Calendar No. 446

104TH CONGRESS
2D SESSION

S. 1477

[Report No. 104–284]

A BILL

To amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to improve the regulation of food, drugs, devices, and biological products, and for other purposes.

JUNE 20, 1996

Reported with an amendment

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IN THE SENATE OF THE UNITED STATES

DECEMBER 13, 1995

Mrs. KASSEBAUM (for herself, Mr. INHOFE, and Mr. FRIST) introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

JUNE 20, 1996

Reported by Mrs. KASSEBAUM, with an amendment

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

A BILL

To amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to improve the regulation of food, drugs, devices, and biological products, and for other purposes.

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

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Food and Drug Administration Performance and Accountability Act of 1995''.

TITLE I—MISSION AND ACCOUNTABILITY

SEC. 101. SHORT TITLE.

This title may be cited as the ''Food and Drug Administration Regulatory Reform Act of 1995''.

SEC. 102. THE MISSION OF THE FOOD AND DRUG ADMINISTRATION.

Section 903(a) (21 U.S.C. 393(a)) is amended by adding at the end thereof the following: ''The mission of the Administration is to promote and protect the health of the American people by—

''(1) facilitating the rapid and efficient development and availability of products subject to its regulation;

''(2) protecting the public from unsafe or ineffective products subject to its regulation; and

''(3) enforcing the applicable statutes and regulations in a timely, fair, consistent, and decisive manner.''.

SEC. 103. PERFORMANCE STANDARDS AND REVIEW.

Section 903(b) (21 U.S.C. 393(b)) is amended by adding at the end thereof the following new paragraph:

"(3) PERFORMANCE STANDARDS AND REVIEW.—Within 180 days after the date of enactment of this paragraph, the Commissioner, after consultation with representatives of patient advocacy groups, health professionals, and the regulated industries, shall publish in the Federal Register quantifiable performance standards for action by the Administration on applications or submissions (including petitions, notifications, or any other similar form of request) for the review of a product that is a new drug, biological product, new animal drug, device, or food additive and that is subject to premarket review or approval of any kind under this Act. The performance standards shall be reviewed, and after consultation with representatives of patient advocacy groups, health professionals, and the regulated industries, may be revised, annually by the Commissioner. The performance standards shall establish objectives for the Administration that—

"(A) expedite action on applications for new drugs and devices under sections 505(b)(1) and 515, and for biological products under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a))—

''(i) for a serious, life-threatening, or seriously debilitating disease or condition; or

''(ii) for any other condition if a new drug, device, or biological product—

''(I) provides therapy not available from other approved therapy; or

''(II) offers significant improvement over other approved therapy;

''(B) reduce backlogs on all applications with the objective of eliminating all backlogs by January 1, 2000; and

''(C) establish a schedule to bring the Administration into full compliance by July 1, 1998, with the time periods specified in this Act for action on all applications.

For applications for which there is no statutory time period, the applicable time period for action shall be 180 days. The Commissioner shall prepare and publish in the Federal Register for public comment an annual report comparing the performance of the Administration with the applicable performance standards, analyzing any failure to achieve any of the standards, and setting forth a plan to achieve compliance with the standards that have not been met.''.

SEC. 104. INFORMATION SYSTEM.

Chapter IX (21 U.S.C. 391 et seq.) is amended by adding at the end thereof the following new section:

"SEC. 906. INFORMATION SYSTEM.

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

SEC. 105. POLICY STATEMENTS.

Section 701(a) (21 U.S.C. 371(a)) is amended—

(1) by striking ''(a) The'' and inserting ''(a)(1) The''; and

(2) by adding at the end thereof the following new paragraph:

''(2)(A) The Secretary shall establish a procedure governing the development and use of all policy statements of general applicability (including any guideline, points-to-consider, protocol, recommendation, or similar document regardless of the form or designation) that are not promulgated as regulation. The procedure shall provide an opportunity for affected persons to participate in the development and continued use of the policy by sharing expertise, experience, or providing comment before the policy is adopted and after the policy is implemented.

''(B) The Secretary shall establish a procedure for the formal publication and compilation of all policy statements of general applicability (including any guideline, points-to-consider, protocol, recommendation, or similar document regardless of the form or designation) that are not promulgated as regulations.''.

SEC. 106. ADVISORY COMMITTEES.

Section 904 (21 U.S.C. 394) is amended—

(1) by striking ''Without'' and inserting ''(a) IN GENERAL.—Without''; and

(2) by adding at the end thereof the following new subsections:

''(b) DELEGATION OF APPOINTMENT AUTHORITY.—The Commissioner may delegate the appointment and oversight authority granted under subsection (a) to a center director. The center director may not authorize any office or division of the center to carry out the appointment and oversight authority granted under this subsection.

''(c) MEMBERSHIP AND MEETING REQUIREMENTS.—

''(1) SCOPE.—A scientific review group may determine the matters that the group will consider and may establish an appropriate agenda with respect to the determination of the matters.

''(2) NONVOTING MEMBERS.—A scientific review group shall include a nonvoting industry representative and a nonvoting public representative.

''(3) NOTIFICATION OF SCOPE OF DISCUSSION.—To the extent feasible, the specific matters and questions to be discussed at a meeting of a scientific review group shall be publicly announced and published in the Federal Register at least 30 days prior to the date of the meeting.

''(4) TERMS.—A member of a scientific review group shall serve for a term of 3 years, which may be renewed for a second term. An individual may serve on more than one scientific review group. The chairperson of a scientific review group shall be a member who has served at least 3 years. The term of the chairperson may be renewed for not more than 3 terms.

''(5) TRAINING.—Prior to service on a scientific review group, a member of the group shall be given adequate education and training relating to the responsibilities of the member.

''(6) FREQUENCY OF MEETINGS.—The Secretary shall take whatever action is necessary to ensure that regular meetings are held by scientific review groups, at appropriate intervals and for a suffi-

cient length of time, so that any matter to be reviewed by any scientific review group shall be presented to the group not more than 90 days after the matter is ready for review by the group. The meetings shall occur not less than 6 times each year unless there are compelling reasons for fewer meetings.

''(d) PERSONS INVOLVEMENT WITH REVIEW GROUPS.—

''(1) IN GENERAL.—All persons, including employees of the Secretary, shall have the same rights and responsibilities regarding—

''(A) the submission of data and information to, and contact and discussion with, a scientific review group;

''(B) the participation of the persons at meetings of the group; and

''(C) access to data and information submitted to a scientific review group (except for data and information that are not available for public disclosure under section 552 of title 5, United States Code).

''(2) SUBMISSION OF INFORMATION TO FDA.—In a case in which a scientific review group reviews an application (including a petition, notification, or other similar request), all related data and informa-

tion that are not available for public disclosure under section 552 of title 5, United States Code, shall be exchanged between the applicant and the Food and Drug Administration at the time the data and information are submitted to the scientific review group but shall not otherwise be publicly disclosed.

''(3) PARTICIPATION IN MEETINGS.—Any meetings of a scientific review group shall provide adequate time for initial presentations and for response to any differing views and shall encourage free and open participation by all interested persons.

''(c) FDA ACTIONS.—Within 60 days after the date a scientific review group makes its conclusions and recommendations on any matter under review of the group, the Food and Drug Administration official responsible for the matter shall review the conclusions and recommendations of the group, shall make a final determination on the matter, and shall notify the affected persons of the determination in writing and, if the determination differs from the conclusions and recommendations of the group, shall include the reasons for the difference.

''(f) DEFINITION.—For purposes of this section, the term 'center director' means a director of a center within the Food and Drug Administration.''.

SEC. 107. APPEALS WITHIN THE FOOD AND DRUG ADMINISTRATION.

Chapter IX (21 U.S.C. 391 et seq.), as amended by section 104, is further amended by adding at the end thereof the following new section:

"SEC. 907. APPEALS WITHIN THE FOOD AND DRUG ADMINISTRATION.

"(a) EMPLOYEE DECISIONS.—The Secretary shall by regulation establish a system for the appeal within the Food and Drug Administration of any decision by an employee of the Food and Drug Administration, except that this subsection shall not apply to decisions involving formal administrative or judicial proceedings. The Secretary shall make publicly known the existence of the internal appeal system and the procedures for an internal appeal.

"(b) REVIEW BY SCIENTIFIC REVIEW GROUP.—

"(1) IN GENERAL.—Any person shall have the right to request an evaluation by an appropriate scientific review group established under section 904 of any significant scientific issue pending before, or significant scientific decision made by, the Secretary under this Act. An appropriate scientific review group shall review the request and determine whether to conduct an evaluation within 30 days after the date the request is received by the Secretary.

"(2) SCOPE.—The issues a scientific review group shall evaluate shall include, but not be limited to, matters involving a decision by the Secretary not to permit a clinical investigation to begin or to continue, a refusal by the Secretary to file an application, a protocol design, and decisions relating to a pending application (including a petition, notification, or other similar request), where the same issue has not previously been reviewed by a scientific review group.

"(3) TIME LIMITATION.—If a scientific review group agrees to conduct an evaluation on an issue under paragraph (1), the evaluation shall be scheduled for the next meeting of the group.

"(c) ADDITIONAL INFORMAL AND FORMAL PROCEDURES.—

"(1) IN GENERAL.—For purposes of obtaining conclusions and recommendations regarding the resolution of any dispute, the Secretary is authorized to use such additional informal and formal procedures as may be considered useful. The procedures may include, but not be limited to, the use of—

"(A) panels of qualified Food and Drug Administration officials;

''(B) panels of qualified government employees who are not employees of the Food and Drug Administration; and

''(C) outside mediators and arbitrators who are not government employees.

''(2) APPLICATION OF FACA.—The Federal Advisory Committee Act (5 U.S.C. App) shall not apply to a panel described in paragraph (1).

''(d) REVIEW OF RECOMMENDATIONS.—Within 60 days after any matter that is presented for resolution pursuant to this section has been the subject of conclusions and recommendations, the Food and Drug Administration official responsible for the matter shall personally review the conclusions and recommendations, make a final determination on the matter, and notify the parties of the determination in writing and if the determination differs from the conclusions and recommendations, the reasons for the difference.''.

TITLE II—EXPEDITED ACCESS TO PRODUCTS FOR SERIOUSLY ILL PATIENTS

SEC. 201. SHORT TITLE.

This title may be cited as the ''Patient Rights Regulatory Reform Act of 1995''.

SEC. 202. ACCESS TO UNAPPROVED THERAPIES.

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

"SEC. 543. EXPANDED ACCESS TO UNAPPROVED THERAPIES AND DIAGNOSTICS.

"(a) IN GENERAL.—Any person may request from a manufacturer or distributor, and any manufacturer or distributor may provide to a person after compliance with the provisions of this section, an investigational drug (including a biological product) or device for the diagnosis, monitoring, or treatment of a serious disease or condition, life-threatening or seriously debilitating disease or condition, and any other disease or condition designated by the Secretary as appropriate for expanded access under this section by the person if—

"(1) the person has no comparable or satisfactory alternative therapy available to treat, diagnose, or monitor the disease or condition; or

"(2) the risk to the person from the investigational drug or device is not greater than the risk from the disease or condition.

"(b) PROTOCOLS.—A manufacturer or distributor may submit to the Secretary one or more expanded access protocols covering expanded access use of a drug or device described in subsection (a). The protocols shall be subject to the provisions of section 505(i) for a drug and section

520 (g) and (m) for a device and may include any form of use of the drug or device outside a clinical investigation, prior to approval of the drug or device for marketing, including but not limited to protocols for treatment, use, parallel track, single patient protocols, emergency use, and uncontrolled trials.

''(c) FEES.—A manufacturer or distributor may charge for an investigational drug or device under an expanded access protocol, but the price of the drug or device may not be more than that necessary to recover the costs of manufacture, research, development, and handling for the drug or device.

''(d) NOTIFICATION OF AVAILABILITY.—The manufacturer or distributor may inform national, State, and local medical associations and societies, and voluntary health associations, about the availability of an investigational drug or device for expanded access use pursuant to this section but—

''(1) shall state that the drug or device is investigational;

''(2) shall not represent that the drug or device is safe or effective for any use; and

''(3) shall not otherwise promote or advertise the availability of the product for expanded access use.

SEC. 203. EXPANDING HUMANITARIAN USE OF DEVICES.

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

(1) in paragraph (2), by inserting at the end thereof the following flush sentences:

''The request shall be in the form of an application to the Secretary. Within 30 days of the date of the receipt of the application, the Secretary shall issue an order approving or denying the application.'';

(2) by striking paragraph (5); and

(3) by striking paragraph (6).

SEC. 204. EXPEDITING APPROVAL OF NEW DRUGS, BIOLOGICS, AND MEDICAL DEVICES FOR SERIOUS CONDITIONS.

(a) NEW DRUGS.—Section 505(c)(1) (21 U.S.C. 355(c)(1)) is amended by adding at the end thereof the following flush sentence:

''In a case in which an application submitted under section 505(b)(1) for a new drug, or section 351(a) of the Public Health Service Act a biological product, for a life-threatening disease or condition, a seriously debilitating disease or condition, or for any other serious disease or condition that provides therapy or diagnosis not available from another approved drug or biological product or offers significant improvement over another approved drug or biological product, the Secretary shall approve or deny approval

of the application within 120 days after the receipt of the application.''.

TITLE III—REVITALIZING THE INVESTIGATION OF NEW PRODUCTS

SEC. 301. SHORT TITLE.

This title may be cited as the ''Investigational Products Regulatory Reform Act of 1995''.

SEC. 302. TIMELY REVIEW AND REASONABLE DATA REQUIREMENTS FOR CLINICAL RESEARCH ON DRUGS AND BIOLOGICAL PRODUCTS.

Section 505(i) (21 U.S.C. 355(i)) is amended—

(1) by striking ''(i) The'' and inserting ''(i)(1) The'';

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

(3) by adding at the end thereof the following new paragraph:

''(2)(A) A clinical investigation of a new drug (including a biological product) may begin 30 days after the date the Secretary receives from the sponsor a notification containing information about the drug and the clinical investigation unless, prior to the 30-day period, the Secretary informs the sponsor in writing that the investigation may

not begin, and specifies the basis for the decision and the information needed in order for the clinical investigation to commence.

''(B) Within 1 year after the date of enactment of the Food and Drug Administration Performance and Accountability Act of 1995, the Secretary, after consultation with representatives of patient advocacy groups and the regulated industries, shall publish in the Federal Register criteria for the type and amount of information relating to the safety of an investigational drug to be included in a notification described in subparagraph (A), taking into account the recommendations of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use. The Secretary shall periodically review, and may revise, the criteria.

''(C) The Commissioner shall establish a mechanism to ensure the fair and consistent application of safety standards for clinical investigations.''.

SEC. 303. TIMELY REVIEW AND REASONABLE DATA REQUIREMENTS FOR CLINICAL RESEARCH ON DEVICES.

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

''(6) The procedures and conditions prescribed pursuant to paragraph (2)(A) shall be subject to subparagraphs (B) and (C) of section 505(i)(2).

''(7) The Secretary shall, within 120 days of the date of enactment of this paragraph, by regulation amend the content of parts 812 and 813 of title 21 of the Code of Federal Regulations to update the procedures and conditions under which devices intended for human use may upon application be granted an exemption from certain requirements under this Act. The regulation shall—

''(A) permit developmental changes in devices, including manufacturing changes, in response to information collected during an investigation without requiring an additional approval of an application for an investigational device exemption or the approval of a supplement to the application, if the changes do not constitute a significant change in design or a significant change in basic principles of operation; and

''(B) permit, without approval of a supplement to an application for an investigational device exemption, changes or modifications to clinical protocols that do not affect the validity of data or information resulting from the completion of an approved protocol.''.

SEC. 304. COLLABORATIVE RESEARCH DESIGN.

Chapter V (21 U.S.C. 351 et seq.), as amended by section 202, is further amended by adding at the end thereof the following new section:

"SEC. 544. COLLABORATIVE RESEARCH DESIGN.

"(a) REVIEW OF DESIGN.—

"(1) REQUEST.—Any person who intends to sponsor a preclinical or clinical investigation of a drug (including a biological product) or device may request a meeting with the Secretary to review the design of one or more protocols or part or all of a development plan for the drug or device.

"(2) FORM.—A request described in paragraph (1) shall be in writing and shall include a proposal for which the review is requested.

"(3) WRITTEN REVIEW.—The Secretary shall meet with the person within 30 days of the request and shall provide to the person a written review of the proposal, including any deficiencies in the proposal. A written summary shall be made of the meeting. The summary shall include the written review of the proposal and, after agreement by the individuals who attended the meeting, shall be made part of the product review file maintained by the Food and Drug Administration.

''(b) MODIFICATION OF AGREEMENTS.—Agreements reached through meetings under subsection (a) may be changed in writing by mutual consent of the sponsor and the Secretary at any time.

''(c) MODIFICATION OF AGREEMENTS BY THE FDA.—Agreements reached through meetings under subsection (a) may be changed unilaterally only—

''(1) by the director of the office of the Food and Drug Administration responsible for regulating a drug or device subject to review under this section, who may not delegate such responsibility; and

''(2) in writing and specifying the basis therefor and demonstrating the substantial public health reasons that require the change.

''(d) PANEL REVIEW.—

''(1) IN GENERAL.—Any person requesting a meeting under subsection (a) may obtain review from a panel established under subsection 513(b) of a determination of the Secretary to disapprove a protocol or product development plan.

''(2) AGREEMENT MODIFICATIONS.—Any person who has reached an agreement with the Secretary under subsection (b) may obtain review from a panel described in paragraph (1) of a modification of the agreement under subsection (c).''.

TITLE IV—EFFICIENT, ACCOUNTABLE, AND FAIR PRODUCT REVIEW

SEC. 401. REFERENCE.

This title may be cited as the ''Product Review Regulatory Reform Act of 1995''.

SEC. 402. THE CONTENT AND REVIEW OF AN APPLICATION.

Chapter VII (21 U.S.C. 371 et seq.) is amended by adding at the end thereof the following new subchapter:

''SUBCHAPTER D—REVIEW OF APPLICATIONS

''SEC. 741. CONTENT AND REVIEW OF AN APPLICATION.

''(a) IN GENERAL.—This section applies to any application (including a petition, notification, or other similar request) submitted for a food additive, new drug, biological product, new animal drug, animal feed bearing or containing a new animal drug, device, or color additive.

''(b) FILING REQUIREMENTS.—The Commissioner shall establish a mechanism to ensure the fair and consistent application of filing requirements.

''(c) CLASSIFICATION OF A PRODUCT.—Within 60 days of the receipt of a written request of any person for information respecting the classification of a product as a drug, biological product, or device or the component of the Food and Drug Administration that will regulate the product (including a request respecting a combination

product subject to section 503(g)) the Secretary shall provide the person a written statement of the classification of the product or the component of the Food and Drug Administration that will regulate the product. The Secretary's statement shall be binding and may not be changed by the Secretary except with the written agreement of the person who submitted the request. If the Secretary does not provide the statement within the 60-day period, the classification and component designated by the person submitting the request shall be final and binding and may not be changed by the Secretary except with the written agreement of the person. All radiopharmaceutical products shall be regulated in a separate division under the Center for Devices and Radiological Health.

''(d) REASONABLE DATA REQUIREMENTS.—Within 1 year after the date of enactment of the Food and Drug Administration Performance and Accountability Act of 1995, the Secretary, after consultation with patient advocacy groups and the regulated industries, shall publish in the Federal Register criteria for the type and amount of information relating to safety and effectiveness to be included in an application for the approval of a product, or a new use of an approved product, described in subsection (c). In developing the criteria, the Secretary shall consider any recommendations of the International Conference on

Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.''.

SEC. 403. CONTRACTS FOR EXPERT REVIEW.

Chapter VII (21 U.S.C. 371 et seq.), as amended by section 402, is further amended by adding at the end thereof the following new section:

''SEC. 742. CONTRACTS FOR EXPERT REVIEW.

''(a) IN GENERAL.—The Secretary may contract with outside organizations and individuals, with expertise in relevant disciplines, to review, evaluate, and make conclusions and recommendations to the Secretary on parts or all of any application (including a petition, notification, or other similar request for Food and Drug Administration action). Any such contract shall be subject to the requirements of section 708. Funds obtained under part 2 of subchapter C may be used for external review of any drug (including a biological product) for which a user fee was paid.

''(b) REVIEW OF EXPERT'S EVALUATION.—

''(1) IN GENERAL.—Subject to paragraph (2), the Food and Drug Administration official responsible for any matter for which expert review is used pursuant to this section shall personally review the conclusions and recommendations of the expert review organization or individual and shall make a

final decision regarding the matter under review within 60 days after receiving the conclusions and recommendation.

''(2) LIMITATION.—A final decision under paragraph (1) shall be made within the applicable prescribed time period for review of an application as set forth in this Act.''.

SEC. 404. PROMPT AND EFFICIENT REVIEW.

Chapter VII (21 U.S.C. 371 et seq.), as amended by section 403, is further amended by adding at the end thereof the following new section:

''SEC. 743. PROMPT AND EFFICIENT REVIEW.

''(a) IN GENERAL.—The provisions of this section shall apply to any of the following applications (including a petition, notification, or other similar request):

''(1) An application for approval of a human food additive or animal feed additive under section 409.

''(2) An application for approval of a new drug under section 505(b)(1).

''(3) An application for approval of a new animal drug or an animal feed bearing or containing a new animal drug under subsection (b)(1) or (m) of section 512, respectively.

''(4) A submission for a determination that a device is substantially equivalent to a predicate device under sections 513(f)(1) and 513(i).

''(5) An application for approval of a device under section 515.

''(6) An application for the listing of a color additive under section 721.

''(b) REVIEW PROCEDURES AND POLICIES.—The Secretary shall establish procedures and policies to facilitate a collaborative review process between the Food and Drug Administration and the applicant with respect to an application or submission described in subsection (a). As part of this collaborative process—

''(1) open, informal, and prompt communications shall be encouraged;

''(2) meetings (except meetings with respect to submissions to determine substantial equivalence of a device to a predicate device) shall be held after the expiration of one-half of the statutory time period for review of the application and after the expiration of three-quarters of such period, or within 15 days after a scientific review group has convened and made recommendations on an application, unless the Food and Drug Administration and the applicant determine that a meeting is unnecessary; and

"(3) the Secretary shall, prior to the meetings described in paragraph (2), present to the applicant in writing a description of any deficiencies of the application and the information necessary to bring the application into a form that would require approval.

"(c) APPROVAL, DISAPPROVAL, AND CLASSIFICATION.—

"(1) APPROVAL BASED ON FAILURE TO ACT.—Beginning 1 year after the date of publication of an applicable performance standard under section 903(b), or 18 months after the date of enactment of the Food and Drug Administration Performance and Accountability Act of 1995, whichever occurs first, if the Secretary fails to meet a time period for action on an application established in the standard and the product that is a new drug, biological product, new animal drug, device, or food additive that is the subject of the application has met the marketing requirements of the European Union or the United Kingdom, at the request of the applicant the application shall be deemed to be approved unless, within 30 days after the expiration of the time period established in the standard, the Secretary notifies the applicant in writing that the application is disapproved, setting forth the reasons for disapproval,

and, with the consent of the applicant, publishes a notice, within 30 days of notifying the applicant, in the Federal Register disapproving the application under paragraph (2) and setting forth the reasons for the disapproval.

''(2) APPEAL.—A person whose application has been disapproved under this subsection may appeal using one of the following procedures:

''(A) PROCEDURES UNDER THE ACT.—The procedures established for the product under other provisions of this Act.

''(B) APPEAL.—An appeal to a United States District Court to determine whether the Secretary's decision is supported by substantial evidence in the administrative record.

''(d) CONTRACTS FOR EXPERT REVIEW.—

''(1) IN GENERAL.—Beginning July 1, 1998, if the Secretary in any fiscal year fails to meet the statutory time period for action on an application for at least 95 percent of the applications in a particular category, the Secretary shall in the following fiscal year, with the consent of the applicant, contract with expert individuals and organizations under section 742 to review new applications and applications for which the Secretary has failed to

meet the statutory time period for action for the particular product category.

''(2) APPROVAL.—If an individual or organization selected to conduct a review under paragraph (1) determines that an application described in paragraph (1) should be approved, the application shall be considered to be approved unless, within 30 days after the date the Secretary receives the determination of the individual or organization, the Secretary publishes a notice in the Federal Register disapproving the application and setting forth the reasons for disapproval. An applicant may appeal the disapproval under subsection (c)(2).''.

SEC. 405. GOOD MANUFACTURING PRACTICE INSPECTION.

Chapter VII is (21 U.S.C. 371 et seq.), as amended by section 404, is further amended by adding at the end thereof the following new section:

''SEC. 744. GOOD MANUFACTURING PRACTICE INSPECTION.

''(a) IN GENERAL.—In order to comply with inspection requirements of this Act, the Secretary may accredit organizations to conduct inspections under section 704 to evaluate compliance of a manufacturer with applicable requirements for good manufacturing practice.

''(b) ELIGIBILITY REQUIREMENTS.—The Secretary shall by regulation establish the requirements that an or-

ganization shall meet to be eligible to be accredited to participate as a qualified organization to conduct inspections under subsection (a).

''(c) ACCREDITATION.—Within 90 days after the date the Secretary receives an application for accreditation under this section, the Secretary shall review the application and determine whether an applicant is in compliance with the requirements established under this section. Within the 90-day period, the Secretary shall grant accreditation or shall deny accreditation and specify in writing the reasons for the denial and the requirements that shall be met to obtain accreditation.

''(d) REVOCATION OF ACCREDITATION.—The Secretary may at any time revoke accreditation granted under subsection (c) for failure to comply with the requirements established under this section after specifying in writing the reasons for the revocation and the requirements that shall be met to retain accreditation and after an informal hearing on the revocation.

''(e) INSPECTIONS.—Any organization accredited under this subsection that conducts an inspection under this subsection at the request of the Secretary shall—

''(1) apply all relevant principles of good manufacturing practice established in this Act and in regulations promulgated by the Secretary; and

''(2) provide to the Secretary and the manufacturer within 30 days after the completion of the inspection an adequate report of the findings of the inspection.

''(f) LIMITATION.—When an accredited organization has conducted a good manufacturing practice inspection under section 704, the Secretary may not perform such an inspection for a period of 2 years after the date of the receipt of the report required under subsection (c)(2), unless justified by good cause.''.

SEC. 406. ENVIRONMENTAL IMPACT REVIEW.

Chapter VII (21 U.S.C. 371 et seq.), as amended by section 405, is further amended by adding at the end thereof the following new section:

''SEC. 745. ENVIRONMENTAL IMPACT REVIEW.

''Notwithstanding any provision of other law, no action by the Secretary pursuant to this Act shall be subject to an environmental assessment, an environmental impact statement, or other environmental consideration unless the director of the office responsible for the action demonstrates, in writing and specifying the basis therefor—

''(1) that there is a reasonable probability that the environmental impact of the action is sufficiently substantial and within the factors that the Secretary is authorized to consider under this Act, and

''(2) that consideration of the environmental impact will directly affect the decision on the action.''.

SEC. 407. INFORMATION EXCHANGE.

Chapter VII (21 U.S.C. 371 et seq.), as amended by section 406, is further amended by adding at the end thereof the following new sections:

''SEC. 746. DISSEMINATION OF INFORMATION ON DRUGS.

''(a) DISSEMINATION.—

''(1) IN GENERAL.—Notwithstanding sections 301(d) and 502(f), and subject to the requirements of paragraph (2) and subsection (b), a person may disseminate to any person that is a health care practitioner or other provider of health care goods or services, a pharmacy benefit manager, a health maintenance organization or other managed health care organization, or a health care insurer or governmental agency, written information, or an oral or written summary of the written information, concerning—

''(A) a treatment use for an investigational new drug (including a biological product) approved by the Secretary for such treatment use; or

"(B) a use (whether or not such use is contained in the official labeling) of a new drug for which an approval of an application filed under section 505(b) is in effect.

"(2) REQUIREMENTS.—A person may disseminate information under paragraph (1)(B) only if—

"(A) the information is an unabridged—

"(i) reprint or copy of a peer-reviewed article from a scientific or medical journal that is published by an organization that is independent of the pharmaceutical industry; or

"(ii) chapter, authored by an expert or experts in the disease to which the use relates, from a recognized reference textbook that is published by an organization that is independent of the pharmaceutical industry;

"(B) the text of the information has been approved by a continuing medical education accrediting agency that is independent of the pharmaceutical industry as part of a scientific or medical educational program approved by the agency;

"(C) the information relates to a use that is recognized under Federal law for purposes of third-party coverage or reimbursement, and—

"(i) the text of the information has been approved by an organization referred to in such Federal law; and

"(ii) the information is part of a disease management program or treatment guideline with respect to the use; or

"(D) the information is an accurate and truthful summary of the information described in subparagraph (A), (B), or (C).

"(b) DISCLOSURE STATEMENT.—In order to afford a full and fair evaluation of the information described in subsection (a), a person disseminating the information shall include a statement that discloses—

"(1) if applicable, that the use of a new drug described in subparagraph (A) or (B) of subsection (a)(1) and the information with respect to the use have not been approved by the Food and Drug Administration;

"(2) if applicable, that the information is being disseminated at the expense of the sponsor of the new drug;

''(3) if applicable, that one or more authors of the information being disseminated are employees of or consultants to the sponsor of the new drug; and

''(4) the official labeling for the drug and biological product, or in the case of a treatment use of an investigational new drug, the investigator brochure and all updates thereof.

''(c) DEFINITION.—As used in this section, the term 'expense' includes financial, in-kind, and other contributions provided for the purpose of disseminating the information described in subsection (a).

''(d) SPECIAL RULE.—In the case of a professional disagreement between the Secretary and other qualified experts with respect to the application of section 502(a), the Secretary may not use section 502 to prohibit the dissemination of information in the types of circumstances and under the conditions set forth in subsections (a) and (b).

''SEC. 747. DISSEMINATION OF INFORMATION ON DEVICES.

''(a) IN GENERAL.—Notwithstanding sections 301, 501(f), 501(i), 502(a), 502(f), and 502(o), or any other provision of law, and subject to subsections (b) and (c), a person may disseminate to any person that is a health care practitioner or other provider of health care goods or services, a pharmacy benefit manager, a health mainte-

nance organization or other managed health care organization, or a health care insurer or governmental agency, written or oral information (including information exchanged at scientific and educational meetings, workshops, or demonstrations) relating to a use, whether or not the use is described in the official labeling, of a device produced by a manufacturer registered pursuant to section 510.

''(b) DISCLOSURE STATEMENTS AND REQUIREMENTS.—

''(1) DISCLOSURE STATEMENTS.—To the extent practicable, the requirement with respect to a statement of disclosure under subsection (b) of section 746 shall apply to the dissemination of written and oral information under this section, except that this paragraph shall not apply to the dissemination of written or oral information with respect to the intended use described in the labeling of a device.

''(2) ADDITIONAL REQUIREMENTS.—A person may disseminate information under subsection (a) only if—

''(A) the information is an unabridged—

''(i) reprint or copy of a peer-reviewed article from a scientific or medical journal that is published by an organization that is

independent of the medical device industry; or

''(ii) chapter, authored by an expert or experts in the medical specialty to which the use relates, from a recognized reference textbook that is published by an organization that is independent of the medical device industry;

''(B) the information has been approved by a continuing medical education accrediting agency that is independent of the medical device industry as part of a scientific or medical educational program approved by the agency;

''(C) the information relates to a use that is recognized under Federal law for purposes of third-party reimbursement, and—

''(i) the text of the information has been approved by an organization referred to in such Federal law; and

''(ii) the information is part of a disease management program or treatment guideline with respect to such use; or

''(D) the oral or written information is—

''(i) part of an exchange of information solely among health care practitioners,

health care reimbursement officials, and the industry;

''(ii) exchanged for educational or scientific purposes; or

''(iii) presented at continuing medical education programs, seminars, workshops, or demonstrations.

''(3) APPLICABILITY.—The requirements under subsection (a)(1)(A) and (B) of section 746 shall not apply with respect to devices.

''SEC. 748. POLICY ON INFORMATION DISSEMINATION.

''(a) CONSTRUCTION.—Notwithstanding section 502 (a), (f), and (o), or any other provision of law, the written or oral dissemination of information relating to a new use of a new drug or device, in accordance with sections 746 and 747, shall not be construed as evidence of a new intended use of the new drug or device that is different from the intended use of the new drug or device set forth in the official labeling. The dissemination shall not be considered as labeling, adulteration, or misbranding of the new drug or device.

''(b) RESPOND TO UNSOLICITED QUESTIONS.—Nothing in this Act shall affect the ability of manufacturers to respond fully to unsolicited questions from health care

practitioners and other persons about drugs (including biological products) or devices.

"SEC. 749. APPROVAL OF NEW USES.

"(a) IN GENERAL.—As an alternative to the procedures established in section 505(c)(1) for a new drug (including a biological product) and section 515(d)(1)(A) for a device, the Secretary shall approve an application under this section for a new use of a previously approved new drug or device if experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs or devices conclude that a new use that has not been reviewed or approved by the Secretary represents sound medical practice based upon reliable clinical experience and other confirmatory information, unless the Secretary demonstrates that there are other compelling public health reasons related to the safety or effectiveness of the drug or device why approval would harm the health of individual patients.

"(b) PETITION.—The holder of an approved application may submit a petition to the Secretary presenting information that new use of a previously approved new drug or device meets the criteria for approval established in this subsection. The petition shall include data and information relating to the new use and shall demonstrate that the new use—

''(1) has existed in clinical practice for at least five years;

''(2) is common among clinicians experienced in the field; and

''(3) represents reasonable medical practice based upon reliable clinical experience and other confirmatory information.

''(c) ACTION ON PETITION.—Upon receipt of the petition, the Secretary shall obtain the conclusions and recommendations of a scientific review group established under section 904 and grant or deny the petition within 180 days of the receipt of the petition.''.

SEC. 408. EFFECTIVENESS, OUTCOME, AND COST-EFFECTIVENESS STANDARDS.

Section 741, as added by section 402, is amended by adding at the end thereof the following new subsection:

''(e) In reviewing an application for a product that is a new drug, biological product, new animal drug, animal feed bearing or containing a new animal drug, or device the determination of effectiveness shall not include the evaluation of—

''(1) relative effectiveness, unless the effectiveness of the product is explicitly compared to the effectiveness of another product in the labeling;

''(2) any potential use not explicitly included in the labeling;

''(3) the cost-effectiveness of the product described in this subsection as compared to the cost-effectiveness of a similar product, unless the labeling explicitly includes a representation about cost-effectiveness; and

''(4) the clinical outcome resulting from use of a device, unless the labeling explicitly includes a representation regarding clinical outcome.''.

SEC. 409. DEFINITION OF A DAY FOR PURPOSES OF PRODUCT REVIEW.

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

''(gg) For purposes of reviewing any application, notification or petition, or any document, with respect to a product that is a new drug, biological product, new animal drug, device, or food additive that is submitted to the Secretary to obtain approval of marketing, or to establish or clarify the regulatory status of the product, the term 'day' means a calendar day (excluding any calendar day between the date of receipt by the submitter of a written communication from the Secretary setting forth the action of the Secretary on a submission and the date of receipt by the Secretary of the written response of the submitter

to the action) in which the Secretary has responsibility to review such a submission.''.

TITLE V—DRUG, BIOLOGICAL PRODUCTS, DEVICES EXPORT REFORM

SEC. 501. SHORT TITLE.

This title may be cited as the ''Drug, Biological Products, Devices Export Reform Act of 1995''.

SEC. 502. EXPORT OF DRUGS AND DEVICES.

(a) EXPORTS AND IMPORTS.—Section 801 (21 U.S.C. 381) is amended—

(1) in subsection (d), by adding at the end thereof the following new paragraph:

''(3) No component, part or accessory of a drug, biological product, or device, including a drug in bulk form, shall be excluded from importation into the United States under paragraph (a), if the component, part, or accessory will be incorporated into a device, drug, or biological product that will be exported from the United States in accordance with subsection (e) of section 802 or section 351(h) of the Public Health Service Act.'';

(2) in subsection (e)(1), by striking the second sentence; and

(3) in subsection (e)(2), by inserting before the period at the end thereof the following: ''or that the device is eligible for export under section 802''.

(b) EXPORT OF CERTAIN UNAPPROVED DRUGS AND DEVICES.—Section 802 (21 U.S.C. 382) is amended to read as follows:

''SEC. 802. EXPORTS OF CERTAIN UNAPPROVED PRODUCTS.

''(a) IN GENERAL.—A drug (including a biological product) intended for human or animal use or a device for human use—

''(1)(A) which, in the case of a drug—

''(i) requires approval by the Secretary under section 505 or section 512; or

''(ii) requires licensing by the Secretary under section 351 of the Public Health Service Act or by the Secretary of Agriculture under the Act of March 4, 1913 (known as the Virus-Serum Toxin Act),

before the drug may be introduced or delivered for introduction into interstate commerce to a country; and

''(B) which—

''(i) does not have such approval or license;

''(ii) is not exempt from such sections or Act; and

‘‘(iii) is introduced or delivered for introduction into interstate commerce to a country; or

‘‘(2) which, in the case of a device—

‘‘(A) does not comply with an applicable requirement under section 514 or 515;

‘‘(B) is exempt under section 520(g) from section 514 or 515; or

‘‘(C) is a banned device under section 516, is adulterated, misbranded, and in violation of such sections or Act unless the export of the drug or device is authorized under subsection (b), (c), (e), or (f) or under section 801(e)(2).

‘‘(b) EXPORTATION TO ANY COUNTRY OR A SPECIFIC COUNTRY.—

‘‘(1) EXPORTATIONS TO ANY COUNTRY.—Except as otherwise provided in this section, a drug (including a biological product) or device may be exported to any country, if the drug or device complies with the laws of that country and has valid marketing authorization by the appropriate approval authority—

‘‘(A) in Australia, Canada, Israel, Japan, New Zealand, or Switzerland; or

"(B) in the European Union or a country in the European Economic Area (the countries in the European Union and the European Free Trade Association) if the drug or device is marketed in that country or the drug or device is authorized for general marketing in the European Economic Area.

"(2) EXPORTATION TO A CERTAIN COUNTRY.—A drug or device may be exported to the countries described in paragraph (1) if the drug or device complies with the laws of any such country and has a valid marketing authorization by the appropriate approval authority in that country.

"(c) EXPORTATION TO A COUNTRY WITH A REGULATORY SYSTEM.—

"(1) IN GENERAL.—A drug or device may be exported under this section to any other country that has an adequate regulatory system to protect the health of the citizens of such a country. The Comptroller General, in consultation with the Secretary and other appropriate parties, shall develop a list of countries to which a drug or device may be exported under this paragraph and a list of recommended criteria for additions or deletions of countries to the list of countries.

"(2) REQUEST DESIGNATION.—An appropriate country official, manufacturer, or exporter, may request the Secretary to designate a country to receive drugs or devices exported under this section that meets the requirements of paragraph (1) by submitting documentation in support of such designation to the Secretary. Any person other than an appropriate country official requesting such designation shall provide a letter from the country indicating the desire of the country to be designated.

"(3) TIME LIMITATION FOR DESIGNATION.—If the Secretary fails to, within 90 days of the date of the receipt of a request under paragraph (2), respond to the request with a denial of the requested designation, the request shall be considered granted and the country that is the subject of the request shall be designated as eligible to receive drugs or devices exported under this subsection.

"(4) WITHDRAWAL OF DESIGNATION.—If information is provided to the Secretary that indicates that, due to a public health emergency or systematic patterns of abuse of the regulatory system in a country designated under paragraph (3), the country is no longer able to carry out the functions described in paragraph (1), or if the country no longer meets

the requirements for designation under this subsection, the Secretary may withdraw the designation of the country.

''(d) LIMITATIONS.—A drug or device may not be exported under this section if—

''(1) the drug or device is not manufactured, processed, packaged, and held in conformity with current good manufacturing practice or is adulterated under paragraph (1), (2)(A), or (3) of section 501(a) or subsection (c) or (d) of section 501;

''(2) the drug or device is not labeled and advertised in accordance with the requirements and conditions for use of any country in which the drug or device is approved, either in English or the predominant language of the country to which the drug or device is being exported, except that with respect to advertising alternative methods of communication that are consistent with the requirements of the approving country shall be allowed if authorized by the receiving country;

''(3) the requirements of subparagraphs (A) through (D) of section 801(e)(1) have not been met;

''(4) the drug or device has been the subject of a finding by the Secretary under section 505, 512 or 515 or under section 351 of the Public Health

Service Act (42 U.S.C. 262), or by the Secretary of Agriculture under the Act of March 4, 1913 (37 Stat. 832–833) (commonly known as the 'Virus Serum Toxin Act') that the drug or device has not been shown to be safe or effective for labeled indication of the drug or device;

"(5) the Secretary finds that the drug or device poses an unreasonable and substantial risk to public health in the receiving country;

"(6) the drug or device is the subject of a notice by the Secretary or the Secretary of Agriculture of a determination that the possibility of reimportation of the exported drug or device would present an imminent hazard to the public health and safety of the United States and the only means of limiting the hazard is to prohibit the export of the drug or device; or

"(7) the drug or device will be re-exported or transshipped to a country not authorized to receive an exported drug or device under this section.

In making a finding under paragraph (5), the Secretary, to the maximum extent possible, shall consult with the affected country.

"(c) EXPORTATION OF DRUG FOR INVESTIGATIONAL USE.—A drug intended for investigational use in any

country described in subsection (b) or designated under subsection (c) may be exported in accordance with the laws of that country and still be exempt from regulation under section 505(i) or section 512(j).

"(f) EXPORTATION OF A DRUG FOR TROPICAL DISEASE.—

"(1) IN GENERAL.—A drug (including a biological product) that is to be used in the prevention or treatment of a tropical disease may, upon approval of an application submitted under paragraph (2), be exported if—

"(A) the Secretary finds, based on credible scientific evidence, including clinical investigations, that the drug is safe and effective in the country to which the drug is to be exported in the prevention or treatment of a tropical disease in such country;

"(B) the drug is manufactured, processed, packaged, and held in conformity with current good manufacturing practice and is not adulterated under paragraphs (1), (2)(A), and (3) of subsection (a), and subsection (c) or (d), of section 501;

"(C) the outside of the shipping package is labeled with the following statement: 'This drug

may be sold or offered for sale only in the following countries:', the blank space being filled with a list of the countries to which export of the drug is authorized under this subsection;

''(D) the drug is not the subject of a notice by the Secretary or the Secretary of Agriculture of a determination that the manufacture of the drug in the United States for export to a country is contrary to the public health and safety of the United States; and

''(E) the requirements of subparagraphs (A) through (D) of section 801(d)(1) have been met.

''(2) APPLICATION.—Any person may apply to have a drug exported under paragraph (1). The application shall—

''(A) describe the drug to be exported;

''(B) list each country to which the drug is to be exported;

''(C) contain a certification by the applicant that the drug will not be exported to a country for which the Secretary cannot make a finding described in paragraph (1)(A);

''(D) identify the establishments in which the drug is manufactured; and

‘‘(E) demonstrate to the Secretary that the drug meets the requirements of paragraph (1).

‘‘(3) REQUIRED REPORTING.—The holder of an approved application for the export of a drug under this subsection shall report to the Secretary—

‘‘(A) the receipt of any information indicating that the drug is being or may have been exported from a country for which the Secretary made a finding under paragraph (1)(A) to a country for which the Secretary cannot make such a finding; and

‘‘(B) the receipt of any information indicating any adverse reactions to such drug.

‘‘(4) ADDITIONAL LIMITATIONS.—

‘‘(A) FAILURE TO MEET CERTAIN REQUIREMENTS.—If the Secretary determines that—

‘‘(i) a drug for which an application is approved under paragraph (2) does not continue to meet the requirements of paragraph (1);

‘‘(ii) the holder of the application has not made the report required by paragraph (3); or

"(iii) the manufacture of the drug in the United States for export is contrary to the public health and safety of the United States and an application for the export of the drug has been approved under paragraph (2),

then before taking action against the holder of an application for which a determination was made under clause (i), (ii), or (iii), the Secretary shall notify the holder in writing of the determination and provide the holder 30 days to take such corrective actions as may be required by the Secretary to prevent the Secretary from taking action against the holder. If the Secretary takes action against the holder because of the determination, the Secretary shall provide the holder a written statement specifying the reasons for the determination and provide the holder, on request, an opportunity for an informal hearing with respect to the determination.

"(B) LIMITATION ON THE EXPORTATION OF A HAZARDOUS DRUG BY AN IMPORTER.—If at any time the Secretary, or in the absence of the Secretary, the official designated to act on behalf of the Secretary determines that—

"(i) the holder of an approved application under paragraph (2) is exporting a drug from the United States to an importer;

"(ii) the importer is exporting the drug to a country for which the Secretary cannot make a finding under paragraph (1)(A); and

"(iii) the export presents an imminent hazard to the public health in the country,

the Secretary shall immediately prohibit the export of the drug to the importer, provide the person exporting the drug from the United States prompt notice of the determination, and afford the person an opportunity for an expedited hearing. A determination by the Secretary under this subparagraph may not be stayed pending final action by a reviewing court. The authority conferred by this subparagraph may not be delegated by the Secretary.

"(C) LIMITATION ON THE EXPORTATION OF A HAZARD DRUG BY A HOLDER.—If the Secretary, or in the absence of the Secretary, the official designated to act on behalf of the Secretary determines that the holder of an ap-

proved application under paragraph (2) is exporting a drug to a country for which the Secretary cannot make a finding under paragraph (1)(A), and that the export of the drug presents an imminent hazard, the Secretary shall immediately prohibit the export of the drug to such country, provide the holder prompt notice of the determination, and afford the holder an opportunity for an expedited hearing. A determination by the Secretary under this subparagraph may not be stayed pending final action by a reviewing court. The authority conferred by this subparagraph shall not be delegated by the Secretary.

''(D) LIMITATION ON THE EXPORTATION OF OTHER DRUGS BY A HOLDER.—If the Secretary receives credible evidence that the holder of an application approved under paragraph (2) is exporting a drug to a country for which the Secretary cannot make a finding under paragraph (1)(A), the Secretary shall give the holder 60 days to provide information to the Secretary respecting such evidence and shall provide the holder an opportunity for an informal hearing on such evidence. Upon the expiration

of such 60 days, the Secretary shall prohibit the export of such drug to such country if the Secretary determines the holder is exporting the drug to a country for which the Secretary cannot make a finding under paragraph (1)(A).

''(E) LIMITATION OF THE EXPORTATION OF OTHER DRUGS BY AN IMPORTER.—If the Secretary receives credible evidence that an importer is exporting a drug to a country for which the Secretary cannot make a finding under paragraph (1)(A), the Secretary shall notify the holder of the application authorizing the export of such drug of such evidence and shall require the holder to investigate the export by such importer and to report to the Secretary within 14 days of the receipt of such notice the findings of the holder. If the Secretary determines that the importer has exported a drug to such a country, the Secretary shall prohibit such holder from exporting such drug to the importer unless the Secretary determines that the export by the importer was unintentional.''.

SEC. 503. PARTIALLY PROCESSED BIOLOGICAL PRODUCTS.

Subsection (h) of section 351 of the Public Health Service Act (42 U.S.C. 262) is amended to read as follows:

''(h) A partially processed biological product that—

''(1) is not in a form applicable to the prevention, treatment, or cure of diseases or injuries of man;

''(2) is not intended for sale in the United States; and

''(3) is intended for further manufacture into final dosage form outside the United States,

shall be subject to no restriction on the export of the product under this Act or the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.) if the product is manufactured, processed, packaged, and held in conformity with current good manufacturing practice and meets the requirements of section 801(e)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(e)(1)).''.

TITLE VI—DRUG AND BIOLOGICAL PRODUCTS REGULATORY REFORM

SEC. 601. SHORT TITLE.

This title may be cited as the ''Drug and Biological Product Regulatory Reform Act of 1995''.

SEC. 602. NEW DRUG APPROVAL STANDARD.

Section 505(d) (21 U.S.C. 355(d)) is amended by adding at the end thereof the following new sentence: ''Substantial evidence may consist of data from one well-

controlled clinical investigation (which may be waived by the Secretary) and confirmatory evidence (obtained either before or after such investigation).''.

SEC. 603. PILOT AND SMALL SCALE MANUFACTURE.

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

''(4) A new drug or biological product manufactured in a pilot or other small facility may be used to demonstrate the safety and effectiveness of the drug or product and to obtain approval prior to scaling up to a larger facility, unless the Secretary demonstrates in writing and specifying in detail the reasons, after an informal hearing, that a full scale production facility is necessary to ensure the safety or effectiveness of the drug or product.''.

SEC. 604. MANUFACTURING CHANGES.

Chapter VII (21 U.S.C. 371 et seq.), as amended by section 407, is further amended by adding at the end thereof the following new section:

''SEC. 750. MANUFACTURING CHANGES.

''(a) IN GENERAL.—A change in the manufacture of a new drug, biological product, or new animal drug, may be made in accordance with this section.

''(b) DRUG AND BIOLOGICAL PRODUCT.—A change in the manufacture of a new drug, a biological product that is the subject of a monograph in an official compen-

dium, a biological product that can be adequately characterized by chemical, physical, or biological means, or a new animal drug shall require—

"(1) validation; and

"(2)(A) if there is no change in the approved qualitative and quantitative formulation or in the approved release specifications, or if there is a change in the approved qualitative or quantitative formula or in the approved release specifications of a type permitted by the Secretary by regulation, may be made at any time and shall be reported annually to the Secretary; and

"(B) for any other change, shall require completion of an appropriate study demonstrating equivalence according to criteria established by the Secretary (unless such requirement is waived by the Secretary), may be made at any time, and shall be reported to the Secretary through a supplement or amendment submitted at the time the change is made.

"(c) BIOLOGICAL PRODUCT NOT SUBJECT TO A MONOGRAPH.—A change in the manufacture of a biological product that is not the subject of a monograph in an official compendium and cannot be adequately character-

ized by chemical, physical, or biological means shall require validation and—

"(1) if the change relates solely to a modification of the manufacturing facility or change in personnel, with no change in the approved manufacturing process or release specifications, may be made at any time and shall be reported annually to the Secretary; and

"(2) for any other change, shall require completion of a bioassay or other appropriate study demonstrating equivalence according to criteria established by the Secretary (unless such requirement is waived by the Secretary), may be made at any time, and shall be reported to the Secretary through an amendment submitted at the time the change is made.

"(d) SPECIAL DETERMINATION FOR A BIOLOGICAL PRODUCT.—A determination shall be made prior to approval of a biological product under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) whether the product can be adequately characterized for purposes of this subsection. With respect to biological products approved prior to the date of enactment of the Food and Drug Administration Performance and Accountability Act of 1995, the determination shall be made within 90 days

after the date of enactment of such Act. Any determination under this subsection is subject to change based upon new scientific information.''.

SEC. 605. INSULIN AND ANTIBIOTICS.

(a) CERTIFICATION OF DRUGS CONTAINING INSULIN.—Section 506 (21 U.S.C. 356) is repealed.

(b) CERTIFICATION OF ANTIBIOTICS.—Section 507 (21 U.S.C. 357) is repealed.

(c) EXPORTATION.—Section 802 (21 U.S.C. 382), as amended by section 502(b), is further amended by adding at the end thereof the following new subsection:

''(g) EXPORTATION OF UNAPPROVED PRODUCTS.—Insulin and antibiotics may be exported without regard to the requirements in this section if the insulin and antibiotics meet the requirements in subsection (e)(1).''.

SEC. 606. BIOLOGICAL PRODUCTS.

(a) MODERNIZATION OF REGULATION OF BIOLOGICAL PRODUCTS.—

(1) IN GENERAL.—Section 351 of the Public Health Service Act (42 U.S.C. 262) is amended by striking ''SEC. 351. (a)'' and all that follows through ''exchange the same.'' and inserting the following:

''SEC. 351. (a)(1) Except as provided in paragraph (4), no person shall introduce or deliver for introduction into interstate commerce any biological product unless—

‘‘(A) a product license has been issued for the biological product;

‘‘(B) the biological product has been propagated, manufactured, or prepared in accordance with good manufacturing practices established by the Secretary under section 501(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351(a)); and

‘‘(C) each package of the biological product is plainly marked with the proper name of the biological product contained therein, the name, address and license number of the manufacturer of the biological product, and the expiration date of the biological product.

‘‘(2) The Secretary shall establish, by regulation, requirements for product license applications for biological products. A product license application for a biological product, other than blood, blood components, and blood products, shall be approved based upon a demonstration that the product that is the subject of the application is safe and effective in accordance with section 505(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(d)). A license application for blood, a blood component, or a blood product shall be approved based upon a demonstration that the product that is the subject of the application is safe, pure, and, where appropriate, potent.

''(3)(A) If the Secretary determines that grounds for a suspension or revocation of a license for a biological product exist that constitute a danger to health, the Secretary shall suspend the license, notify the licensee of the suspension, and require notification of the suspension to any consignee. Within 30 days after the date of the receipt by the licensee of a notification of suspension, the Secretary shall afford the licensee an opportunity for a hearing in accordance with section 554 of title 5, United States Code.

''(B) If at any time before the Secretary has taken final action to suspend or revoke a license the licensee requests an inspection by the Secretary to determine whether the licensee is in compliance with applicable standards, the Secretary shall conduct an inspection within 30 days of the date of the request. If the Secretary fails to conduct the inspection within the 30 days, the action to suspend or revoke the license shall become null and void. If the inspection confirms that the licensee is in compliance with all applicable requirements, the Secretary shall withdraw any proposed action within 30 days of the inspection.

''(4) The requirements of paragraph (1) do not apply to a biological product for which there is in effect an investigational new drug application under section 505(i) of the Federal Food, Drug, and Cosmetic Act.''.

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

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

(3) INSPECTION.—Section 351(c) of the Public Health Service Act (42 U.S.C. 262(c)) is amended by striking ''virus, serum, toxin, antitoxin, vaccine, blood, blood component, or blood product, or derivative allergenic product or other product aforesaid'' and inserting ''biological product''.

(4) DEFINITION; APPLICATION.—Part F of title III of the Public Health Service Act (42 U.S.C. 262 et seq.) is amended by adding at the end thereof the following new subsections:

''(i) For purposes of this section, the term 'biological product' means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic biologic product, or arsphenamine or its derivative (or any other analogous biological product) applicable to the prevention, treatment, or cure of diseases or conditions of human beings.

''(j)(1) Sections 505(i), 903, and 904 of the Federal Food, Drug, and Cosmetic Act shall apply to all biological products and references in those sections to new drug applications shall be deemed to include product license applications.

''(2) Requirements involving labeling or advertising for biological products shall be established in accordance with sections 201(m) and 502(n) of the Federal Food, Drug, and Cosmetic Act.

(b) HARMONIZATION OF REGULATION OF BIOLOGICAL PRODUCTS AND NEW DRUGS.—Not later than 2 years after the date of enactment of this section, the Secretary of Health and Human Services shall harmonize regulations governing product license applications required under section 351 of the Public Health Service Act (42 U.S.C. 262) with the regulations governing new drug applications required under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355).

SEC. 607. REQUIREMENTS FOR EMERGING BIOTECHNOLOGY PRODUCTS.

Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services shall establish proposed regulations governing products of human tissue and cell therapy that shall—

(1) ensure the safety and effectiveness of the products under section 351 of the Public Health Service Act (42 U.S.C. 262 et seq.); and

(2) take in account whether regulation of facilities in which the products are manufactured or processed is sufficient to ensure safety and effectiveness of the products.

TITLE VII—DEVICE REGULATORY REFORM

SEC. 701. SHORT TITLE.

This title may be cited as the ''Medical Device Reform Act of 1995''.

SEC. 702. PREMARKET NOTIFICATION.

(a) EXEMPTION OF CERTAIN DEVICES.—Section 510 (21 U.S.C. 360) is amended—

(1) in subsection (k), by striking ''intended for human use'' and inserting '' intended for human use (except a device that is classified into class I under section 513 or 520 or a device that is classified into class II under section 513 or 520, and is exempt from the requirements of this subsection under subsection (l))'';

(2) by adding at the end of subsection (k) (as amended by paragraph (1)) the following:

''The Secretary shall review the notification required by this subsection and make a determination under section 513(f)(1)(A) within 90 days of receiving the notification.''; and

(3) by adding at the end thereof the following new subsections:

''(l) Within 30 days of the date of enactment of this subsection, the Secretary shall publish in the Federal Register a list of each type of class II device that does not require a report under subsection (k) to provide reasonable assurance of safety and effectiveness. Each type of class II device so identified by the Secretary not to require the report shall be exempt from the requirement to file a report under subsection (k) as of the date of the publication of the list in the Federal Register. Beginning on the date that is 1 day after the date of the publication of a list under this subsection, any person may petition the Secretary to exempt a type of class II device from subsection (k). The Secretary shall respond to the petition within 120 days of the receipt of the petition and determine whether or not to grant the petition in whole or in part.

''(m) The Secretary may not withhold a determination of the initial classification of a device under subsection 513(f)(1) because of a failure to comply with any provision of this Act unrelated to a substantial equivalence

decision, including a finding that the facility in which a device is manufactured is not in compliance with good manufacturing practice requirements as set forth in regulations promulgated under the authority of subsection 520(f).''.

(b) INITIAL CLASSIFICATION.—Section 513(f)(1) (21 U.S.C. 360c(f)(1)) is amended in the second sentence, by striking the period at the end thereof and inserting the following: '', unless within 30 days of receiving an order classifying the device into class III, the individual who submits a notification under section 510(k) requests an advisory committee review and recommendation with respect to the classification of the device and a final order of classification from the Secretary. After the request, a device classified into class III under this paragraph shall not be deemed to be finally classified until an advisory committee established under subsection (b) reviews the request with respect to the classification of the device and, within 60 days of the date of receiving the request, recommends to the Secretary a classification for the device based on the classification criteria set forth in subparagraphs (A) through (C) of subsection(a)(1). Thereafter, the Secretary shall have 10 days to determine by order the final classification of the device by applying the classi-

fication criteria set forth in subparagraphs (A) through (C) of subsection(a)(1).

(c) SUBSTANTIAL EQUIVALENCE.—Section 513(i)(1) (21 U.S.C. 360c(i)(1)) is amended by adding at the end thereof the following new subparagraph:

''(C) For the purpose of determining the intended use of a predicate device under paragraph (A), each use included within a general use for the predicate device shall be deemed a legally marketed use of the predicate device for purposes of premarket notifications required under subsection 510(k).''.

(d) DEVICE MODIFICATION.—Section 513(i) (21 U.S.C. 360c(i)) is amended by adding at the end thereof the following new paragraph:

''(4) Any change or modification to a device initially classified under section 513(f), other than a major change (including any major modification) in the intended use, shall not require an additional submission under section 510(k) if such change or modification is supported by appropriate data or information, and the change or modification can be shown to not adversely affect the safety or effectiveness of the device. All data or information relied upon to document that a change to (including any modification of) the device does not require an additional notification under section 510(k) shall be made available to the

Secretary upon request and shall be maintained, at least for a period of time equal to the commercial life of the device.''.

SEC. 703. MEDICAL DEVICE APPROVAL STANDARDS.

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

(1) by striking ''well-controlled investigations'' and inserting ''a scientific investigation'';

(2) by striking ''clinical investigations'' and inserting ''a clinical investigation'';

(3) by striking ''investigations it'' and inserting ''investigation it''; and

(4) by adding the following to the end thereof the following new sentence: ''The Secretary may require a well-controlled clinical investigation to demonstrate effectiveness if the director of the Office of Device Evaluation explains in writing the basis therefor.''.

SEC. 704. TRACKING.

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

''DEVICE TRACKING

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

''(1) the failure of which would be life-threatening or have permanently debilitating effects; and

''(2) which is—

''(A) permanently implanted; or

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

SEC. 705. POSTMARKET SURVEILLANCE.

Section 522(1) (21 U.S.C. 360*l*) is amended to read as follows:

''SEC. 522. POSTMARKET SURVEILLANCE.

''(a) IN GENERAL.—The Secretary may require a manufacturer to conduct postmarket surveillance for any device of the manufacturer first introduced or delivered for introduction into interstate commerce after January 1, 1991, that—

''(1) is a permanent implant the failure of which may cause serious, adverse health consequences or death;

''(2) is intended for a use in supporting or sustaining human life; or

''(3) potentially presents a serious risk to human health.

''(b) SURVEILLANCE APPROVAL.—Each manufacturer required to conduct a surveillance of a device under subsection (a) shall, within 30 days of receiving notice

from the Secretary that the manufacturer is required under this section to conduct the surveillance, submit for the approval of the Secretary, a protocol for the required surveillance. The Secretary, within 60 days of the date of the receipt of the protocol, shall determine if the principal investigator proposed to be used in the surveillance has sufficient qualifications and experience to conduct the surveillance and if the protocol will result in collection of useful data or other information necessary to protect the public health and to provide safety and effectiveness information for the device. The Secretary may not approve the protocol until the protocol has been reviewed by a qualified scientific and technical review committee established by the Secretary.''.

SEC. 706. DEVICE DISTRIBUTOR REPORTING.

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

(1) by striking '', importer, or distributor'' each place it appears and inserting ''or importer'';

(2) in subsection (a)—

(A) in paragraph (8), by striking ''; and'' and inserting a period; and

(B) by striking paragraph (9); and

(3) by striking subsection (f).

SEC. 707. PREMARKET APPROVAL.

(a) ACTION ON APPLICATION.—Section 515(d) (21 U.S.C. 360e(d)) is amended—

(1) in paragraph (1)(A), by striking ''paragraph (2) of this subsection'' each place it appears and inserting ''paragraph (4)'';

(2) in paragraph (1)(B), by adding at the end thereof the following new clause:

''(iii) The Secretary shall accept and review data and any other information from investigations conducted under the authority of regulations required by section 520(g) to make a determination of whether there is a reasonable assurance of safety and effectiveness of a device subject to a pending application under this section if—

''(I) the data or information is derived from investigations of an earlier version of the device, the device has been modified during or after the investigations, and the modification of the device does not constitute a significant change in the design or in the basic principles of operation of the device that would invalidate the data or information; or

''(II) the data or information on a device approved under this section is available for use under this Act and is relevant to the design and intended use of the device subject to the pending application.'';

(3) by redesignating paragraphs (2) and (3) as paragraphs (4) and (5), respectively; and

(4) by inserting after paragraph (1) the following new paragraph:

"(2) Each application received under section 515(c) shall be reviewed in the following manner to achieve final action on the application within 180 days of the receipt of the application:

"(A) The Secretary shall meet with an applicant within 90 days of the receipt of the application to discuss the review status of the application. If the application does not appear in a form that would require an approval under subsection (d), the Secretary shall in writing, and prior to the meeting, present to the applicant a description of any deficiencies in the application and what information is required to bring the application into a form that would require an approval.

"(B) The Secretary shall refer an application to a panel established under section 513 for review and an approval recommendation, unless a panel is not required under subsection (c)(2), within 30 days of the date of the meeting referred to in subparagraph (A) or at the next scheduled panel meeting following

the meeting referred to in subparagraph (A), whichever occurs later.

''(C) The Secretary shall meet with the applicant within 15 days of the date of the panel review to discuss the status of the application, including a discussion on what action is necessary to bring the application into a form that would require approval under this subsection. Prior to the meeting, the Secretary shall in writing shall set forth an agenda for the meeting (including a complete description of the subject matter to the discussed at the meeting), and a full description of the additional information necessary to bring the application into a form that would require an approval under subsection (d). Participation of the applicant at such a meeting shall be at the discretion of the applicant.

''(D) The Secretary shall meet with the applicant not later than 135 days after the receipt of an application under subsection (c), if an advisory panel is not required under subsection (c)(2), and inform the applicant whether or not the application is in a form that would require approval under subsection (d). If the application is in such form, the Secretary shall, at or prior to the meeting, present in writing to the applicant a description of all additional infor-

mation necessary to require an approval of the application under subsection (d). If the application is not in such form, the Secretary shall deny approval of the application and prior to the meeting, present in writing to the applicant each basis for denying approval of the application and the additional information required to bring the application into a form that would require approval.

''(E) The Secretary shall issue an order approving or denying an application within 180 days of the receipt of the application under subsection (c).

''(3)(A) Except as provided in subparagraph (B), the time for the review of an application by the Secretary under this subsection shall take not more than 180 days and may not be extended if the application is amended.

''(B) The Secretary may not take more than 120 days for the review of an application subject to an expedited review under paragraph (1)(A) and may not extend the 120-day period if the application is amended.''.

(b) REGULATIONS.—The Secretary shall revise through notice and comment procedures the regulations set forth in part 814 of title 21 of the Code of Federal Regulations, to conform to the amendment made by paragraph (1) and to eliminate premarket approval of supple-

ments that relate to manufacturing changes and other changes that do not affect device safety or effectiveness.

SEC. 708. DEVICE PERFORMANCE STANDARDS.

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

''PRODUCT REVIEW

''(c)(1) For the purpose of facilitating a review of a device under sections 510(k), 515, and 520, any person may submit a petition under this subsection for the recognition by the Secretary of an existing performance standard for a device.

''(2) A petition under this subsection shall be made following the adoption of a voluntary performance standard by any qualified governmental or nongovernmental organization established to develop performance standards.

''(3) The petition shall identify the specific standard, the organization that adopted the standard, and the date on which the standard was adopted by the organization.

''(4) Upon the receipt of a petition under this subsection, the Secretary shall place the petition on public display and within 30 days after the date of the receipt of the petition, the Secretary shall publish a notice in the Federal Register setting forth the proposed standard, stating that the entire application is publicly available for review, and providing 60 days for public comment.

‘‘(5) Within 150 days after the receipt by the Secretary of the application, the Secretary shall—

‘‘(A)(i) grant the petition in whole or in part; or

‘‘(ii) deny the petition in whole or in part if the Secretary demonstrates that the standard does not establish an adequate performance standard for the functions of a device for which the standard is represented to apply; and

‘‘(B) publish a notice of the determination in the Federal Register.

‘‘(6) Upon the approval of the petition, the Secretary shall publish in the Federal Register the order listing the name of the recognized standard and shall provide any person who requests the recognized standard a copy of the standard.

‘‘(7) Following the publication of a final regulation listing a recognized standard, any premarket notification for a device submitted under sections 510(k), 513(f)(1), and 513(i) and any premarket approval application submitted under section 515 may include a certification of compliance with the standard, which shall constitute full and complete satisfaction of the requirements for safety and effectiveness for the functions of the device for which the standard is represented to apply.

''(8) Any modification of a recognized standard shall be subject to review under the procedure established in this subsection for the modified standard to become a recognized standard.''.

(b) ADULTERATED DEVICE.—Section 501(c) (21 U.S.C. 351(c)) is amended by striking ''section 514'' and inserting ''section 514(b)''.

TITLE VIII—ANIMAL DRUG REGULATORY REFORM

SEC. 801. SHORT TITLE.

This title may be cited as the ''Animal Drug Regulatory Reform Act of 1995''.

SEC. 802. NEW ANIMAL DRUG APPROVAL STANDARDS.

(a) SUBSTANTIAL EVIDENCE.—Section 512(d)(3) (21 U.S.C. 360b(d)(3)) is amended by adding at the end thereof the following new sentences: ''Substantial evidence shall consist of at least data from one scientifically sound study (designed and conducted in a manner that is consistent with generally recognized scientific procedures and principles), which may be waived by the Secretary, and confirmatory evidence obtained before or after the study. The Director of the Center for Veterinary Medicine may require a field trial as part of substantial evidence if the Director of the Center for Veterinary Medicine demonstrates, in writing and specifying the basis therefor, that

no other form of scientifically sound study is adequate to show the effectiveness of the drug.''.

(b) COMBINATION OF DRUGS.—Section 512(d) (21 U.S.C. 360b(d)) is amended by adding at the end thereof the following new paragraph:

''(4) If a new animal drug contains more than one active ingredient or the labeling provides for the drug's use in combination with one or more other animal drugs, in evaluating such combination the Secretary shall consider whether—

''(A) the combination affects the safety of any active ingredient;

''(B) the combination interferes with a method of analysis for any active ingredient;

''(C) if the active ingredients have the same intended effect, each of the active ingredients makes a significant contribution to the labeled effectiveness; and

''(D) if the active ingredients do not have the same intended effect, the active ingredients provide appropriate concurrent therapy for a labeled target population.''.

(c) APPROVAL.—Section 512(c)(2)(F)(iii) (21 U.S.C. 360b(c)(2)(F)(iii)) is amended—

(1) by striking ''reports of new clinical or field investigations (other than bioequivalence or residue studies) and'' and inserting ''substantial evidence of effectiveness as defined in subsection (d)(4), any study of animal safety, or''; and

(2) by striking ''essential to'' and inserting '', required for''.

SEC. 803. RESIDUE LIMITATION.

Section 512(d)(1)(F) (21 U.S.C. 360b(d)(1)(F)) is amended to read as follows:

''(F) on the basis of information in the application or otherwise available to the Secretary, any labeled use of the drug will result in an unsafe residue of the drug;''.

SEC. 804. ADULTERATED DRUGS.

Section 501(a)(2) (21 U.S.C. 351(a)(2)) is amended—

(1) in subparagraph (A), by striking ''health; or'' and inserting ''health''; and

(2) in subparagraph (B), by striking ''possess;'' and inserting the following: ''possess; or (C) if it is a drug intended for use by animals other than man and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or ad-

ministered in conformity with current good manufacturing practice requirements (appropriate for animal drugs) adopted pursuant to regulations issued by the Secretary to ensure that such drug meets the requirements of this Act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess for use in animals other than man;''.

TITLE IX—FOOD REGULATORY REFORM

SEC. 901. SHORT TITLE.

This title may be cited as the ''Food Regulatory Reform Act of 1995''.

SEC. 902. INDIRECT FOOD ADDITIVES.

(a) APPROVAL.—Section 409 (21 U.S.C. 348) is amended by adding at the end thereof the following new subsection:

''ALTERNATIVE APPROVAL PROCEDURE

''(j)(1) As an alternative to the approval procedure established under subsection (b), any person may submit a notification for an indirect food additive under this subsection.

''(2) Any person who proposes to begin the introduction or delivery for introduction into interstate commerce of a product intended for use as an indirect food additive may submit to the Secretary, at least 90 days prior to

making such introduction or delivery, a notification containing information demonstrating that the labeled use of the product is safe.

''(3)(A) Within 90 days after the receipt of the notification by the Secretary, the Secretary shall either—

''(A)(i) approve the notification if the product is safe for its intended use; or

''(ii) disapprove the notification if there is a reasonable possibility that the article is not safe for its intended use; and

''(B) publish a notice of this determination in the Federal Register and, if the notification is approved, promulgate an appropriate regulation pursuant to subsection (c).

If the Secretary does not publish such a notice in the Federal Register within the 90-day period, the notification shall be deemed to be approved and the Secretary shall immediately approve the notification and promulgate an appropriate regulation in the Federal Register pursuant to subsection (c).''.

(b) DEFINITION.—Section 201 (21 U.S.C. 321), as amended by section 606(c), is further amended by adding at the end thereof the following new subsection:

~~''(ii) The term 'indirect food additive' means a food additive that is intended to contact food but that is not intended for consumption as a food ingredient.''.~~

SECTION 1. SHORT TITLE.

This Act may be cited as the "Food and Drug Administration Performance and Accountability Act of 1996".

SEC. 2. TABLE OF CONTENTS.

The table of contents for this Act is as follows:

SEC. 3. REFERENCES.

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

TITLE I—MISSION AND ACCOUNTABILITY

SEC. 101. SHORT TITLE.

This title may be cited as the "Food and Drug Administration Regulatory Reform Act of 1996".

SEC. 102. THE MISSION OF THE FOOD AND DRUG ADMINISTRATION.

Section 903(a) (21 U.S.C. 393(a)) is amended by adding at the end thereof the following: "The mission of the Administration is to promote and protect the public health by—

"(1) facilitating the rapid and efficient development and availability of articles subject to the regulation of the Administration;

"(2) protecting the public from unsafe or ineffective articles subject to the regulation of the Administration; and

"(3) enforcing the applicable statutes and regulations in a timely, fair, consistent, and decisive manner.".

SEC. 103. PERFORMANCE STANDARDS AND REVIEW.

Section 903(b) (21 U.S.C. 393(b)) is amended by adding at the end thereof the following new paragraph:

"(3) PERFORMANCE STANDARDS AND REVIEW.—

"(A) IN GENERAL.—Not later than 180 days after the date of enactment of this paragraph, the Secretary, after consultation with experts in the development, clinical investigation, and regulation of drugs, biological products, new animal drugs, devices, food additives, and color additives and representatives of patient and consumer advocacy groups, health and technology professionals, and the regulated industries, shall develop and publish in the Federal Register quantifiable performance standards for action by the Administration on—

"(i) applications or submissions (including petitions, notifications, or any other similar form of request) for review of a protocol, a product investigation, a product approval, a new use approval, a manufacturing change, a change in labeling, or any

other form of regulatory action relating to the review of an article that is a new drug, biological product, new animal drug, device, food additive, or color additive and that is subject to premarket review or approval under this Act; and

"(ii) the scheduling of advisory committee meetings, and the action taken by the Administration following an advisory committee recommendation, relating to the applications and submissions described in clause (i).

"(B) REVIEW OF PERFORMANCE STANDARDS.—The performance standards required by subparagraph (A) shall be reviewed annually by the Secretary, and after consultation with experts in the development, clinical investigation, and regulation of drugs, biological products, new animal drugs, devices, food additives, and color additives, and representatives of patient and consumer advocacy groups, health and technology professionals, and the regulated industries, may be revised, annually by the Secretary.

"(C) AGENCY OBJECTIVES.—The performance standards required by subparagraph (A)

shall establish objectives for the Administration that—

"(i) expedite the clinical investigation of an article that is a new drug, device, or biological product through closer collaboration between the Administration and the sponsor of the investigation;

"(ii) expedite the review of an application for a new drug, device, or biological product—

"(I) for an immediately life-threatening disease or condition; or

"(II) for any other serious condition if the new drug, device, or biological product provides therapy that is not available from another approved therapy or offers significant improvement over another approved therapy or diagnostic or monitoring agents;

"(iii) reduce backlogs in the review of all applications with the objective of eliminating all backlogs in the review of applications by January 1, 1998;

"(iv) establish a schedule to bring the Administration into full compliance by

July 1, 1998, with the time periods specified in this Act for the review of all applications; and

"(v) improve the consistency and fairness of the regulatory process of the Administration.

The Secretary shall issue such other performance standards that the Secretary determines will contribute to the efficient, fair, and effective operation of the Administration.

"(D) ANNUAL REPORT.—The Secretary shall prepare and publish in the Federal Register for public comment an annual report that—

"(i) provides detailed data on the actual performance of the Administration relating to the action taken by the Administration with respect to the applications and submissions described in subparagraph (A)(i) and the activities relating to advisory committees described in subparagraph (A)(ii);

"(ii) compares the performance of the Administration with each applicable performance standard developed and published under subparagraph (A);

"(iii) describes—

"(I) any priorities established with respect to action to be taken by the Administration on matters relating to the applications and submissions described in subparagraph (A)(i) and the activities relating to advisory committees described in subparagraph (A)(ii);

"(II) how such priorities are implemented; and

"(III) the data on each priority category;

"(iv) analyzes any failure to achieve any of the performance standards;

"(v) identifies regulatory policies that have a significant impact on compliance with the performance standards and analyzes how such policies could be modified in order to achieve compliance with the performance standards; and

"(vi) sets forth a plan to achieve compliance with the performance standards that have not been met.

"(E) STATISTICAL INFORMATION.—The report described in subparagraph (D) shall include

a full statistical presentation relating to all applications, petitions, or notifications for a new drug, device, biological product, new animal drug, food additive, or color additive approved by the Administration during the year, taking into account the date of—

"(i) the submission of any investigational application;

"(ii) the application of any clinical hold;

"(iii) the submission of any application, petition, or notification for approval or clearance;

"(iv) the acceptance for filing of any application, petition, or notification for approval or clearance;

"(v) the occurrence of any unapprovable action;

"(vi) the occurrence of any approvable action; and

"(vii) the approval or clearance of any application, petition, or notification.".

SEC. 104. INTERAGENCY COLLABORATION.

Section 903(b) (21 U.S.C. 393(b)), as amended by section 103, is further amended by adding at the end thereof the following new paragraph:

"(4) INTERAGENCY COLLABORATION.—The Secretary shall implement programs and policies that will foster collaboration between the Administration, the National Institutes of Health, and other Federal science-based agencies, to enhance the scientific expertise available to the Commissioner for the evaluation of emerging medical therapies, including complementary therapies, and advances in nutrition and food science.".

SEC. 105. INFORMATION SYSTEM.

Chapter IX (21 U.S.C. 391 et seq.) is amended by adding at the end thereof the following new section:

"SEC. 906. INFORMATION SYSTEM.

"The Secretary shall establish and maintain an information system to track the status and progress of each application or submission (including a petition, notification, or other similar form of request) for the approval or clearance of a drug, biological product, new animal drug, device, food additive, or color additive submitted to the Food and Drug Administration. The system shall permit access by the applicant, petitioner, or the person who submits a notification.".

SEC. 106. POLICY STATEMENTS.

Section 701(a) (21 U.S.C. 371(a)) is amended—

(1) by striking "(a) The" and inserting "(a)(1) The"; and

(2) by adding at the end thereof the following new paragraph:

"(2)(A) Not later than 180 days after the date of enactment of the Food and Drug Administration Performance and Accountability Act of 1996, the Secretary shall establish a procedure governing the development and use of all policy statements of general applicability that provide guidance relating to the conduct of preclinical or clinical investigations or other testing to support an application or submission (including a petition, notification, or any other similar form of request) under section 409, 505, 510(k), 512, 515, or 721 or that provide guidance on the submission of an application or submission (including a petition, notification, or any other similar form of request) under section 409, 505, 510(k), 512, 515, or 721 (including any guidance, guideline, points-to-consider, protocol, recommendation, or similar document regardless of the form or designation). The procedure shall provide an opportunity for affected persons to participate in the development and continued use of a policy statement by sharing expertise or experience, or providing comment, before the policy statement is adopted and after the policy statement is implemented, except

that if the Secretary determines that there is a public health need to issue the policy statement immediately, the Secretary shall provide an opportunity for affected persons to provide comment promptly after the policy statement is issued.

"(B) The Secretary shall establish a procedure for the periodic compilation and publication of all policy statements of general applicability (including any guideline, points-to-consider, protocol, recommendation, or similar document regardless of the form or designation).".

SEC. 107. SCIENTIFIC REVIEW GROUPS.

Section 904 (21 U.S.C. 394) is amended—

(1) by striking "Without" and inserting "(a) IN GENERAL.—Without"; and

(2) by adding at the end thereof the following new subsections:

"(b) DELEGATION OF APPOINTMENT AUTHORITY.—The Commissioner may not delegate the appointment and oversight authority granted under subsection (a).

"(c) MEMBERSHIP AND MEETING REQUIREMENTS.—

"(1) SCOPE.—The Commissioner shall consult with a scientific review group in determining the matters that the group will consider at the meetings of the scientific review group.

"(2) NOTIFICATION OF SCOPE OF DISCUSSION.—To the extent feasible, the specific matters (including questions) to be discussed at a meeting of a scientific review group shall be publicly announced and published in the Federal Register at least 30 days prior to the date of the meeting.

"(3) TERMS.—A member of a scientific review group shall serve for a term of 3 years, and may have such membership renewed for not more than 1 additional term. An individual may serve on more than one scientific review group. The chairperson of a scientific review group shall be a member who has served on the scientific group for at least 3 years. The term of the chairperson may be renewed for not more than 3 terms.

"(4) TRAINING.—Prior to service on a scientific review group, a member of the group shall be given adequate education and training relating to the responsibilities of the member.

"(5) FREQUENCY OF MEETINGS.—The Secretary shall take whatever action is necessary to ensure that regular meetings are held by scientific review groups, at appropriate intervals and for a sufficient length of time. The meetings shall occur not less than 3 times

each year unless the Secretary determines that there are sufficient reasons for fewer meetings.

"(d) ACCESS TO INFORMATION; PARTICIPATION BY INTERESTED PERSONS IN MEETINGS.—

"(1) IN GENERAL.—When a scientific review group reviews an application or submission (including a petition, notification, or any other similar form of request) for approval or clearance, or some part thereof, submitted for an article under section 409, 505, 510(k), 513(f), 512, 515, or 721, the Secretary shall provide the person who submitted the application or submission with copies of all documents provided to the members of the scientific review group in preparation for a meeting of the scientific review group. The Secretary shall provide such documents to the person at the same time such documents are provided to the members of the scientific review group. Before the meeting, the person shall have an opportunity to submit documents to the members of the scientific review group in response to the Secretary's documents. The person shall provide the documents to the Secretary, who shall immediately provide copies of the documents to the members of the scientific review group.

"(2) PARTICIPATION IN MEETINGS.—Any meeting of a scientific review group shall include adequate time for initial presentations and for response to any differing views and the group shall encourage free and open participation by all interested persons.

"(e) FDA ACTIONS.—Not later than 60 days after the date a scientific review group makes its conclusions and recommendations on any matter under review of the group, the official of the Food and Drug Administration responsible for the matter shall review the conclusions and recommendations of the group, make a final determination on the matter, and notify the affected persons of the determination in writing and, if the determination differs from the conclusions and recommendations of the group, include the reasons for the difference.".

SEC. 108. APPEALS WITHIN THE FOOD AND DRUG ADMINISTRATION.

Chapter IX (21 U.S.C. 391 et seq.), as amended by section 105, is further amended by adding at the end thereof the following new section:

"SEC. 907. APPEALS WITHIN THE FOOD AND DRUG ADMINISTRATION.

"(a) EMPLOYEE DECISIONS.—The Secretary shall by regulation establish an internal appeal system within the Food and Drug Administration for the appeal of any deci-

sion made by an employee of the Food and Drug Administration, except that this subsection shall not apply to decisions involving formal administrative or judicial proceedings. As the final stage in the internal appeal system, the Secretary shall provide for the right to request an evaluation by an appropriate scientific review group of a final decision of the Secretary on an appeal involving a significant scientific issue. Upon receipt of such a request, the Secretary shall refer the request to the chairperson of the appropriate scientific review group, or a member designated by the chairperson, who shall review the request and determine whether the scientific review group should conduct an evaluation. The Secretary shall make publicly known the existence of the internal appeal system and the procedures for an internal appeal.

"(b) REVIEW BY SCIENTIFIC REVIEW GROUP.—

"(1) IN GENERAL.—The sponsor of a preclinical or clinical investigation, or the applicant for the approval or clearance of an application or submission (including a petition, notification, or any other similar form of request), shall have the right to request an evaluation by an appropriate scientific review group established under section 904 of any significant scientific issue pending before, or any significant scientific decision made by, the Secretary under this

Act. An appropriate scientific review group shall review the request and determine whether to conduct an evaluation within 30 days after the date the request is received by the Secretary.

"(2) SCOPE.—The significant scientific issues that a scientific review group may evaluate include matters involving a decision by the Secretary not to permit a clinical investigation to begin or to continue, a refusal by the Secretary to file an application, a protocol design, and decisions relating to a pending application or submission (including a petition, notification, or any other similar form of request). The significant scientific issues shall not have been previously reviewed by a scientific review group.

"(3) TIME LIMITATION.—If a scientific review group agrees to conduct an evaluation on an issue under paragraph (1), the evaluation shall be scheduled for the next meeting of the group.

"(c) ADDITIONAL INFORMAL AND FORMAL PROCEDURES.—

"(1) IN GENERAL.—For purposes of obtaining conclusions and recommendations regarding the resolution of any significant scientific dispute, the Secretary is authorized to use such additional informal

and formal procedures as may be considered useful. The procedures may include the use of—

"(A) panels of qualified Food and Drug Administration officials to make conclusions and recommendations regarding the resolution of any significant scientific dispute;

"(B) panels of qualified Federal Government employees who are not employees of the Food and Drug Administration to make conclusions and recommendations regarding the resolution of any significant scientific dispute; and

"(C) outside mediators and arbitrators who are not Federal Government employees to make conclusions and recommendations regarding the resolution of any significant scientific dispute.

"(2) APPLICATION OF FACA.—The Federal Advisory Committee Act (5 U.S.C. App. 2) shall not apply to a panel described in paragraph (1).

"(d) REVIEW OF RECOMMENDATIONS.—Not later than 60 days after the date on which a matter that is presented for resolution under this section has been the subject of conclusions and recommendations, the official of the Food and Drug Administration responsible for the matter shall review the conclusions and recommendations, make a final determination on the matter, and notify the parties of the deter-

mination in writing and if the determination differs from the conclusions and recommendations, the reasons for the difference.".

SEC. 109. APPOINTMENT AND TERM OF THE COMMISSIONER OF FOOD AND DRUGS.

(a) PURPOSE.—It is the purpose of this section to promote increased accountability of the Commissioner of Food and Drugs by providing for a limited term of appointment for the Commissioner of Food and Drugs.

(b) LIMITATION.—Section 903(b)(1) (21 U.S.C. 393(b)(1)) is amended by striking "the Senate." and inserting "the Senate for a term of 5 years. The Commissioner shall be appointed to serve 1 term. An individual serving in the office of Commissioner may be removed from office only pursuant to a finding by the President of neglect of duty or malfeasance in office.".

(c) APPLICABILITY.—The amendment made by subsection (b) shall not apply to the tenure of the individual who is serving as the Commissioner of Food and Drugs on the date of enactment of this Act.

TITLE II—EXPEDITED ACCESS TO PRODUCTS FOR SERIOUSLY ILL PATIENTS

SEC. 201. SHORT TITLE.

This title may be cited as the "Patient Rights Regulatory Reform Act of 1996".

SEC. 202. ACCESS TO UNAPPROVED THERAPIES.

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

"Subchapter D—Unapproved Therapies and Diagnostics and Collaborative Research

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

"(a) IN GENERAL.—Any person, through a licensed health care practitioner or licensed health care professional, may request from a manufacturer or distributor, and any manufacturer or distributor may provide to a person after compliance with the provisions of this section, an investigational drug (including a biological product) or investigational device for the diagnosis, monitoring, or treatment of a serious disease or condition, an immediately life-threatening or seriously debilitating disease or condition, or any other disease or condition designated by the Secretary as appropriate for expanded access under this section if—

"(1) the person has no comparable or satisfactory alternative therapy available to treat, diagnose, or monitor the disease or condition;

"(2) the risk to the person from the investigational drug or device is not greater than the risk from the disease or condition; and

"(3) an exemption for the investigational drug or device is in effect under a regulation promulgated pursuant to section 505(i) or 520(g) and the sponsor and investigators comply with such regulation.

"(b) PROTOCOLS.—A manufacturer or distributor may submit to the Secretary 1 or more expanded access protocols covering expanded access use of a drug or device described in subsection (a). The protocols shall be subject to the provisions of section 505(i) for a drug and section 520(g) for a device and may include any form of use of the drug or device outside a clinical investigation, prior to approval of the drug or device for marketing, including protocols for treatment, use, parallel track, emergency use, uncontrolled trials, and single patient protocols.

"(c) FEES.—A manufacturer or distributor may assess a fee for an investigational drug or device under an expanded access protocol so long as the fee is not more than that necessary to recover the costs of the manufacture and

handling of the drug or device. The Secretary shall be notified in advance of the assessing of any such fees.

"(d) NOTIFICATION OF AVAILABILITY.—The Commissioner shall inform national, State, and local medical associations and societies, voluntary health associations, and other appropriate persons about the availability of an investigational drug or device under expanded access protocols under this section. Such notification shall identify—

"(1) the investigational drug or device;

"(2) the expanded access use of the investigational drug or device; and

"(3) the name and address of the manufacturer or distributor that is providing the investigational drug or device for expanded access use.".

SEC. 203. EXPANDING HUMANITARIAN USE OF DEVICES.

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

(1) in paragraph (2), by inserting at the end thereof the following flush sentences:

"The request shall be in the form of an application submitted to the Secretary. Not later than 30 days after the date of the receipt of the application, the Secretary shall issue an order approving or denying the application.";

(2) by striking paragraph (5); and

(3) by striking paragraph (6).

SEC. 204. EXPEDITING APPROVAL OF NEW DRUGS, BIOLOGICS, AND MEDICAL DEVICES FOR SERIOUS CONDITIONS.

(a) NEW DRUGS.—Section 505(c)(1) (21 U.S.C. 355(c)(1)) is amended by adding at the end thereof the following flush sentence:

"In a case in which an application is submitted under subsection (b)(1) for a new drug, or section 351(a) of the Public Health Service Act for a biological product, that is intended for use for an immediately life-threatening or serious disease or condition and that provides therapy or diagnosis not available from another approved drug or biological product or offers significant improvement over another approved drug or biological product, the Secretary shall approve or deny approval of the application within 180 days after the receipt of the application.".

(b) PREMARKET APPROVAL.—

(1) AMENDMENT.—Section 515(d)(1)(A) (21 U.S.C. 360e(d)(1)(A)) is amended by adding at the end thereof the following flush sentence:

"With respect to an application submitted under this subsection for a device for a life-threatening disease or condition, a seriously debilitating disease or condition, or for any other serious disease or condition that provides therapy or diagnosis not available from another approved device or offers a significant improvement over another approved de-

vice, the Secretary shall approve or deny the approval of the application within 180 days after the receipt of the application.".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on July 1, 1998.

TITLE III—REVITALIZING THE INVESTIGATION OF NEW PRODUCTS

SEC. 301. SHORT TITLE.

This title may be cited as the "Investigational Products Regulatory Reform Act of 1996".

SEC. 302. TIMELY REVIEW AND REASONABLE DATA REQUIREMENTS FOR CLINICAL RESEARCH ON DRUGS AND BIOLOGICAL PRODUCTS.

Section 505(i) (21 U.S.C. 355(i)) is amended—

(1) by striking "(i) The" and inserting "(i)(1) The";

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

(3) by adding at the end thereof the following new paragraphs:

"(2)(A) A clinical investigation of a new drug (including a biological product) may begin 30 days after the date on which the Secretary receives from the sponsor of the investigation a notification containing information about the

drug and the clinical investigation unless, prior to the 30-day period, the Secretary informs the sponsor in writing that the investigation may not begin, and specifies the basis for the decision and the information needed in order for the clinical investigation to commence.

"(B) Not later than 1 year after the date of enactment of the Food and Drug Administration Performance and Accountability Act of 1996, the Secretary, after consultation with experts in the development, clinical investigation, and regulation of drugs, physicians and other health care practitioners, and representatives of patient and consumer advocacy groups and the regulated industries, shall publish in the Federal Register criteria for the type and amount of information relating to the safety of an investigational drug to be included in a notification described in subparagraph (A). In the establishment of the criteria, the Secretary shall take into account the recommendations of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use. The Secretary shall periodically review, and may revise, the criteria.

"(C) The Secretary shall establish a mechanism to ensure the fair and consistent application of safety standards for clinical investigations.

"(3)(A) The Secretary may place a clinical hold on any ongoing clinical investigation if the Secretary determines that such action is necessary for the protection of human subjects.

"(B) If the Secretary places a clinical hold on a clinical investigation, the Secretary shall immediately advise the sponsor for the investigation in writing of such action, and provide the sponsor an opportunity to meet with the Secretary, not later than 10 business days after the receipt of such a communication, to discuss the clinical hold. Not later than 10 days after such a meeting, the Secretary shall provide to the sponsor in writing the conditions for the withdrawal of the clinical hold. Any written request received by the Secretary from the sponsor requesting that a clinical hold be removed shall receive a decision, in writing and specifying the reasons therefor, not later than 20 days after the receipt of the request.".

SEC. 303. TIMELY REVIEW AND REASONABLE DATA REQUIREMENTS FOR CLINICAL RESEARCH ON DEVICES.

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

"(6) The procedures and conditions prescribed pursuant to paragraph (2)(A) shall be subject to subparagraphs (B) and (C) of section 505(i)(2), except that the provision

of subparagraph (B) of such section relating to the consideration of the recommendations of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use shall not apply to this paragraph.

"(7) The Secretary shall, not later than 120 days after the date of enactment of this paragraph, by regulation amend the content of parts 812 and 813 of title 21 of the Code of Federal Regulations to update the procedures and conditions under which devices intended for human use may upon application be granted an exemption from certain requirements under this Act. The regulation shall—

"(A) permit developmental changes in devices, including manufacturing changes, in response to information collected during an investigation without requiring an additional approval of an application for an investigational device exemption or the approval of a supplement to the application, if the sponsor of the investigation determines that, prior to making any changes, the changes do not constitute a significant change in design or a significant change in basic principles of operation; and

"(B) permit, without approval of a supplement to an application for an investigational device exemption, changes or modifications to clinical protocols

that do not affect the validity of data or information resulting from the completion of an approved protocol so long as such changes do not affect any patient protection provisions of the protocol.''.

SEC. 304. SENSE OF THE COMMITTEE CONCERNING MUTUAL RECOGNITION AGREEMENTS.

(a) FINDINGS.—The Committee on Labor and Human Resources of the Senate finds that there have been lengthy discussions between the members of the European Union and the Commissioner of Food and Drugs on the issue of mutual recognition agreements relating to the regulation of drugs, biological products, devices, foods, food additives, and color additives, and the regulation of good manufacturing practices.

(b) SENSE OF THE COMMITTEE.—It is the sense of the Committee on Labor and Human Resources of the Senate that—

(1) the Secretary of Health and Human Services, in consultation with the Secretary of Commerce, should move toward the acceptance of mutual recognition agreements relating to the regulation of drugs, biological products, devices, foods, food additives, and color additives, and the regulation of good manufacturing practices, reached between the European Union and the Commissioner of Food and Drugs;

(2) the Secretary of Health and Human Services should regularly participate in meetings with other foreign governments to discuss and reach agreement on methods and approaches to harmonize regulatory requirements; and

(3) the Office of International Relations of the Department of Health and Human Services (as established under section 803 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 383)) should have the responsibility of ensuring that the process of harmonizing international regulatory requirements is continuous.

SEC. 305. COLLABORATIVE RESEARCH DESIGN.

Chapter V (21 U.S.C. 351 et seq.), as amended by section 202, is further amended by adding at the end thereof the following new section:

"SEC. 552. COLLABORATIVE RESEARCH DESIGN.

"(a) REVIEW OF DESIGN.—

"(1) REQUEST.—Any person who intends to sponsor a preclinical or clinical investigation of a drug (including a biological product) or device may request a meeting with the Secretary to review the design of 1 or more protocols for the preclinical or clinical testing of the drug or device.

"(2) FORM.—A request described in paragraph (1) shall be in writing and shall include any protocol for which the review is requested. A protocol shall be designed so that the fewest number of patients and procedures necessary to obtain data necessary for the approval of a new drug, biological product, or device is required, consistent with public health and safety.

"(3) WRITTEN REVIEW.—The Secretary shall meet with the person within 30 days after the request and shall provide to the person a written review of the protocol, including any deficiencies in the protocol. A written summary shall be made of the meeting. The summary shall include the written review of the protocol and, after agreement by the person and the Secretary, shall be made part of the product review file maintained by the Food and Drug Administration.

"(b) MODIFICATION OF AGREEMENTS.—Any agreements reached through meetings with respect to the design of any protocol under subsection (a) may be modified only in accordance with the following provisions:

"(1) An agreement may be modified at any time by mutual consent of the sponsor of a preclinical or clinical investigation and the Secretary.

"(2) An agreement may be modified by the sponsor unilaterally, if the change is to a protocol and the change is one that would not require the approval of the Secretary under the applicable regulations.

"(3) An agreement may be modified by the Secretary unilaterally, if the change to the agreement is—

"(A) made by the director of the office of the Food and Drug Administration responsible for regulating the drug or device that is the subject of the agreement; and

"(B) set forth in writing, including an explanation of the scientific or clinical need for the change.

The director described in paragraph (3)(A) may not delegate the regulatory responsibility described in such paragraph.

"(c) APPEALS.—Any person requesting a meeting under subsection (a) may appeal the decision of the Secretary to disapprove or modify an agreement or protocol under section 907.

"(d) GUIDELINES AND LIMITATION.—The Secretary shall issue guidelines to implement this section. Such guidelines shall address the responsibilities of the person requesting the meeting, as well as the responsibilities of the Sec-

retary. Repeated failure to follow the guidelines may be grounds for a refusal by the Secretary to meet with a person requesting a meeting under this section.".

TITLE IV—EFFICIENT, ACCOUNTABLE, AND FAIR PRODUCT REVIEW

SEC. 401. SHORT TITLE.

This title may be cited as the "Product Review Regulatory Reform Act of 1996".

SEC. 402. THE CONTENT AND REVIEW OF AN APPLICATION.

Chapter VII (21 U.S.C. 371 et seq.) is amended by adding at the end thereof the following new subchapter:

"Subchapter D—Review of Applications, Inspections, Environmental Impact Reviews, and Manufacturing Changes

"SEC. 741. CONTENT AND REVIEW OF AN APPLICATION.

"(a) IN GENERAL.—This section applies to an application or submission (including a petition, notification, or any other similar form of request) submitted for approval or clearance of a new drug, device, biological product, new animal drug, animal feed bearing or containing a new animal drug, color additive, or food additive.

"(b) FILING REQUIREMENTS.—Not later than 60 days after the date of enactment of this section, the Commissioner shall establish and publish in the Federal Register a mecha-

nism to ensure the fair and consistent application of filing requirements.

"(c) CLASSIFICATION OF A PRODUCT.—Not later than 60 days after the receipt of a written request of a person who submits an application or submission (including a petition, notification, or any other similar form of request) for information respecting the classification of an article as a drug, biological product, or device or the component of the Food and Drug Administration that will regulate the article (including a request respecting a combination product subject to section 503(g)), the Secretary shall provide the person a written statement that identifies the classification of the article or the component of the Food and Drug Administration that will regulate the article. The Secretary's statement shall be binding and may not be modified by the Secretary except with the written agreement of the person who submitted the request. If the Secretary does not provide the statement within the 60-day period, the classification and component designated by the person submitting the request shall be final and binding and may not be modified by the Secretary except with the written agreement of the person.

"(d) REASONABLE DATA REQUIREMENTS.—Not later than 1 year after the date of enactment of the Food and Drug Administration Performance and Accountability Act

of 1996, the Secretary, after consultation with experts in the development and testing of articles that are new drugs, biological products, devices, food additives, new animal drugs, animal feed bearing or containing a new animal drug, color additives, or food additives, experts in the regulation of such articles, consumer and patient advocacy groups, and the regulated industries, shall publish in the Federal Register criteria for the type and amount of information relating to safety or effectiveness to be included in an application for the approval of an article that is a new drug, biological product, device, food additive, new animal drug, animal feed bearing or containing a new animal drug, color additive, or food additive, or a new use of an approved article that is a new drug, biological product, device, food additive, new animal drug, animal feed bearing or containing a new animal drug, color additive, or food additive. In establishing the criteria for drugs, the Secretary shall consider any recommendations of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.''.

SEC. 403. CONTRACTS FOR EXPERT REVIEW.

Chapter VII (21 U.S.C. 371 et seq.), as amended by section 402, is further amended by adding at the end thereof the following new section:

"SEC. 742. CONTRACTS FOR EXPERT REVIEW.

"(a) IN GENERAL.—

"(1) AUTHORITY.—The Secretary may contract with outside organizations and individuals, with expertise in relevant disciplines, to review, evaluate, and make conclusions and recommendations to the Secretary on parts or all of any application or submission (including a petition, notification, or any other similar form of request). The Secretary shall retain full authority to make determinations with respect to the approval or disapproval of any article, or the classification of a device under section 513(f)(1). Any such contract shall be subject to the requirements of section 708. Funds obtained under part 2 of subchapter C may be used for external review of any drug (including a biological product) for which a user fee was paid.

"(2) INCREASED EFFICIENCY AND EXPERTISE THROUGH CONTRACTS.—The Secretary shall use the authority granted in paragraph (1)—

"(A) for the review of categories of indirect food additive petitions and notifications for clearance under section 510(k);

"(B) whenever contracts will improve the efficiency, timeliness, and quality of the review of applications or submissions (including petitions,

notifications, or any other similar form of requests) for the approval or clearance of new drugs, new animal drugs, biological products, devices, and food additives; and

"(C) whenever contracts will increase the scientific and technical expertise that is necessary to keep informed of emerging new therapies and technologies that pose significant new scientific and technical issues.

The Secretary shall retain full authority to make determinations with respect to the approval or disapproval of an article, or the classification of an article as a device under section 513(f)(1).

"(b) ELIGIBILITY REQUIREMENTS.—Not later than 90 days after the date of enactment of this section, the Secretary shall by regulation establish the requirements that an organization or individual shall meet to be eligible to conduct reviews under subsection (a). Such regulations shall provide for the protection of confidential or proprietary information and shall provide for protection against conflicts of interest.

"(c) REVIEW OF EXPERT'S EVALUATION.—

"(1) IN GENERAL.—Subject to paragraph (2), the official of the Food and Drug Administration responsible for any matter for which expert review is used

pursuant to this section shall review the conclusions and recommendations of the expert review organization or individual and shall make a final decision regarding the matter under review within 60 days after receiving the conclusions and recommendation.

"(2) LIMITATION.—A final decision under paragraph (1) shall be made within the applicable prescribed time period for review of an application as set forth in this Act.

"(d) REPORT TO CONGRESS.—Not later than 2 years after the date of enactment of this section, the Secretary shall prepare and submit to Congress a report on the use of the authority to contract with outside organizations and individuals for expert reviews. Such report shall include an evaluation of the extent to which such contracting improves the efficiency of review and the expertise available to the Food and Drug Administration.".

SEC. 404. PROMPT AND EFFICIENT REVIEW.

Chapter VII (21 U.S.C. 371 et seq.), as amended by section 403, is further amended by adding at the end thereof the following new section:

"SEC. 743. PROMPT AND EFFICIENT REVIEW.

"(a) IN GENERAL.—The provisions of this section shall apply to any of the following applications, petitions, and notifications:

"(1) A petition for the issuance of a regulation prescribing the safe use of a human food additive or animal feed additive under section 409.

"(2) An application for approval of a new drug under section 505.

"(3) An application for approval of a new animal drug or an animal feed bearing or containing a new animal drug under subsection (b) or (m) of section 512, respectively.

"(4) A notification submitted under section 510(k) for classification of a device.

"(5) An application for approval of a device under section 515.

"(6) A petition for issuance of a regulation for the listing of a color additive under section 721.

"(b) REVIEW PROCEDURES AND POLICIES.—The Secretary shall establish procedures and policies to facilitate a collaborative review process between the Commissioner and the applicant, petitioner, or person who submits a notification with respect to an application, petition, or notification described in subsection (a). As part of this collaborative process—

"(1) open, informal, and prompt communications shall be encouraged;

"(2) meetings (except that meetings shall not be required with respect to matters relating to a notification submitted under section 510(k)) shall be held before the expiration of one-half of the statutory time period for review of the application or petition and before the expiration of three-quarters of such period, or within 15 days after a scientific review group has convened and made recommendations on an application or petition, unless the Commissioner and the applicant or petitioner determine that a meeting is unnecessary;

"(3) by mutual consent, the Commissioner and the applicant or petitioner may establish a different schedule for meetings required under paragraph (2); and

"(4) the Secretary shall, prior to the meetings described in paragraph (2), present to the applicant or petitioner in writing a description of any deficiencies of the application or petition and the information necessary to bring the application or petition into a form that would require approval.

The Secretary and the applicant or petitioner may agree to supersede any procedures and policies adopted under this section and the requirements of paragraphs (2) and (3).

Any such agreement shall be in writing, and shall specify how any such agreement shall be modified or set aside.

"(c) APPROVAL, DISAPPROVAL, AND CLASSIFICATION.—

"(1) CONSIDERATION OF INTERNATIONAL APPROVALS.—Beginning July 1, 1998, if the Secretary fails to meet a time period for action on an application or notification for the approval or clearance of an article that is a new drug, device, biological product, or new animal drug that offers a significant improvement over an existing approved article or a petition for the approval of a direct food additive that has the potential to make foods more wholesome and contribute to a healthier diet, and such an article has been approved for marketing in the European Union or the United Kingdom, the Secretary shall, within 30 days after a request of a person who submits an application, notification, or petition described in this paragraph, either approve or disapprove the application, notification, or petition and notify the person in writing of that decision. In the case of a disapproval, or a determination that a device is not substantially equivalent, such notification shall set forth the reasons for the disapproval or the determination.

"(2) APPEAL.—A person whose application, notification, or petition has been disapproved (including a determination that a device does not meet the requirements relating to substantial equivalence) under paragraph (1) may obtain judicial review under—

"(A) section 505(h) for the disapproval of a new drug under paragraph (1);

"(B) section 517 for the disapproval of a device or a determination of not substantially equivalent relating to a device under paragraph (1);

"(C) chapter VII of title 5, United States Code, for the disapproval of a license for a biological product under paragraph (1);

"(D) section 512(h) for the disapproval of a new animal drug under paragraph (1); and

"(E) section 409(g) for the disapproval of a direct food additive under paragraph (1).

"(d) CONTRACTS FOR EXPERT REVIEW.—

"(1) IN GENERAL.—Beginning July 1, 1998, if the Secretary in any fiscal year fails to meet the statutory time period for action on an application, notification, or petition for at least 95 percent of the applications, notifications, and petitions submitted in a particular product category, the Secretary shall—

"(A) in the following fiscal year, contract with expert organizations and individuals under section 742, to review applications, notifications, and petitions of persons who submit the applications, notifications, and petitions in that following fiscal year and who consent to the review; and

"(B) in the following fiscal year and with the consent of the persons described in this subparagraph, contract with expert organizations and individuals under section 742, to review applications, notifications, and petitions that were submitted by persons in any preceding fiscal year and that the Secretary has failed to review within the statutory time period for action on the applications, notifications, and petitions with respect to the particular product category.

"(2) APPROVAL.—If an organization or individual selected to conduct a review under paragraph (1) recommends the approval or clearance of an application, notification, or petition described in paragraph (1), the Secretary shall, within 60 days after receiving the determination of the organization or individual (but not later than the time period for review set forth in this Act), either approve or disapprove the

application, notification, or petition, and, in the case of a disapproval, notify the person who submitted the application, notification, or petition in writing of the basis for the disapproval. The person may appeal an adverse decision under subsection (c)(2).".

SEC. 405. GOOD MANUFACTURING PRACTICE INSPECTION.

Chapter VII is (21 U.S.C. 371 et seq.), as amended by section 404, is further amended by adding at the end thereof the following new section:

"SEC. 744. GOOD MANUFACTURING PRACTICE INSPECTION.

"(a) IN GENERAL.—In order to comply with the inspection requirements of this Act, the Secretary may accredit organizations to conduct inspections under section 704 to evaluate compliance of a manufacturer with applicable requirements for good manufacturing practice.

"(b) ELIGIBILITY REQUIREMENTS.—If the Secretary elects to accredit organizations to conduct inspections under section 704, the Secretary shall by regulation, within 90 days after the date of enactment of this section, establish the requirements that an organization shall meet to be eligible to be accredited to participate as a qualified organization to conduct inspections under subsection (a). Such regulation shall provide for the protection of confidential or proprietary information and shall provide for protection against conflicts of interest.

"(c) ACCREDITATION.—Not later than 90 days after the date on which the Secretary receives an application for accreditation under this section, the Secretary shall review the application and determine whether an applicant is in compliance with the requirements established under this section. Within the 90-day period, the Secretary shall grant accreditation or shall deny accreditation and specify in writing the reasons for the denial and the requirements that shall be met to obtain accreditation.

"(d) REVOCATION OF ACCREDITATION.—The Secretary may at any time revoke accreditation granted under subsection (c) for failure to comply with the requirements established under this section after specifying in writing the reasons for the revocation and the requirements that shall be met to retain accreditation and after an informal hearing on the revocation.

"(e) INSPECTIONS.—Any organization accredited under this section that conducts an inspection under this section at the request of the Secretary shall—

"(1) apply all relevant principles of good manufacturing practice established in this Act and in regulations promulgated by the Secretary;

"(2) provide to the Secretary and the manufacturer within 30 days after the completion of the inspection a report of the findings of the inspection; and

"(3) immediately provide the Secretary with a notice of any condition that could cause or contribute to a significant threat to the public health.".

SEC. 406. ENVIRONMENTAL IMPACT REVIEW.

Chapter VII (21 U.S.C. 371 et seq.), as amended by section 405, is further amended by adding at the end thereof the following new section:

"SEC. 745. ENVIRONMENTAL IMPACT REVIEW.

"Notwithstanding any other provision of law, no action by the Secretary pursuant to this Act shall be subject to an environmental assessment, an environmental impact statement, or other environmental consideration unless the director of the office responsible for the action demonstrates, in writing—

"(1) that there is a reasonable probability that the environmental impact of the action is sufficiently substantial and within the factors that the Secretary is authorized to consider under this Act; and

"(2) that consideration of the environmental impact will directly affect the decision on the action.".

SEC. 407. EFFECTIVENESS, OUTCOME, AND COST-EFFECTIVENESS STANDARDS.

Section 741, as added by section 402, is amended by adding at the end thereof the following new subsection:

"(e) LIMITATION ON DETERMINATION OF EFFECTIVENESS.—In a review of an application for an article that is a new drug, device, biological product, new animal drug, or animal feed bearing or containing a new animal drug, the determination of effectiveness shall not include the evaluation of—

"(1) any potential use not included in the labeling;

"(2) the cost-effectiveness of an article described in this subsection, unless the proposed labeling explicitly includes a representation about cost-effectiveness; and

"(3) the clinical outcome resulting from the use of a diagnostic device, unless the labeling explicitly includes a representation regarding clinical outcome.".

SEC. 408. DEFINITION OF A DAY FOR PURPOSES OF PRODUCT REVIEW.

Section 201 (21 U.S.C. 321) is amended by adding at the end thereof the following new paragraph:

"(gg) For purposes of reviewing any application or submission (including a petition, notification, or any other similar form of request), or any document, with respect to an article that is a new drug, device, biological product, new animal drug, an animal feed bearing or containing

a new animal drug, color additive, or food additive, that is submitted to the Secretary to obtain marketing approval, to obtain classification of a device under section 513(f)(1), or to establish or clarify the regulatory status of the article, the term 'day' means a calendar day in which the Secretary has responsibility to review such a submission (excluding any calendar day between the date of receipt by the submitter of a written communication from the Secretary setting forth the action of the Secretary on a submission and the date of receipt by the Secretary of the written response of the submitter to the action).".

SEC. 409. APPROVAL OF SUPPLEMENTAL APPLICATIONS FOR APPROVED PRODUCTS.

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

(b) GUIDANCE TO INDUSTRY.—Not later than 180 days after the date of enactment of this section, the Secretary of Health and Human Services shall issue guidances to clarify the requirements and facilitate the submission of data to support the approval of supplemental applications

for the approved articles described in subsection (a). The guidances shall—

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

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

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

(c) RESPONSIBILITIES OF CENTERS.—The Secretary of Health and Human Services shall designate an individual in each center within the Food and Drug Administration (except the Center for Food Safety and Applied Nutrition) to be responsible for—

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

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

(d) COLLABORATION.—The Secretary of Health and Human Services shall implement programs and policies that will foster collaboration between the Food and Drug Administration, the National Institutes of Health, profes-

sional medical and scientific societies, and others persons, to identify published and unpublished studies that could support a supplemental application, and to encourage sponsors to make supplemental applications or conduct further research in support of a supplemental application based, in whole or in part, on such studies.

SEC. 410. PEDIATRIC STUDIES MARKETING EXCLUSIVITY.

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 505 the following new section:

"SEC. 505A. PEDIATRIC STUDIES FOR NEW DRUG APPLICATIONS.

"(a) MARKET EXCLUSIVITY FOR APPROVED APPLICATIONS WITH PEDIATRIC STUDIES SUBMITTED BY AN APPLICANT.—If an application submitted under section 505(b)(1) is approved on or after the date of enactment of this section, and such application includes reports of pediatric studies described and requested in subsection (c), and such studies are completed and the reports thereof submitted in accordance with subsection (c)(2) or completed and the reports thereof accepted in accordance with subsection (c)(3), the Secretary may not make the approval of an application submitted under section 505(b)(2) or 505(j) that refers to the drug for which the section 505(b)(1) approval is granted effective prior to the expiration of 6 months from

the earliest date on which the approval of such application for the drug under section 505(b)(2) or 505(j), respectively, could otherwise be made effective under the applicable provisions of this chapter.

"(b) MARKET EXCLUSIVITY FOR APPROVED APPLICATIONS WITH PEDIATRIC STUDIES REQUESTED BY THE SECRETARY.—If the Secretary makes a written request for pediatric studies described in subsection (c) to the holder of an approval under section 505(b)(1) for a drug, and such studies are completed and the reports thereof submitted in accordance with subsection (c)(2) or completed and the reports thereof accepted in accordance with subsection (c)(3), the Secretary may not make the approval of an application submitted under section 505(b)(2) or 505(j) that refers to the drug subject to the section 505(b)(1) approval effective prior to the expiration of 6 months from the earliest date on which an approval of such application under section 505(b)(2) or 505(j), respectively, could otherwise be made effective under the applicable provisions of this chapter. Nothing in this subsection shall affect the ability of the Secretary to make effective a section 505(b)(2) or 505(j) approval for a subject drug if such approval is proper under such section and is made effective prior to the submission of the reports of pediatric studies described in subsection (c).

"(c) CONDUCT OF PEDIATRIC STUDIES.—

"(1) AGREEMENT FOR STUDIES.—The Secretary may, pursuant to a written request for studies and after consultation with the sponsor of an application or holder of an approval for a drug under section 505(b)(1), agree with the sponsor or holder concerning the conduct of pediatric studies for such drug.

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

"(3) OTHER METHODS TO MEET THE STUDIES REQUIREMENT.—If the sponsor or holder and the Secretary have not agreed in writing on the protocols for the studies, the studies requirement of subsection (a) or (b) is satisfied when such studies have been com-

pleted and the reports accepted by the Secretary. Not later than 90 days after the submission of the reports of the studies, the Secretary shall accept or reject such reports and so notify the sponsor or holder. The Secretary's only responsibility in accepting or rejecting the reports shall be to determine, within 90 days, that the studies fairly respond to the written request, that such studies have been conducted in accordance with commonly accepted scientific principles and protocols, and that such studies have been reported in accordance with the requirements of the Secretary for filing.

"(d) DELAY OF EFFECTIVE DATE FOR CERTAIN APPLICATIONS; PERIOD OF MARKET EXCLUSIVITY.—If the Secretary determines that an approval of an application under section 505(b)(2) or 505(j) for a drug may be made effective after the submission of reports of pediatric studies under this section but before the Secretary has determined whether the requirements of subsection (c) have been satisfied, the Secretary may delay the effective date of any approval under section 505(b)(2) or 505(j), respectively, until the determination under subsection (c) is made, but such delay shall not exceed 90 days. In the event that the requirements of this section are satisfied, the 6-month period referred to in subsection (a) or (b) shall be deemed to have begun on the date an approval of an application under section

505(b)(2) or 505(j), respectively, would have been permitted absent action under this subsection.

"(e) NOTICE OF DETERMINATIONS ON STUDIES REQUIREMENT.—The Secretary shall publish notice of any determination that the requirements of paragraph (2) or (3) of subsection (c) have been met and that approvals under section 505(b)(2) or 505(j) for a drug will be subject to deferred effective dates under this section.

"(f) DEFINITIONS.—As used in this section, the term 'pediatric studies' or 'studies' means at least 1 human clinical investigation in a population of adolescent age or younger. At the Secretary's discretion, pharmacokinetic studies may be considered as clinical investigations.".

SEC. 411. NOTIFICATIONS FOR DEVICE MARKET CLEARANCE.

Section 510(k) (21 U.S.C. 360(k)) is amended by striking "report to" and inserting "shall notify the Secretary to report to".

TITLE V—DRUG AND BIOLOGICAL PRODUCTS REGULATORY REFORM

SEC. 501. SHORT TITLE.

This title may be cited as the "Drug and Biological Product Regulatory Reform Act of 1996".

SEC. 502. NEW DRUG APPROVAL STANDARD.

Section 505(d) (21 U.S.C. 355(d)) is amended by adding at the end thereof the following new sentence: "Substantial evidence may consist of data from 1 well-controlled clinical investigation and confirmatory evidence obtained prior to, or after, such investigation.".

SEC. 503. PILOT AND SMALL SCALE MANUFACTURE.

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

"(4) A new drug or biological product manufactured in a pilot or other small facility may be used to demonstrate the safety and effectiveness of the drug or product and to obtain approval prior to scaling up to a larger facility, unless the Secretary demonstrates in writing and specifies in detail the reasons, after an informal hearing, that a full scale production facility is necessary to ensure the safety or effectiveness of the drug or product.".

SEC. 504. MANUFACTURING CHANGES.

Chapter VII (21 U.S.C. 371 et seq.), as amended by section 406, is further amended by adding at the end thereof the following new section:

"SEC. 746. MANUFACTURING CHANGES.

"(a) IN GENERAL.—A change in the manufacture of a new drug, biological product, or new animal drug, may be made in accordance with this section.

"(b) DRUG AND BIOLOGICAL PRODUCT.—A change in the manufacture of a new drug, a biological product that is the subject of a monograph in an official compendium, a biological product that can be adequately characterized by chemical, physical, or biological means, or a new animal drug—

"(1) shall require validation; and

"(2)(A) if there is no change in the approved qualitative and quantitative formulation relating to the new drug, biological product, or new animal drug or in the approved release specifications relating to the new drug, biological product, or new animal drug, or if there is a change in the approved qualitative or quantitative formula or in the approved release specifications of a type permitted by the Secretary by regulation, may be made at any time so long as the change is reported annually to the Secretary; or

"(B) in the case of a change other than a change described in subparagraph (A), shall require completion of an appropriate study demonstrating equivalence according to criteria established by the Secretary (unless such requirement is waived by the Secretary), may be made at any time, and shall be reported to the Secretary through a supplement or amendment submitted at the time the change is made.

"(c) BIOLOGICAL PRODUCT NOT SUBJECT TO A MONOGRAPH.—A change in the manufacture of a biological product that is not the subject of a monograph in an official compendium and cannot be adequately characterized by chemical, physical, or biological means—

"(1) shall require validation; and

"(2)(A) if the change relates solely to a modification of the manufacturing facility or change in personnel, with no change in the approved manufacturing process or release specifications, may be made at any time so long as the change is reported annually to the Secretary; or

"(B) in the case of a change other than a change described in subparagraph (A), shall require completion of a bioassay or other appropriate study demonstrating equivalence according to criteria established by the Secretary (unless such requirement is waived by the Secretary), may be made at any time, and shall be reported to the Secretary through an amendment submitted at the time the change is made.

"(d) SPECIAL DETERMINATION FOR A BIOLOGICAL PRODUCT.—A determination shall be made, prior to the approval of a biological product under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)), whether the product can be adequately characterized for purposes of this

section. With respect to biological products approved prior to the date of enactment of the Food and Drug Administration Performance and Accountability Act of 1996, the determination shall be made not later than 90 days after the date of enactment of such Act. Any determination made under this subsection is subject to change based upon new scientific information.".

SEC. 505. INSULIN AND ANTIBIOTICS.

(a) CERTIFICATION OF DRUGS CONTAINING INSULIN.—Section 506 (21 U.S.C. 356) is repealed.

(b) CERTIFICATION OF ANTIBIOTICS.—Section 507 (21 U.S.C. 357) is repealed.

(c) EXPORTATION.—Section 802 (21 U.S.C. 382) is amended—

(1) by redesignating subsection (h) as subsection (i); and

(2) by inserting after subsection (g) the following new subsection:

"(h) EXPORTATION OF UNAPPROVED PRODUCTS.—Insulin and antibiotics may be exported without regard to the requirements in this section if the insulin and antibiotics meet the requirements of section 801(e)(1).".

SEC. 506. MODERNIZATION OF REGULATION OF BIOLOGICAL PRODUCTS.

(a) IN GENERAL.—Section 351 of the Public Health Service Act (42 U.S.C. 262) is amended by striking "SEC. 351. (a)" and all that follows through "barter, or exchange the same." and inserting the following:

"SEC. 351. (a)(1) Except as provided in paragraph (6), no person shall introduce or deliver for introduction into interstate commerce any biological product unless—

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

"(B) each package of the biological product is plainly marked with the proper name of the biological product contained therein, the name, address, and applicable license number of the manufacturer of the biological product, and the expiration date of the biological product.

"(2) The license required under paragraph (1)(A) shall, as determined by the Secretary, cover the biological product, any facility in which the biological product is manufactured, processed, packed, or held, or both the product and facility.

"(3)(A) The Secretary shall establish, by regulation, requirements for license applications for biological products.

"(B) Except as provided in subparagraph (D), a license application that covers a biological product shall be approved based upon a demonstration that—

"(i) the product that is the subject of the application is safe and effective in accordance with sections 505(c) and 505(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355 (c) and (d)), or meets standards designed to ensure that the product is safe, pure, and where appropriate, potent; and

"(ii) the methods used in, and the facilities and control used for, the manufacture, processing, packing, and holding of such product meet standards designed to ensure that the product meets the requirements of clause (i).

"(C) A license application that covers a facility shall ensure that the product and the facility meet standards designed to ensure that the product meets applicable requirements of subparagraph (B).

"(D) A license application for blood or a blood component (including plasma) shall be approved based on a demonstration that the product is safe, pure, and where appropriate, potent, and that the facility in which the product is manufactured, processed, packed, or held meets standards designed to ensure that such product is safe, pure, and where appropriate, potent.

"(4)(A) Requirements prescribed under paragraph (3) shall include a requirement for preapproval inspection under subsection (c).

"(B) A license shall be approved only on condition that the licensee agrees to permit inspection of the facility of the licensee in accordance with subsection (c).

"(5)(A) Except as provided in subparagraph (C), an approved license for a biological product may be revoked if the Secretary determines, on the record after providing an opportunity for a hearing in accordance with section 554 of title 5, United States Code, that the requirements for approval as specified in paragraph (3) are no longer met with respect to such product, or that other public health reasons, prescribed by regulation, exist. No action to revoke a license based on the findings of an inspection shall be initiated prior to the submission and review by the Secretary of a written response submitted by the licensee to a notice of inspectional findings so long as such written response is received within 30 days after the date of receipt by the licensee of the findings. The revocation of any product license shall not prevent the continued use of any licensed biological product that has been sold and delivered by the licensee unless the biological product is subject to recall under subsection (d).

"(B) If at any time before the Secretary has taken final action to revoke a license, the licensee requests an inspection by the Secretary to determine whether the licensee is in compliance with applicable standards, the Secretary shall conduct an inspection within 30 days after the date of the request. If the inspection confirms that the licensee is not in compliance with applicable standards, the 30-day requirement for inspection shall not apply to any subsequent request by the licensee under this subparagraph for inspection. If the inspection confirms that the licensee is in compliance with all applicable requirements, the Secretary shall withdraw any proposed action within 30 days after the inspection.

"(C) If the Secretary determines that conditions exist that constitute a danger to health, the Secretary shall suspend the license, notify the licensee that the licensee's license is suspended, and require notification of the suspension to any consignee. Within 30 days thereafter, the Secretary shall initiate the hearing process under subparagraph (A).

"(6) The requirements of paragraph (1) do not apply to a biological product for which there is in effect an investigational new drug application under section 505(i) of the Federal Food, Drug, and Cosmetic Act.".

(b) DELETION OF ELA REQUIREMENT.—Section 351(d) of the Public Health Service Act (42 U.S.C. 262(d)) is amended—

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

(2) by redesignating paragraph (2)(A) as subsection (d)(1);

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

(4) in paragraph (2) (as so redesignated), by striking "subparagraph (A)" and inserting "paragraph (1)".

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

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

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

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

"(i) For purposes of this section, the term 'biological product' means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic biologic product, or arsphenamine or its derivative (or any other analogous biological product) applicable to the prevention, treatment, or cure of diseases or conditions of human beings.

"(j)(1) Sections 505(i), 903, and 904 of the Federal Food, Drug, and Cosmetic Act shall apply to all biological products, and references in such sections to new drug applications shall be deemed to include product license applications for biological products.

"(2) Requirements involving labeling or advertising for biological products shall be established in accordance with sections 201(m) and 502(n) of the Federal Food, Drug, and Cosmetic Act.".

SEC. 507. EFFECTIVE MEDICATION GUIDES.

Chapter IX (21 U.S.C. 391 et seq.), as amended by section 108, is further amended by adding at the end thereof the following new section:

"SEC. 908. EFFECTIVE MEDICATION GUIDES.

"(a) IN GENERAL.—Not later than 30 days after the date of enactment of this section, the Secretary shall request that national organizations representing health care professionals, consumer organizations, voluntary health agencies,

the pharmaceutical industry, drug wholesalers, patient drug information database companies, and other relevant parties collaborate to develop a long-range comprehensive action plan to achieve goals consistent with the goals of the proposed rule of the Food and Drug Administration on 'Prescription Drug Product Labeling: Medication Guide Requirements (60 Fed. Reg. 44182; relating to the provision of oral and written prescription information to consumers).

"(b) PLAN.—The plan described in subsection (a) shall—

"(1) identify the plan goals;

"(2) assess the effectiveness of the current private-sector approaches used to provide oral and written prescription information to consumers;

"(3) develop guidelines for providing effective oral and written prescription information consistent with the findings of any such assessment;

"(4) develop a mechanism to assess periodically the quality of the oral and written prescription information and the frequency with which the information is provided to consumers; and

"(5) provide for compliance with relevant State board regulations.

"(c) LIMITATION ON THE AUTHORITY OF THE SECRETARY.—The Secretary shall have no authority to imple-

ment the proposed rule described in subsection (a), or to develop any similar regulation, policy statement, or other guideline specifying a uniform content or format for written information voluntarily provided to consumers about prescription drugs if, not later than 120 days after the date of enactment of this section, the national organizations described in subsection (a) develop and begin to implement a comprehensive, long-range action plan (as described in subsection (a)) regarding the provision of oral and written prescription information.

"(d) SECRETARY REVIEW.—Not later than January 1, 2001, the Secretary shall review the status of private-sector initiatives designed to achieve the goals of the plan described in subsection (a), and if such goals are not achieved, the limitation in subsection (c) shall not apply, and the Secretary shall seek public comment on other initiatives that may be carried out to meet such goals. The Secretary shall not delegate such review authority to the Commissioner.".

SEC. 508. STATE AND LOCAL REQUIREMENTS RESPECTING NONPRESCRIPTION DRUGS INTENDED FOR HUMAN USE.

Subchapter A of chapter V (21 U.S.C. 351 et seq.) is amended by inserting after section 522 the following new section:

"SEC. 523. STATE AND LOCAL REQUIREMENTS RESPECTING NONPRESCRIPTION DRUGS INTENDED FOR HUMAN USE.

"(a) LIMITATION.—

"(1) IN GENERAL.—Except as provided in subsection (b), no State or political subdivision thereof may establish or continue in effect any requirement—

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

"(B) that is different from or in addition to, or that is otherwise not identical with, a requirement of this Act or the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.), and the administrative implementation of such Act.

"(2) SPECIAL RULE.—For purposes of this section, a requirement relating to the regulation of a drug described in paragraph (1) shall be deemed to include any requirement relating to the subject matter in any provision of this Act, the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.), and any requirement relating to the dissemination of information in any manner about such drug, but shall not include any requirement relating to the dispensing of a drug only upon prescription of a practitioner licensed by law to administer such drug.

"(b) EXEMPTION.—Upon application of a State, the Secretary may by regulation, after providing notice and an opportunity for written and oral presentation of views, exempt from the provisions of subsection (a), under such conditions as the Secretary may impose, a proposed requirement relating to the regulation of a drug intended for human use—

"(1) that is justified by compelling local conditions or protects an important public interest that would otherwise be unprotected;

"(2) that would not cause any drug intended for human use that is not subject to the requirements of section 503(b)(1) to be in violation of any applicable requirement or prohibition under Federal law; and

"(3) that would not unduly burden interstate commerce.".

SEC. 509. REQUIREMENT OF RADIOPHARMACEUTICALS.

(a) REQUIREMENTS.—

(1) REGULATIONS.—Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services, after consultation with patient advocacy groups, associations, physicians licensed to use radiopharmaceuticals, and the regulated industry, shall establish proposed regulations governing the approval of a

radiopharmaceutical designed for diagnosis and monitoring that shall assess the safety and effectiveness of the radiopharmaceutical taking into account the appropriate use of the radiopharmaceutical in the practice of medicine, the pharmacological and toxicological activity of the radiopharmaceutical, and the estimated absorbed radiation dose of the radiopharmaceutical. Not later than 1 year after the date of enactment of this Act, the Secretary shall issue final regulations.

(2) SPECIAL RULE.—In the case of a radiopharmaceutical intended to be used for diagnostic purposes, the indications for which such radiopharmaceutical is approved under this section may refer to manifestations of disease (such as biochemical, physiological, anatomic, or pathological processes) common to or present in 1 or more disease states, or may refer to a diagnostic procedure used in the diagnosis of 1 or more diseases or conditions.

(b) APPROVAL.—All applications or petitions requesting approval of a radiopharmaceutical and all other matters relating to such radiopharmaceutical shall be reviewed and acted upon by a single office in the Center for Drug Evaluation and Research, and that office shall report directly to the director of the Center for Drug Evaluation and

Research. A single scientific review group may provide conclusions and recommendations regarding any such matter relating to the approval of a radiopharmaceutical. Such group shall be appointed and administered pursuant to section 904 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 394), as amended by section 107.

(c) DEFINITION.—As used in this section, the term "radiopharmaceutical" means—

(1) an article that is intended for use in vivo in the diagnosis, cure, mitigation, treatment, or prevention of a disease or a manifestation of disease in man, and that exerts its primary effect by the spontaneous disintegration of unstable nuclei with the emission of ionizing radiation; or

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

(d) APPROVAL ASSESSED UNDER PERFORMANCE STANDARDS.—The approval of radiopharmaceuticals shall be assessed under quantifiable performance standards established by the Secretary under section 903(b)(3) of the Federal Food, Drug, and Cosmetic Act, as added by section 103.

TITLE VI—DEVICE REGULATORY REFORM

SEC. 601. SHORT TITLE.

This title may be cited as the "Medical Device Reform Act of 1996".

SEC. 602. PREMARKET NOTIFICATION.

(a) EXEMPTION OF CERTAIN DEVICES.—Section 510 (21 U.S.C. 360) is amended—

(1) in subsection (k), by striking "intended for human use" and inserting "intended for human use (except a device that is classified into class I under section 513 or 520 and is not identified in a list under subsection (n), or a device that is classified into class II under section 513 or 520 and is exempt from the requirements of this subsection under subsection (l))";

(2) by adding at the end of subsection (k) the following flush sentence:

"The Secretary shall review the notification required by this subsection and make a determination under section 513(f)(1)(A) within 90 days of receiving the notification."; and

(3) by adding at the end thereof the following new subsections:

"(l) Not later than 30 days after the date of enactment of this subsection, the Secretary shall publish in the Federal Register a list of each type of class II device that does not require a notification under subsection (k) to provide reasonable assurance of safety and effectiveness. Each type of class II device so identified by the Secretary not to require the notification shall be exempt from the requirement to provide notification under subsection (k) as of the date of the publication of the list in the Federal Register. Beginning on the date that is 1 day after the date of the publication of a list under this subsection, any person may petition the Secretary to exempt a type of class II device from the notification requirement of subsection (k). The Secretary shall respond to the petition within 120 days of the receipt of the petition and determine whether or not to grant the petition in whole or in part.

"(m) The Secretary may not withhold a determination of the initial classification of a device under section 513(f)(1) because of a failure to comply with any provision of this Act unrelated to a substantial equivalence decision, including a failure to comply with good manufacturing practices under section 520(f).

"(n) Not later than 15 days after the date of enactment of this subsection, the Secretary shall publish in the Federal Register a list of each type of class I device that shall not

be considered exempt from the notification requirement of section 510(k) because such notification is necessary to protect the public health. If the Secretary fails to publish the list within 15 days after the date of enactment of this subsection, all types of class I devices shall be exempt from the requirement to provide notification under section 510(k).".

(b) INITIAL CLASSIFICATION.—Section 513(f)(1) (21 U.S.C. 360c(f)(1)) is amended in the second sentence, by striking the period at the end thereof and inserting the following: ", unless within 30 days of receiving an order classifying the device into class III, the individual who submits a notification under section 510(k) requests an advisory committee review and recommendation with respect to the classification of the device and a final order of classification from the Secretary. After the request, a device classified into class III under this paragraph shall not be deemed to be finally classified until an advisory committee established under subsection (b) reviews the request with respect to the classification of the device and, within 60 days of the date of receiving the request, recommends to the Secretary a classification for the device based on the classification criteria set forth in subparagraphs (A) through (C) of subsection(a)(1). Thereafter, the Secretary shall have 10 days after the date of receiving the recommendation of the advisory committee to determine by order the final classi-

fication of the device by applying the classification criteria set forth in subparagraphs (A) through (C) of subsection(a)(1).".

(c) SUBSTANTIAL EQUIVALENCE.—Section 513(i)(1)(A) (21 U.S.C. 360c(i)(1)(A)) is amended by inserting after "intended use" the following: ", which, as determined by the Secretary, shall include each use reasonably included within a general use,".

(d) DEVICE MODIFICATION.—Section 513(i) (21 U.S.C. 360c(i)) is amended by adding at the end thereof the following new paragraph:

"(4)(A) Any change or modification to a device initially classified under section 513(f), other than a major change (including any major modification) in the intended use or a change or modification in design that is significant and significantly affects safety or effectiveness, shall not require an additional notification under section 510(k) if, prior to the commercial distribution of the device—

"(i) the change or modification is supported by appropriate data or information, (including data or information demonstrating compliance with good manufacturing practice regulations promulgated under section 520(f)); and

"(ii) the change or modification is shown by such data or information to not adversely affect the safety or effectiveness of the device.

"(B) All data or information relied upon to document that a change to (including any modification of) the device does not require an additional notification under section 510(k) shall be made available to the Secretary upon request and shall be maintained, at least for a period of time equal to the expected life of the device or 2 years after the date of commercial distribution of the device by the manufacturer, whichever is greater.".

SEC. 603. MEDICAL DEVICE APPROVAL STANDARDS.

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

(1) by striking "well-controlled" and inserting "one or more well-controlled"; and

(2) by striking "clinical investigations" and inserting "one or more clinical investigations".

(b) SUPPLEMENT TO APPLICATION.—Section 513(a)(3) (21 U.S.C. 360c(a)(3)) is amended by adding at the end thereof the following new subparagraphs:

"(C) The Secretary shall accept, for the purpose of facilitating a review of a premarket application, a supplement to a premarket application, or a premarket notification of a device, retrospective or historical clinical data as

a control, or for use, in determining whether there is a reasonable assurance of effectiveness of a device if sufficient valid data are available and the effects of the device on the cure, mitigation, treatment, or prevention of a disease are clearly defined and well understood.

"(D) The Secretary may not require a person intending to conduct clinical trials to conduct clinical trials using prospective concurrent controls in determining whether there is a reasonable assurance of effectiveness for a device or whether a device is substantially equivalent to a predicate device unless—

"(i) the effects of the device on the cure, mitigation, treatment, or prevention of a disease or condition are not clearly defined and well understood as determined by the Secretary;

"(ii) retrospective or historical data are not available that meet the standards of the Secretary for quality and completeness; or

"(iii) there is a compelling public health reason to not rely on retrospective or historical data as a control.".

SEC. 604. TRACKING.

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

"Device Tracking

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

"(1) the failure of which would be reasonably likely to be life-threatening or have serious adverse health consequences; and

"(2) which is—

"(A) permanently implantable; or

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

Any patient receiving a device subject to tracking under this section may refuse to release, or refuse permission to release, the patient's name, address, social security number, or other identifying information for the purpose of tracking.".

SEC. 605. POSTMARKET SURVEILLANCE.

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

"SEC. 522. POSTMARKET SURVEILLANCE.

"(a) IN GENERAL.—The Secretary may require a manufacturer to conduct postmarket surveillance for any device of the manufacturer that—

"(1) is a permanent implant the failure of which may cause serious, adverse health consequences or death;

"(2) is intended for a use in supporting or sustaining human life; or

"(3) potentially presents a serious risk to human health or creates public health concerns that justify surveillance under this section.

"(b) SURVEILLANCE APPROVAL.—Each manufacturer required to conduct a surveillance of a device under subsection (a) shall, within 30 days of receiving notice from the Secretary that the manufacturer is required under this section to conduct the surveillance, submit for the approval of the Secretary, a protocol for the required surveillance. The Secretary, within 60 days of the date of the receipt of the protocol, shall determine if the principal investigator proposed to be used in the surveillance has sufficient qualifications and experience to conduct the surveillance and if the protocol will result in collection of useful data or other information necessary to protect the public health and to provide safety and effectiveness information for the device. The Secretary may not approve the protocol until the protocol has been reviewed by a qualified scientific and technical review committee established by the Secretary.".

SEC. 606. DEVICE DISTRIBUTOR REPORTING.

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

(1) by striking ", importer, or distributor" each place it appears and inserting "or importer";

(2) in subsection (a)—

(A) in paragraph (7), by striking the semicolon at the end thereof and inserting "; and";

(B) in paragraph (8), by striking "; and" and inserting a period; and

(C) by striking paragraph (9); and

(3) in subsection (d), by striking ", importer, and distributor" and inserting "and importer".

SEC. 607. PREMARKET APPROVAL.

(a) ACTION ON APPLICATION.—Section 515(d) (21 U.S.C. 360e(d)) is amended—

(1) in paragraph (1)(A), by striking "paragraph (2) of this subsection" each place it appears and inserting "paragraph (4)";

(2) in paragraph (1)(B), by adding at the end thereof the following new clause:

"(iii) The Secretary shall accept and review data and any other information from investigations conducted under the authority of regulations required by section 520(g) to make a determination of whether there is a reasonable assurance of safety and effectiveness of a device subject to a pending application under this section if—

"(I) the data or information is derived from investigations of an earlier version of the device, the device has been modified during or after the investigations, and the modification of the device does not constitute a significant change in the design or in the basic principles of operation of the device that would invalidate the data or information; or

"(II) the data or information on a device approved under this section is available for use under this Act and is relevant to the design and intended use of the device subject to the pending application.";

(3) by redesignating paragraphs (2) and (3) as paragraphs (4) and (5), respectively; and

(4) by inserting after paragraph (1) the following new paragraphs:

"(2) Each application received under section 515(c) shall be reviewed in the following manner to achieve final action on the application within 180 days of the receipt of the application:

"(A) The Secretary shall meet with an applicant within 90 days of the receipt of the application to discuss the review status of the application. If the application does not appear in a form that would require an approval under this subsection, the Secretary shall in writing, and prior to the meeting,

present to the applicant a description of any deficiencies in the application and what information is required to bring the application into a form that would require an approval.

"(B) The Secretary shall refer an application to a panel established under section 513 for review and an approval recommendation (unless a panel is not required under subsection (c)(2)) within 30 days of the date of the meeting referred to in subparagraph (A) or at the next scheduled panel meeting following the meeting referred to in subparagraph (A), whichever occurs first.

"(C) The Secretary shall meet with the applicant within 15 days of the date of the panel review to discuss the status of the application, including a discussion on what action is necessary to bring the application into a form that would require approval under this subsection. Prior to the meeting, the Secretary shall in writing, set forth an agenda for the meeting (including a complete description of the subject matter to be discussed at the meeting), and a full description of the additional information required to bring the application into a form that would require an approval under this subsection. Participation of the ap-

plicant at such a meeting shall be at the discretion of the applicant.

"(D) The Secretary shall meet with the applicant not later than 135 days after the receipt of an application under subsection (c), if an advisory panel is not required under subsection (c)(2), and inform the applicant whether or not the application is in a form that would require approval under this subsection. If the application is in such form, the Secretary shall, at or prior to the meeting, present in writing to the applicant a description of all additional information necessary to require an approval of the application under this subsection. If the application is not in such form, the Secretary shall deny approval of the application and prior to the meeting, present in writing to the applicant each basis for denying approval of the application and the additional information required to bring the application into a form that would require approval.

"(E) The Secretary shall issue an order approving or denying an application within 180 days of the receipt of the application under subsection (c).

"(3) The time for the review of an application by the Secretary under this subsection shall not take more than

180 days and such time may not be extended if the application is amended.".

(b) REVISIONS OF REGULATIONS.—

(1) PREMARKET APPROVAL OF APPLICATIONS.—The Secretary of Health and Human Services shall revise, through notice and comment procedures, the regulations set forth in part 814 of title 21 of the Code of Federal Regulations, to conform to the amendment made by subsection (a).

(2) PREMARKET APPROVAL OF SUPPLEMENTS.—The Secretary of Health and Human Services shall revise regulations relating to premarket approval of devices to eliminate premarket approval of supplements that relate to manufacturing or product changes (excluding changes in intended use) of a device that have been demonstrated through appropriate data or information to not adversely affect safety or effectiveness. The Secretary of Health and Human Services shall require the manufacturer of a device to notify the Secretary of Health and Human Services of significant manufacturing changes or other changes not subject to a supplement under section 515 within 10 days of implementing such changes. All information relied upon in making such changes shall be made a part of the device master record. The informa-

tion shall be maintained for a period of time equal to the period of time for the design and expected life of the device, but not less than 2 years after the date of release of the device for commercial distribution by the manufacturer.

SEC. 608. DEVICE PERFORMANCE STANDARDS.

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

"Performance Standards of Standard-Setting Organizations

"(c)(1) For the purpose of facilitating a review of a device under section 510(k), 513(f), 515, or 520, the Secretary shall recognize appropriate device performance standards developed by any standard-setting organization accredited by the American National Standards Institute (ANSI), the International Standards Organization (ISO), or the International Electrotechnical Commission (IEC).

"(2)(A) For any standard-setting organization not identified in paragraph (1), and for the purpose of facilitating a review of devices under section 510(k), 513(f), 515, or 520, the Secretary shall establish a procedure governing the certification by the Food and Drug Administration of the competence of such an organization to develop standards for devices.

"(B) A certification of a standard-setting organization not identified in paragraph (1) shall be based on formal, written criteria that include requirements with respect to the role of the organization in the scientific community, scientific or medical expertise, standard-writing experience, conflict of interest considerations, and the openness of the standard-setting process of the organization.

"(C) The Secretary may impose a reasonable one-time fee on the standard-setting organization for certification pursuant to this paragraph.

"(3)(A) Upon being notified by a standard-setting organization described in paragraph (1) that a standard has been adopted by the organization, the Secretary shall recognize the standard by publishing a notice in the Federal Register listing the name of the standard.

"(B) Upon being notified by a standard-setting organization certified under paragraph (2) that a standard has been adopted by the organization, the Secretary shall review and may recognize the standard by publishing a notice in the Federal Register listing the name of the standard.

"(4) The Secretary may withdraw recognition of a performance standard adopted by a standard-setting organization described in paragraph (1) or a standard-setting organization certified under paragraph (2) if the Secretary determines that the standard is insufficient to facilitate a

review of a device. The Secretary shall notify the standard-setting organization and specify the basis for the withdrawal.

"(5) The Secretary shall promulgate regulations under which the Secretary may withdraw the certification of a standard-setting organization described in paragraph (2), or may no longer rely upon standards adopted by a standard-setting organization described in paragraph (1), if the Secretary determines that such organization no longer possesses the appropriate scientific or medical expertise, conflict of interest practices, standard-writing experience, or any other qualification necessary to the development of device standards.

"(6) As provided for in this section, the Secretary may promulgate performance standards for a device that differs from or is not established by, an organization described in paragraph (1) or an organization certified under paragraph (2).

"(7) The Secretary shall not require, as a condition for approving an application under section 515 or 520 or classifying a device under sections 510(k) and 513(f), conformity with a device standard recognized under this subsection if the person requesting such approval or classification submits evidence to demonstrate a reasonable assurance that the device is substantially equivalent to a legally

marketed predicate device or provides reasonable assurance that the device is safe and effective.

"(8) A performance standard recognized pursuant to this subsection for a device—

"(A) shall include provisions to provide reasonable assurance of the safe and effective performance of the device;

"(B) shall, where necessary to provide reasonable assurances of the safe and effective performance of the device, include—

"(i) provisions with respect to the construction, components, ingredients, and properties of the device and the compatibility of the device with power systems and connections to the systems;

"(ii) provisions for the testing (on a sample basis or, if necessary, on an individual basis) of the device or, if it is determined that no other more practicable means are available to the Secretary to assure the conformity of a device to the standard, provisions for the testing (on a sample basis or, if necessary, on an individual basis) of the device by the Secretary or by another person at the direction of the Secretary;

"(iii) provisions for the measurement of the performance characteristics of the device; and

"(iv) provisions requiring that the results of each or certain of the tests of the device required to be made under clause (ii) demonstrate that the device is in conformity with those portions of the standard for which the test or tests were required; and

"(C) shall, where appropriate, require the procedures, for the proper installation, maintenance, operation, and use of the device.

"(9) The Secretary shall accept a certification by a person who has made a submission pursuant to section 510(k), 515, or 520 that the device conforms with each standard identified in the certification. The Secretary may, where appropriate, require data demonstrating conformity with a standard recognized under this subsection.

"(10) The Secretary shall require a person who makes a certification under paragraph (9) that a device conforms to an applicable performance standard recognized under this subsection or who makes a certification that a device conforms to a standard established under subsection (a) or (b) to maintain data demonstrating conformity of the device to the standard for a period of time equal to the period of time for the design and expected life of the device. Such

data shall be made available to the Secretary upon request.".

(b) ADULTERATED DEVICE.—Section 501(e) (21 U.S.C. 351(e)) is amended—

(1) by striking "(e)" and inserting "(e)(1)";

(2) by striking "section 514" and inserting "section 514(b)"; and

(3) by inserting at the end thereof the following:

"(2) If it is, or purports to be or is represented as, a device which is certified to be in compliance with any voluntary standard recognized under section 514(c), unless such a device is in all respects in conformity with such a standard.".

SEC. 609. ACCREDITED-PARTY PARTICIPATION.

Subchapter A of chapter V (21 U.S.C. 351 et seq.), as amended by section 508, is further amended by adding at the end the following new section:

"SEC. 523A. ACCREDITED-PARTY PARTICIPATION.

"(a) IN GENERAL.—Not later than 1 year after the date of enactment of this section, the Secretary shall accredit persons, including any entity or any individual who is not an employee of the Department to review and initially classify devices under section 513(f)(1) that are subject to a report under section 510(k) and to review and rec-

ommend to the Secretary approval or denial of applications submitted under section 515(c)(1).

"(b) ACCREDITATION.—Not later than 6 months after the date of enactment of this section, the Secretary shall establish and publish in the Federal Register requirements to accredit or deny accreditation to a person who makes a request for accreditation to carry out the activities described in subsection (a). The requirements shall, at a minimum, advise such person how to become accredited, and set forth criteria for accreditation including criteria to avoid conflicts of interest and to ensure that persons to be accredited are capable of maintaining the confidentiality of submissions consistent with section 552 of title 5, United States Code, and the regulations of the Food and Drug Administration. The Secretary shall respond to a request for accreditation not later than 60 days after the receipt of the request. The accreditation of a person shall specify the activities under subsection (a) which such person is authorized to carry out in the place of the Secretary.

"(c) WITHDRAWAL OF ACCREDITATION.—The Secretary may suspend or withdraw the accreditation of any person accredited under this section, after providing notice and an opportunity for an informal hearing, if such person acts in a manner that is substantially inconsistent with the purposes of this section, including the failure to avoid con-

flicts of interest, the failure to protect confidentiality of information, or the failure to competently review premarket submissions for devices.

"(d) SELECTION AND COMPENSATION.—A person who submits a premarket submission for a device to the Secretary for review and classification, or approval of a device, shall have the option to select an accredited person to review such submission. The Secretary shall identify for the person no less than 2 accredited persons from whom the selection may be made. Compensation for an accredited person shall be determined by agreement between the accredited person and the person who engages the services of the accredited person.

"(e) REVIEW BY SECRETARY.—

"(1) IN GENERAL.—If a person exercises the option to obtain review of a premarket submission that is an application or a notification by an accredited person, the Secretary shall complete a filing review for a premarket approval application under section 515(c)(1) not later than 30 days after the receipt of such application, or shall ensure the completeness of a premarket notification submission under section 510(k) not later than 15 days after the receipt of such submission, prior to referring the premarket submis-

sion for review by the accredited person selected by the person submitting the premarket submission.

"(2) REPORT ON CLASSIFICATION, APPROVAL, OR DENIAL.—The Secretary shall require an accredited person, upon recommending a classification of a device or approval or disapproval of an application for a device, to report to the Secretary the reasons of the accredited person for such classification or approval or disapproval. For devices reviewed and initially classified under section 513(f)(1) and subject to a report under section 510(k), the Secretary shall have not more than 15 days to review the submission. For applications submitted under section 515(c)(1), the Secretary shall have not more than 45 days to review the application. The Secretary may change the classification under section 513(f)(1), or the approval or disapproval of the application under section 515(d), that is recommended by the accredited person, and in such case shall notify the person making the submission of the detailed reasons for the change.

"(f) DURATION.—This section shall remain in force for a period of 3 years from the date on which the Secretary accredits the first person to conduct initial classifications under section 513(f)(1) and to conduct premarket approval reviews under section 515.

"(g) REPORTS.—

"(1) IMPLEMENTATION OF ACCREDITATION PROCESS.—Not later than 1 year after the date of enactment of this section, the Secretary shall prepare and submit to the committees of Congress with oversight authority over the Food and Drug Administration a report concerning each action the Secretary has taken to implement the accreditation of persons to undertake the activities described in subsection (a).

"(2) EXAMINATION OF THE USE OF ACCREDITED PERSONS.—

"(A) IN GENERAL.—Not later than 2 years after the date on which the Secretary accredits the first person to conduct initial classifications under section 513(f)(1) and to conduct premarket approval reviews under section 515, the Secretary shall contract with an independent research organization to prepare and submit to the Secretary a written report examining the use of accredited persons under this section. The Secretary shall submit the report to the committees described in paragraph (1) not later than 30 months after the date on which the Secretary accredits the first person to conduct initial classi-

fications under section 513(f)(1) and to conduct premarket approval reviews under section 515.

"(B) CONTENTS.—The report by the independent research organization described in subparagraph (A) shall identify the benefits or detriments to public and patient health of using accredited persons to conduct such reviews, and shall summarize all relevant data, including data on the review of accredited persons (including review times, recommendations, and compensation), and data on the review of the Secretary (including review times, changes, and reasons for changes).".

TITLE VII—ANIMAL DRUG REGULATORY REFORM

SEC. 701. SHORT TITLE.

This title may be cited as the "Animal Drug Regulatory Reform Act of 1996".

SEC. 702. EVIDENCE OF EFFECTIVENESS.

(a) SUBSTANTIAL EVIDENCE.—Section 512(d) (21 U.S.C. 360b(d)) is amended—

(1) by striking paragraph (3); and

(2) by adding at the end thereof the following new paragraph:

"(4)(A) As used in this subsection and subsections (c)(2)(F)(iii) and (e)(1)(C), the term 'substantial evidence' means evidence from 1 or more scientifically sound studies, including as appropriate in vitro studies, studies in laboratory animals (including a target species), bioequivalence studies, and any studies voluntarily undertaken by or for the applicant, that taken together provide reasonable assurance that the drug will have the claimed or intended effect of the drug.

"(B) For purposes of subparagraph (A), a study shall be considered to be scientifically sound if the study is designed and conducted in a manner that is consistent with generally recognized scientific procedures and principles.".

(b) COMBINATION OF DRUGS.—Section 512(d) (21 U.S.C. 360b(d)) is amended by inserting before paragraph (4) (as added by subsection (a)) the following new paragraph:

"(3) In a case in which a new animal drug contains more than 1 active ingredient, or the labeling of the drug prescribes, recommends, or suggests use of the drug in combination with another animal drug, and the active ingredients or drugs in the combination have been separately approved for particular uses and species prior to the approval of the application for the same uses and species in combination (or, in the absence of such approvals, after evaluating

the safety and efficacy of the combination itself), the Secretary may only consider with respect to the combination whether any of the active ingredients or any of the drugs in the combination, respectively, at the longest withdrawal time of any of the active ingredients or drugs in the combination, respectively—

"(A) is above its safe concentration (such as exceeding its established tolerance, as measured by its marker residue); or

"(B) interferes with the methods of analysis for another of the active ingredients or drugs in the combination, respectively.".

(c) SUPPLEMENTAL APPLICATIONS.—Section 512(c)(2)(F)(iii) (21 U.S.C. 360b(c)(2)(F)(iii)) is amended—

(1) by striking "reports of new clinical or field investigations (other than bioequivalence or residue studies) and" and inserting "substantial evidence of effectiveness as defined in subsection (d)(4), any study of animal safety, or"; and

(2) by striking "essential to" and inserting ", required for".

(d) MINOR SPECIES AND USES.—Section 512(d)(1) (21 U.S.C. 360b(d)(1)) is amended by adding at the end the following new sentence: "Subparagraph (E) shall not

apply to a claim for use of the drug described in subparagraph (E) in a minor species, or for a minor use of the drug, as the terms 'minor species' and 'minor use' are defined in regulations issued by the Secretary, if there is an application filed under subsection (b) for the drug, and the application is approved, prior to the submission of the claim.".

(e) WITHDRAWAL OF APPROVAL.—Section 512(e)(1)(C) (21 U.S.C. 360b(e)(1)(C)) is amended by inserting after "substantial evidence" the following: "(as defined in subsection (d)(4))".

(f) IMPLEMENTATION.—

(1) IN GENERAL.—Not later than 6 months after the date of enactment of this Act, the Secretary shall issue proposed regulations implementing the amendments made by this section. Not later than 18 months after the date of enactment of this Act, the Secretary shall issue final regulations implementing the amendments.

(2) CONTENTS.—In issuing regulations implementing the amendments made by this section, and in taking an action to review an application for approval of a new animal drug under section 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b), or a request for an investigational exemption

for a new animal drug under subsection (j) of such section, that is pending or has been submitted prior to the effective date of the regulations, the Secretary shall—

(A) further define the term "substantial evidence", as defined in subsection (d)(4) of such section, in a manner that encourages the submission of applications for production drugs that conserve food resources, of applications for veterinary prescription drugs whose use is designed to rely on the experience and training of practitioners in establishing effective doses for such drugs, and of supplemental applications, including applications seeking approval for uses of animal drugs in minor species, for minor uses of such drugs, and for permitted unlabeled uses of such drugs;

(B) take into account the proposals contained in the citizen petition (FDA Docket No. 91P–0434/CP) jointly submitted by the American Veterinary Medical Association and the Animal Health Institute, dated October 21, 1991; and

(C)(i) provide for the opportunity for a conference prior to the submission of an application

for approval of a new animal drug under such section, and prior to the submission of a request for an investigational exemption under subsection (j) of such section, to make a decision establishing any submission or investigational requirement relating to the application or request (which decision shall bind the Secretary and the applicant or requester unless the Secretary by order determines that a documented scientific issue that occurred subsequent to the conference requires the decision to be modified in order to ensure that an appropriate determination can be made with respect to the safety or effectiveness of the animal drug involved); and

(ii) not later than 10 days after each such conference, by written order, provide a scientific justification specific to the animal drug and intended uses under consideration for requiring studies of types other than the types of studies specified in subsection (d)(4) of such section, as being essential to provide substantial evidence of effectiveness for the intended uses of the drug.

SEC. 703. LIMITATION OF RESIDUES.

Section 512(d)(1)(F) (21 U.S.C. 360b(d)(1)(F)) is amended to read as follows:

"(F) on the basis of information submitted to the Secretary as part of the application or any other information before the Secretary with respect to such drug, any use prescribed, recommended, or suggested in labeling proposed for such drug will result in a residue of such drug in excess of a tolerance found by the Secretary to be safe for such drug;".

SEC. 704. ADULTERATED DRUGS.

Section 501(a)(2) (21 U.S.C. 351(a)(2)) is amended—

(1) in subparagraph (A), by striking "health; or" and inserting "health;"; and

(2) in subparagraph (B), by striking "possess;" and inserting the following: "possess; or (C) if it is a drug intended for use by animals other than man and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice requirements (appropriate for animal drugs) adopted pursuant to regulations issued by the Secretary to ensure that such drug meets the requirements of this Act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess for use in animals other than man;".

SEC. 705. VETERINARY FEED DIRECTIVES.

(a) WRITTEN OR ORAL ORDERS.—Section 503(f)(1)(A) (21 U.S.C. 353(f)(1)(A)) is amended by striking "other than man" and inserting the following: "other than man, other than a veterinary feed directive drug intended for use in animal feed or an animal feed bearing or containing a veterinary feed directive drug,".

(b) GENERAL REQUIREMENTS.—Chapter V (21 U.S.C. 351 et seq.) is amended by inserting after section 503 the following new section:

"VETERINARY FEED DIRECTIVES DRUGS

"SEC. 504. (a)(1) A drug intended for use in or on animal feed that is limited by an approved application filed pursuant to section 512(b) to use under the professional supervision of a licensed veterinarian is a veterinary feed directive drug. Any animal feed bearing or containing a veterinary feed directive drug shall be fed to animals only by or upon the lawful veterinary feed directive issued by a licensed veterinarian in the course of the professional practice of the veterinarian. When labeled, distributed, held, and used in accordance with this section, a veterinary feed directive drug and any animal feed bearing or containing a veterinary feed directive drug shall be exempt from section 502(f).

"(2) A veterinary feed directive is lawful if it—

"(A) contains such information as the Secretary may, by general regulation or by order, require; and

"(B) is in compliance with the conditions and indications for use of the drug set forth in the notice published pursuant to section 512(i).

"(3)(A) Any persons involved in the distribution or use of animal feed bearing or containing a veterinary feed directive drug, and the licensed veterinarian issuing the veterinary feed directive, shall maintain a copy of the veterinary feed directive applicable to each such feed, except in the case of a person distributing such feed to another person for further distribution, such person distributing the feed shall maintain a written acknowledgment from the person to whom the feed is shipped stating that that person shall not ship or move such feed to an animal production facility without a veterinary feed directive or ship such feed to another person for further distribution unless that person has provided the same written acknowledgment to the immediate supplier of that person.

"(B) Every person required under subparagraph (A) to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

"(C) Any person who distributes animal feed bearing or containing a veterinary feed directive drug shall upon first engaging in such distribution notify the Secretary of the name and place of business of that person. The failure to provide such notification shall be deemed to be an act which results in the drug being misbranded.

"(b) A veterinary feed directive drug and any feed bearing or containing a veterinary feed directive drug shall be deemed to be misbranded if the drug and feed labeling fails to bear such cautionary statement and such other information as the Secretary may, by general regulation or by order, prescribe, or the drug and feed advertising fails to conform to the conditions and indications for use published pursuant to section 512(i) or fails to contain the general cautionary statement prescribed by the Secretary.

"(c) Neither a drug subject to this section, nor animal feed bearing or containing such a drug, shall be deemed to be a prescription article under any Federal or State law.".

(c) CONFORMING AMENDMENTS.—Section 512 (21 U.S.C. 360b) is amended—

(1) in subsection (a)(2)(C), by striking "its labeling" and inserting "its labeling, its distribution, its holding,";

(2) in subsection (i), by striking "requirements)" and inserting "requirements and any requirement

that an animal feed bearing or containing the new animal drug be limited to use under the professional supervision of a licensed veterinarian)"; and

(3) in subsection (m)(4)(B)(i)—

(A) by striking "paragraph (5)(A) of this subsection" and inserting "paragraph (5)(A) or under section 504(a)(3)(A)"; and

(B) by striking "subparagraph (B) of such paragraph" and inserting "paragraph (5)(B) or section 504(a)(3)(B)".

(d) PROHIBITED ACTS.—Section 301(e) (21 U.S.C. 331(e)) is amended—

(1) by striking "section 412" and inserting "section 412, 504,"; and

(2) by striking "under section 412," and inserting "under section 412, 504,".

SEC. 706. TIMEFRAMES FOR APPROVAL.

The first sentence of section 512(c)(1) (21 U.S.C. 360b(c)(1)) is amended by striking "one hundred and eighty" and inserting "90".

TITLE VIII—FOOD REGULATORY REFORM

SEC. 801. SHORT TITLE.

This title may be cited as the "Food Regulatory Reform Act of 1996".

SEC. 802. INDIRECT FOOD ADDITIVES.

(a) APPROVAL.—Section 409 (21 U.S.C. 348) is amended by adding at the end thereof the following new subsection:

"Alternative Approval Procedure

"(j)(1) As an alternative to the approval procedure established under subsection (b), any person may submit a notification for an indirect food additive under this subsection.

"(2) Any person who proposes to begin the introduction or delivery for introduction into interstate commerce of an article intended for use as an indirect food additive may submit to the Secretary, at least 90 days prior to making such introduction or delivery, a notification containing information demonstrating that the labeled use of the article is safe.

"(3) Within 90 days after the receipt of the notification by the Secretary, the Secretary shall—

"(A) either—

"(i) approve the notification if the article is safe for its intended use; or

"(ii) disapprove the notification if the article has not been shown to be safe for its intended use; and

"(B) publish a notice of this determination in the Federal Register and, if the notification is ap-

proved, promulgate an appropriate regulation pursuant to subsection (c).".

(b) DEFINITION.—Section 201 (21 U.S.C. 321), as amended by section 408, is further amended by adding at the end thereof the following new paragraph:

"(hh) The term 'indirect food additive' means a food additive that is intended to contact food but that is not intended for consumption as a food ingredient.".

SEC. 803. HEALTH CLAIMS OF FOOD PRODUCTS.

Section 403(r)(3) (21 U.S.C. 343(r)(3)) is amended by adding at the end thereof the following new subparagraph:

"(C) Notwithstanding the provisions of subparagraphs (A)(i) and (B), a claim of the type described in paragraph (1)(B) which is not authorized by the Secretary in a regulation promulgated in accordance with subparagraph (B) shall be authorized and may be made if—

"(i) an authoritative scientific body of the United States Government with official responsibility for public health protection or research directly relating to human nutrition (such as the National Institutes of Health or the Centers for Disease Control and Prevention), the National Academy of Sciences, or subdivisions of the scientific body or the National Academy of Sciences, has published statements, conclusions, or recommendations in effect recognizing

that the relationship between the nutrient and disease or health-related condition to which the claim refers is supported by pertinent scientific evidence; and

"(ii) the manufacturer or distributor of the food for which such claim is made has submitted to the Secretary at least 90 days before the first introduction of such food into interstate commerce a notice of claim, including a concise description of the basis upon which such manufacturer or distributor relied for determining that the requirements of clause (i) have been satisfied.".

TITLE IX—ESTABLISHMENT OF CENTERS FOR EDUCATION AND RESEARCH ON DRUGS, DEVICES, AND BIOLOGICAL PRODUCTS

SEC. 901. CENTERS FOR EDUCATION AND RESEARCH ON DRUGS, DEVICES, AND BIOLOGICAL PRODUCTS.

Chapter IX (21 U.S.C. 391 et seq.), as amended by section 507, is further amended by adding at the end thereof the following new section:

"SEC. 909. CENTERS FOR EDUCATION AND RESEARCH ON DRUGS, DEVICES, AND BIOLOGICAL PRODUCTS.

"(a) IN GENERAL.—The Secretary, acting through the Commissioner, shall establish a consortium of 3 or more centers for research and education on drugs, devices, and biological products in accordance with subsection (b).

"(b) GRANT AUTHORITY.—The Secretary, acting through the Commissioner, shall make grants to 3 or more private entities to assist each of the entities in the establishment and operation of a center for research and education on drugs, devices, and biological products. In awarding a grant under this subsection, the Secretary shall use a peer-review selection procedure.

"(c) AUTHORIZED GRANT ACTIVITIES.—

"(1) REQUIRED ACTIVITIES.—A grant awarded under subsection (b) shall be used to—

"(A) conduct state-of-the-art clinical and laboratory research that—

"(i) increases awareness of new uses of drugs, devices, or biological products and the unforeseen risks of new uses of drugs, devices, or biological products;

"(ii) provides objective clinical information to—

"(I) health care practitioners or other providers of health care goods or services;

"(II) pharmacy benefit managers;

"(III) health maintenance organizations or other managed health care organizations; and

"(IV) health care insurers or governmental agencies; and

"(iii) improves the quality of health care while reducing the cost of health care through the prevention of adverse effects of drugs, devices, or biological products and the consequences of such effects, such as unnecessary hospitalizations; and

"(B) conduct research on the comparative effectiveness and safety of drugs, devices, or biological products.

"(2) DISCRETIONARY ACTIVITIES.—A grant awarded under subsection (b) may be used to conduct—

"(A) surveillance of the adverse effects of drugs, devices, or biological products;

"(B) a study of new or unapproved uses for marketed drugs, devices, or biological products; or

"(C) a study of the therapeutic characteristics of clinically special populations, such as children, women, and elderly individuals.

"(3) LIMITATION.—A grant awarded under subsection (b) may not be used to assist the Secretary in the review of new drugs.

"(d) APPLICATION.—An entity that desires to receive a grant under this section shall submit to the Secretary an application at such time, in such manner, and accompanied by such information as the Secretary may require.

"(e) ESTABLISHMENT OF AN OVERSIGHT COMMITTEE.—The Secretary shall establish within the Food and Drug Administration a committee to provide oversight of the research and educational activities of the consortium of centers described in subsection (a). The committee shall be composed of—

"(1) a representative from each of the centers;

"(2) a representative from the Food and Drug Administration;

"(3) a representative from consumer advocacy groups; and

"(4) a representative from the pharmaceutical, device, or biological products industry.

"(f) REPORT.—Not later than September 30, 1999, the Secretary shall prepare and submit to the Chairmen and Ranking Members of the Committee on Labor and Human Resources of the Senate and the Committee on Commerce of the House of Representatives a report on the activities of the consortium of centers established pursuant to this section. The report shall include an analysis on the impact of the centers on the safe use of drugs, devices, and biological products and recommendations on whether the funding for the centers should be extended and increased.

"(g) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $9,000,000 for fiscal year 1997, $12,000,000 for fiscal year 1998, $15,000,000 for fiscal year 1999, and $15,000,000 for fiscal year 2000.".

TITLE X—PROGRAM IN CLINICAL PHARMACOLOGY

SEC. 1001. REAUTHORIZATION OF CLINICAL PHARMACOLOGY PROGRAM.

Section 2(b) of Public Law 102–222 (105 Stat. 1677) is amended by striking "to carry out this section" and inserting ", and fiscal years 1997 and 1998, $1,900,000 for each fiscal year, to carry out this section".