of views, exempt from subsection (a), under such con-*
17 *ditions as may be prescribed in such regulation, a State*
18 *or political subdivision requirement for labeling and pack-*
19 *aging that—*

20 “(1) *protects an important public interest that*
21 *would otherwise be unprotected;*

22 “(2) *would not cause a cosmetic to be in viola-*
23 *tion of any applicable requirements or prohibition*
24 *under Federal law; and*

25 “(3) *would not unduly burden interstate*
26 *commerce.*

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

18 (a) *LIST AND ANALYSIS.*—*The Secretary of Health and*
19 *Human Services shall, through the Food and Drug Admin-*
20 *istration—*

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

5 *(b) STUDY.—The Secretary of Health and Human*
6 *Services, acting through the Food and Drug Administra-*
7 *tion, shall conduct a study of the effect on humans of the*
8 *use of mercury compounds in nasal sprays. Such study*
9 *shall include data from other studies that have been made*
10 *of such use.*

11 *(c) STUDY OF MERCURY SALES.—*

12 *(1) STUDY.—The Secretary of Health and*
13 *Human Services, acting through the Food and Drug*
14 *Administration and subject to appropriations, shall*
15 *conduct, or shall contract with the Institute of Medi-*
16 *cine of the National Academy of Sciences to conduct,*
17 *a study of the effect on humans of the use of ele-*
18 *mental, organic or inorganic mercury when offered*
19 *for sale as a drug or dietary supplement. Such study*
20 *shall, among other things, evaluate—*

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

23 *(B) the adverse effects on health of children*
24 *and other sensitive populations resulting from*

1 *exposure to, or ingestion or inhalation of, mer-*
2 *cury when so used.*

3 *In conducting such study, the Secretary shall consult*
4 *with the Administrator of the Environmental Protec-*
5 *tion Agency, the Chair of the Consumer Product Safe-*
6 *ty Commission, and the Administrator of the Agency*
7 *for Toxic Substances and Disease Registry, and, to*
8 *the extent the Secretary believes necessary or appro-*
9 *priate, with any other Federal or private entity.*

10 (2) *REGULATIONS.—If, in the opinion of the Sec-*
11 *retary, the use of elemental, organic or inorganic mer-*
12 *cury offered for sale as a drug or dietary supplement*
13 *poses a threat to human health, the Secretary shall*
14 *promulgate regulations restricting the sale of mercury*
15 *intended for such use. At a minimum, such regula-*
16 *tions shall be designed to protect the health of children*
17 *and other sensitive populations from adverse effects*
18 *resulting from exposure to, or ingestion or inhalation*
19 *of, mercury. Such regulations, to the extent feasible,*
20 *should not unnecessarily interfere with the availabil-*
21 *ity of mercury for use in religious ceremonies.*

1 **SEC. 32. NOTIFICATION OF DISCONTINUANCE OF A LIFE**
 2 **SAVING PRODUCT.**

3 *Chapter VII (21 U.S.C. 371 et seq.), as amended by*
 4 *section 30, is further amended by adding at the end the*
 5 *following:*

6 “*SUBCHAPTER I—NOTIFICATION OF THE*
 7 *DISCONTINUANCE OF A LIFE SAVING PRODUCT*

8 “**SEC. 781. DISCONTINUANCE OF A LIFE SAVING PRODUCT.**

9 “(a) *IN GENERAL.*—*A manufacturer that is the sole*
 10 *manufacturer of a drug or device—*

11 “(1) *that is—*

12 “(A) *life supporting;*

13 “(B) *life sustaining; or*

14 “(C) *intended for use in the prevention of a*
 15 *debilitating disease or condition; and*

16 “(2) *for which an application has been approved*
 17 *under section 505(b), 505(j), or 515(d),*

18 *shall notify the Secretary of a discontinuance of the manu-*
 19 *facture of the drug or device at least 6 months prior to*
 20 *the date of the discontinuance.*

21 “(b) *REDUCTION IN NOTIFICATION PERIOD.*—*On ap-*
 22 *plication of a manufacturer, the Secretary may reduce the*
 23 *notification period required under subsection (a) for the*
 24 *manufacturer if good cause exists for the reduction, such*
 25 *as a situation in which—*

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

4 “(2) a biomaterials shortage prevents the con-
5 tinuation of the manufacturing for the 6-month pe-
6 riod;

7 “(3) a liability problem may exist for the manu-
8 facturer if the manufacturing is continued for the 6-
9 month period;

10 “(4) continuation of the manufacturing for the
11 6-month period may cause substantial economic hard-
12 ship for the manufacturer;

13 “(5) the manufacturer has filed for bankruptcy
14 under chapter 7 or 11 of title 11, United States Code;
15 or

16 “(6) the Secretary determines that there would be
17 no adverse impact from the discontinuance of a drug
18 or device.

19 “(c) *DISTRIBUTION*.—To the maximum extent prac-
20 ticable, the Secretary shall distribute information on the
21 discontinuation of the drugs and devices described in sub-
22 section (a) to appropriate physician and patient organiza-
23 tions.”.