105TH CONGRESS
1ST SESSION

S. 830

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

IN THE SENATE OF THE UNITED STATES

JUNE 5, 1997

Mr. JEFFORDS introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

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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 Modernization and Accountability Act of 1997''.

SEC. 2. TABLE OF CONTENTS.

The table of contents for this Act is as follows:

SEC. 3. REFERENCES.

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

TITLE I—IMPROVING PATIENT ACCESS

SEC. 101. MISSION OF THE FOOD AND DRUG ADMINISTRATION.

Section 903 (21 U.S.C. 393) is amended—

(1) by redesignating subsections (b) and (c) as subsections (c) and (d), respectively; and

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

''(b) MISSION.—

''(1) IN GENERAL.—The Food and Drug Administration shall protect the public health by ensuring that—

''(A) foods are safe, wholesome, and sanitary;

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

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

''(D) cosmetics are safe; and

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

''(2) SPECIAL RULES.—The Food and Drug Administration shall promptly and efficiently review clinical research and take appropriate action on the marketing of regulated products in a manner that does not unduly impede innovation or product availability. The Food and Drug Administration shall participate with other countries to reduce the burden of regulation, to harmonize regulatory requirements,

and to achieve appropriate reciprocal arrangements.''.

SEC. 102. EXPEDITED ACCESS TO INVESTIGATIONAL THERAPIES.

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

''SUBCHAPTER D—UNAPPROVED THERAPIES AND DIAGNOSTICS

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

''(a) IN GENERAL.—Any person, acting through a medical practitioner licensed in accordance with State law, 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, or any other disease or condition designated by the Secretary as appropriate for expanded access under this section if—

''(1) the licensed medical practitioner determines that the person has no comparable or satisfactory alternative therapy available to diagnose, monitor, or treat the disease or condition involved;

''(2) the licensed medical practioner determines that the risk to the person from the investigational drug or investigational device is not greater than the risk from the disease or condition;

''(3) the Secretary determines that an exemption for the investigational drug or investigational device is in effect under a regulation promulgated pursuant to section 505(i) or 520(g) and the sponsor of the drug or device and investigators comply with such regulation;

''(4) the Secretary determines that the manufacturer of the investigational drug or investigational device is actively pursuing marketing approval with due diligence; and

''(5) expanded access will not interfere with adequate enrollment of patients by the investigator in the ongoing clinical investigation authorized under section 505(i) or 520(g).

''(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) or 520(g) 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, emergency use, or uncontrolled trials, and single patient protocols.

''(c) NOTIFICATION OF AVAILABILITY.—The Secretary 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 investigational device under expanded access protocols submitted under this section.''.

(d) TERMINATION.—FDA may at any time terminate expanded access under subsection (a) if the requirements under this section are no longer met.

SEC. 103. EXPANDED HUMANITARIAN USE OF DEVICES.

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

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

''The request shall be in the form of an application submitted to the Secretary. Not later than 60 days after the date of the receipt of the application, the Secretary shall issue an order approving or denying the application.'';

(2) in paragraph (4)(B), by inserting after ''(2)(A)'' the following: '', unless a physician determines that waiting for such an approval from an institutional review committee will cause harm or death to a patient, and after making a good faith ef-

fort, the physician does not receive a timely response from an institutional review committee on the physician's request for approval to use the device.

(3) by striking paragraph (5) and inserting the following:

''(5) The Secretary may require a person granted an exemption under paragraph (2) to demonstrate continued compliance with the requirements of this subsection if the Secretary believes such demonstration to be necessary to protect the public health or if the Secretary has reason to believe that the criteria for the exemption are no longer met. Nothing in this section shall be construed to prevent the Secretary from using any of the controls authorized by or under section 501, 502, 510, 516, 518, 519, or 520, any combination of such controls, or any of the special controls established under section 513(a)(1)(B), in connection with a device for which an exemption has been granted under paragraph (2).''.

TITLE II—INCREASING ACCESS TO EXPERTISE AND RESOURCES

SEC. 201. INTERAGENCY COLLABORATION.

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

''(3) INTERAGENCY COLLABORATION.—The Secretary shall implement programs and policies

that will foster collaboration between the Administration, the National Institutes of Health, and other science-based Federal agencies, to enhance the scientific and technical expertise available to the Secretary in the conduct of the Secretary's duties with respect to the development, clinical investigation, evaluation, and postmarket monitoring of emerging medical therapies, including complementary therapies, and advances in nutrition and food science.''.

SEC. 202. SENSE OF THE COMMITTEE REGARDING MUTUAL RECOGNITION AGREEMENTS AND GLOBAL HARMONIZATION EFFORTS.

It is the sense of the Committee 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 United States;

(2) the Secretary of Health and Human Services should regularly participate in meetings with representatives of other foreign governments to dis-

cuss and reach agreement on methods and approaches to harmonize regulatory requirements; and

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

SEC. 203. CONTRACTS FOR EXPERT REVIEW.

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

"SEC. 906. CONTRACTS FOR EXPERT REVIEW.

''(a) IN GENERAL.—

''(1) AUTHORITY.—The Secretary may enter into a contract with any organization or any individual (who is not an employee of the Department) with expertise in a relevant discipline, to review, evaluate, and make recommendations to the Secretary on part or all of any application or submission (including a petition, notification, and any other similar form of request) made under this Act for the approval of an article or made under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) with respect to a biological product. Any such con-

tract shall be subject to the requirements of section 708 relating to the confidentiality of information.

''(2) INCREASED EFFICIENCY AND EXPERTISE THROUGH CONTRACTS.—The Secretary shall use the authority granted in paragraph (1) whenever the Secretary determines that a contract described in paragraph (1) will improve the timeliness or quality of the review of an application or submission described in paragraph (1). Such improvement may include providing the Secretary increased scientific or technical expertise that is necessary to review or evaluate new therapies and technologies.

''(b) REVIEW OF EXPERT'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 subsection (a) shall review the recommendations of the organization or individual who conducted the expert review and shall make a final decision regarding the matter within 60 days after receiving the recommendations.

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

''(3) AUTHORITY OF SECRETARY.—Notwithstanding subsection (a), the Secretary shall retain full authority to make determinations with respect to the approval or disapproval of an article under this Act, or the classification of an article as a device under section 513(f)(1).''.

SEC. 204. ACCREDITED-PARTY REVIEWS.

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

''SEC. 523. ACCREDITED-PARTY PARTICIPATION.

''(a) ACCREDITATION.—

''(1) IN GENERAL.—Not later than 1 year after the date of enactment of this section, the Secretary shall accredit persons, including any entity or individual who is not an employee of United States Government, to review and make recommendations regarding submissions made to the Secretary under section 510(k) except that this paragraph does not apply to submissions for devices that are—

''(A) life-supporting;

''(B) life sustaining; or

''(C) intended for implantation in the human body for a period of over 1 year.

''(2) SPECIAL RULE.—The Secretary shall have the discretion to accredit persons, including any en-

tity or individual who is not an employee of the United States Government, to review and make recommendations regarding devices described in subparagraphs (A) through (C) of paragraph (1) or devices subject to premarket approval under section 515.

''(b) ACCREDITATION.—Within 180 days after the date of enactment of this section, the Secretary shall adopt methods of accreditation that ensure that persons who conduct reviews and make recommendations under this section are qualified, properly trained, knowledgeable about handling confidential documents and information, and free of conflicts of interest. The Secretary shall publish the methods of accreditation in the Federal Register on the adoption of the methods.

''(c) WITHDRAWAL OF ACCREDITATION.—The Secretary may suspend or withdraw the accreditation of any 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 not in compliance with the requirements established by the Secretary, including the failure to avoid conflicts of interest, the failure to protect confidentiality of information, or the failure to competently review premarket submissions for devices.

''(d) SELECTION AND COMPENSATION.—A person who intends to submit a premarket submission for a device to the Secretary under subsection (a) shall have the option to select an accredited person to review such submission. Upon the request of a person intending to make a premarket submission for a device, 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 and shall be paid by the person who engages such services.

''(e) REVIEW BY SECRETARY.—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 recommendation of 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 30 days to review the submission. For applications submitted under section 515(c)(1), the Secretary shall have not more than 60 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 in writing the person making the submission of the detailed reasons for the change.

''(f) DURATION.—The authority provided by this section terminates—

''(1) 5 years after the date on which the Secretary notifies Congress that at least 2 persons accredited under subsection (b) are available to review devices in each of at least 70 percent of generic types of devices required for review under subsection (a); or

''(2) 4 years after the date on which the Secretary notifies Congress that at least 35 percent of the devices required for review under subsection (a) that were the subject of final action by the Secretary in the fiscal year preceding the date on which the Secretary notifies the Congress were reviewed by the Secretary under subsection (e),

whichever occurs first.

''(g) REPORT.—

''(1) IN GENERAL.—Not later than 1 year after the date of enactment of this section, the Secretary shall contract with an independent research organization to prepare and submit to the Secretary a

written report examining the use of accredited persons under this section. The Secretary shall submit the report to Congress not later than 6 months prior to the conclusion of the applicable period described in subsection (f).

''(2) CONTENTS.—The report by the independent research organization described in paragraph (1) shall identify the benefits or detriments to public and patient health of using accredited 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).''.

SEC. 205. DEVICE PERFORMANCE STANDARDS.

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

''RECOGNITION OF A STANDARD

''(c)(1)(A) In addition to establishing performance standards under this section, the Secretary may, by publication in the Federal Register, recognize all or part of a performance standard established by a nationally or internationally recognized standard development organization for which a person may submit a declaration of conformity

in order to meet premarket submission requirements or other requirements under this Act to which such standards are applicable.

''(B) If a person elects to use a performance standard recognized by the Secretary under subparagraph (A) to meet the requirements described in subparagraph (A), the person shall provide a declaration of conformity to the Secretary that certifies that the device is in conformity with such standard. A person may elect to use data, or information, other than data required by a standard recognized under subparagraph (A) to fulfill or satisfy any requirement under this Act.

''(2) The Secretary may withdraw such recognition of a performance standard through publication of a notice in the Federal Register that the Secretary will no longer recognize the standard, if the Secretary determines that the standard is no longer appropriate for meeting the requirements under the Act.

''(3)(A) Subject to subparagraph (B), the Secretary shall accept a declaration of conformity that a device is in conformity with a standard recognized under paragraph (1) unless, the Secretary finds—

''(i) that the data or information submitted to support such declaration does not demonstrate that

the device is in conformity with the standard identified in the declaration of conformity; or

''(ii) that the standard identified in the declaration of conformity is not applicable to the particular device under review.

''(B) The Secretary may request, at any time, the data or information relied on by the person to make a declaration of conformity with respect to a standard recognized under paragraph (1).

''(C) A person relying on a declaration of conformity with respect to a standard recognized under paragraph (1) shall maintain the data and information demonstrating conformity of the device to the standard for a period of 2 years after the date of the Secretary's classification or approval of the device or a time equal to the expected design life of a device, whichever is longer.''.

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

''(x) The falsification of a declaration of conformity under subsection (c)(3) of section 514 or the failure or refusal to provide data or information requested by the Secretary under such subsection.''.

(c) SECTION 501.—Section 501(e) (21 U.S.C. 351(e)) is amended—

(1) by striking ''(e)'' and inserting ''(e)(1)''; and

(2) by inserting at the end the following:

''(2) If it is, purports to be, or is represented as, a device that is declared to be in conformity with any performance standard recognized under section 514(c) unless such device is in all respects in conformity with such standard.''.

TITLE III—IMPROVING COLLABORATION AND COMMUNICATION

SEC. 301. COLLABORATIVE DETERMINATIONS OF DEVICE DATA REQUIREMENTS.

Section 513(a)(3) (21 U.S.C. 360c(a)(3)) is amended by adding at the end the following:

''(C)(i) The Secretary, upon the written request of any person intending to submit an application under section 515, shall meet with such person to determine the type of valid scientific evidence within the meaning of subparagraphs (A) and (B) that will be necessary to demonstrate the effectiveness of a device for the conditions of use proposed by such person, to support an approval of an application. Within 30 days after such meeting, the Secretary shall specify in writing the type of valid scientific evidence that will provide a reasonable assurance

that a device is effective under the conditions of use proposed by such person. Any clinical data, including 1 or more well-controlled investigations, specified in writing by the Secretary for demonstrating a reasonable assurance of device effectiveness shall be specified as a result of a determination by the Secretary that such data are necessary to establish device effectiveness and that no other less burdensome means of evaluating device effectiveness are available which would have a reasonable likelihood of resulting in an approval.

''(ii) The determination of the Secretary with respect to the specification of valid scientific evidence under clause (i) shall be binding upon the Secretary, unless—

''(I) such determination by the Secretary would be contrary to the public health; or

''(II) based on new information obtained by the Secretary prior to the approval of an application for an investigational device exemption under section 520(g), the Secretary finds that such determination is scientifically inappropriate.''.

SEC. 302. COLLABORATIVE REVIEW PROCESS.

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

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

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

(3) by inserting after paragraph (1) the following:

''(2)(A) The Secretary shall meet with an applicant not later than 100 days after the receipt of an application that has been filed as complete under subsection (c) 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, provide to the applicant a description of any deficiencies in the application identified by the Secretary and identify the information (other than information the Secretary needs to making a finding under paragraph (4)(C)) that is required to bring the application into a form that would require an approval. The Secretary and the applicant may, by mutual consent, establish a different schedule for a meeting required under this paragraph.

''(B) The Secretary shall notify the applicant immediately of any deficiency identified in the application that was not described as a deficiency in the written description provided by the Secretary under subparagraph (A).''.

TITLE IV—IMPROVING CERTAINTY AND CLARITY OF RULES

SEC. 401. POLICY STATEMENTS.

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

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

(2) by adding at the end the following:

''(2) Not later than February 27, 1999, the Secretary, after evaluating the effectiveness of the Good Guidance Practices document published in the Federal Register at 62 Fed. Reg. 8961, shall promulgate as a regulation in the Federal Register the policies and procedures of the Food and Drug Administration for the development, issuance, and use of guidance documents.''.

SEC. 402. PRODUCT CLASSIFICATION.

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

''SUBCHAPTER D—REVIEW OF APPLICATIONS AND ENVIRONMENTAL IMPACT REVIEWS

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

''(a) CLASSIFICATION OF A PRODUCT.—

''(1) REQUEST.—A person who submits an application or submission (including a petition, notifi-

cation, and any other similar form of request) under this Act, may submit a request to the Secretary respecting the classification of an article (including an article that is a combination product subject to section 503(g)) as a drug, biological product, or device, or respecting the component of the Food and Drug Administration that will regulate the article. In submitting the request, the person shall recommend a classification for the article, or the component that should regulate the article, as appropriate.

''(2) STATEMENT.—Not later than 60 days after the receipt of the request described in paragraph (1), the Secretary shall determine the classification of the article or the component of the Food and Drug Administration that will regulate the article and shall provide to the person a written statement that identifies the classification of the article or the component of the Food and Drug Administration that will regulate the article and the reasons for such determination. The Secretary may not modify such statement except with the written consent of the person or for public health reasons.

''(3) INACTION OF SECRETARY.—If the Secretary does not provide the statement within the 60-day period described in paragraph (2), the rec-

ommendation made by the person under paragraph (1) shall be considered to be a final determination by the Secretary of the classification of the article or the component of the Food and Drug Administration that will regulate the article and may not be modified by the Secretary except with the written consent of the person or for public health reasons.''.

SEC. 403. USE OF DATA RELATING TO PREMARKET APPROVAL.

Section 520(h)(4) (21 U.S.C. 360j(h)(4)) is amended to read as follows:

''(4)(A) Any information contained in an application for premarket approval filed with the Secretary pursuant to section 515(c) (including clinical and preclinical tests or studies that demonstrate the safety and effectiveness of a device, but excluding descriptions of methods of manufacture and product composition) shall be available, 6 years after the application has been approved by the Secretary, for use by the Secretary in—

''(i) approving devices;

''(ii) determining whether a product development protocol has been completed, under section 515;

''(iii) establishing a performance standard or special control under section 514; and

''(iv) classifying or reclassifying devices under section 513 and subsection (l)(2).

''(B) The publicly available detailed summaries of information respecting the safety and effectiveness of devices required by paragraph (1)(A) shall be available for use by the Secretary as the evidentiary basis for the regulatory action described in subparagraph (A).''.

SEC. 404. CONSIDERATION OF LABELING CLAIMS FOR PRODUCT REVIEW.

(a) PREMARKET APPROVAL.—Section 515(d)(1)(A) (21 U.S.C. 360e(d)(1)(A)) is amended by adding at the end the following flush sentences:

''In making the determination whether to approve or deny an application, the Secretary shall rely on the conditions of use proposed in the labeling of a device as the basis for determining whether or not there is a reasonable assurance of safety and effectiveness. If, based on a fair evaluation of all material facts, the proposed labeling is neither false nor misleading in any particular, the Secretary, in making the determination, shall not consider conditions of use not included in the proposed labeling.''.

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

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

''(D) Any determinations of substantial equivalence by the Secretary shall be based upon the intended uses proposed in labeling submitted in a report under section 510(k).''.

SEC. 405. DEFINITION OF A DAY FOR PURPOSES OF PRODUCT REVIEW.

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

''(ii) In any provision relating to a review of any application or submission (including a petition, notification, and any other similar form of request), made under this Act 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 regu-

latory status of the article, the term 'day' means a calendar day in which the Secretary has responsibility to review such an application or submission (excluding any calendar day between the date of receipt, by the person submitting the application or submission, of a written communication from the Secretary setting forth the action of the Secretary on the application or submission and the date of receipt by the Secretary of the written response of the person to the action).''.

SEC. 406. CERTAINTY OF REVIEW TIMEFRAMES.

(a) CLARIFICATION ON THE 90-DAY TIMEFRAME FOR PREMARKET NOTIFICATION REVIEWS.—Section 510(k) (21 U.S.C. 360) is amended by adding at the end the following flush sentence:

''The Secretary shall review the notification required by this subsection and make a determination under section 513(f)(1) not later than 90 days after receiving the notification.''.

(b) CERTAINTY OF 180-DAY REVIEW TIME FRAME.—Section 515(d) (21 U.S.C. 360e(d)), as amended by section 302, is amended by inserting after paragraph (2) the following:

''(3) The time for the review of an application by the Secretary under this subsection shall take not more than

180 days and such time may not be extended if the application is amended.''.

SEC. 407. LIMITATIONS ON INITIAL CLASSIFICATION DETERMINATIONS.

Section 510 (21 U.S.C. 360) is amended by adding at the end the following:

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

''(2) Nothing in this provision shall be construed to prevent the Secretary from using any of the controls authorized by or under section 501, 502, 510, 516, 518, 519, or 520, or any combination of such controls, or any of the special controls established under section 513(a)(1)(B) to regulate a marketed device.''.

SEC. 408. CLARIFICATION WITH RESPECT TO A GENERAL USE AND SPECIFIC USE OF A DEVICE.

Not later than 270 days after the date of enactment of this section, the Secretary shall promulgate a final regulation specifying the general principles that the Secretary will consider in determining when a specific intended use

of a device is not reasonably included within a general use of such device for purposes of a determination of substantial equivalence under section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(f)(1)) .

SEC. 409. CLARIFICATION OF THE NUMBER OF REQUIRED CLINICAL INVESTIGATIONS FOR APPROVAL.

(a) DEVICE CLASSES.—Section 513(a)(3)(A) (21 U.S.C. 360c(a)(3)(A)) is amended by striking ''clinical investigations'' and inserting ''one or more clinical investigations''.

(b) NEW DRUGS.—Section 505(d) (21 U.S.C. 355(d)) is amended by adding at the end the following: ''If the Secretary determines that only one investigation is required, then the Secretary may require appropriate supporting scientific evidence obtained prior to or after such investigation. The Secretary shall establish a mechanism to ensure the fair and consistent application of this provision to new drugs''.

SEC. 410. PROHIBITED ACTS.

Section 301(*l*) (21 U.S.C. 331(*l*) is repealed.

TITLE V—IMPROVING ACCOUNTABILITY

SEC. 501. AGENCY PLAN FOR STATUTORY COMPLIANCE AND ANNUAL REPORT.

Section 903(b) (21 U.S.C. 393(b)), as amended by section 201, is further amended by adding at the end the following:

''(4) AGENCY PLAN FOR STATUTORY COMPLIANCE.—

''(A) IN GENERAL.—Not later than 180 days after the date of enactment of this paragraph, the Secretary, after consultation with relevant experts, health care professionals, and representatives of patient and consumer advocacy groups, and the regulated industry, shall develop and publish in the Federal Register a plan bringing the Secretary into compliance with each of the obligations of the Secretary under this Act and other relevant statutes. The Secretary shall biannually review the plan and shall revise the plan as necessary, in consultation with such persons.

''(B) OBJECTIVES OF AGENCY PLAN.—The plan required by subparagraph (A) shall establish objectives for and mechanisms to be used

by the Secretary, acting through the Commissioner, including objectives and mechanisms that—

''(i) minimize deaths of, and harm to, persons who use or may use an article regulated under this Act;

''(ii) maximize the clarity of, and the availability of information about, the process for review of applications and submissions (including petitions, notifications, and any other similar forms of request) made under this Act, including information for potential consumers and patients concerning new products;

''(iii) implement all inspection and postmarket monitoring provisions of this Act by July 1, 1999;

''(iv) ensure access to the scientific and technical expertise necessary to ensure compliance by the Secretary with the statutory obligations described in subparagraph (A);

''(v) establish a schedule to bring the Administration into full compliance by July 1, 1999, with the time periods speci-

fied in this Act for the review of all applications and submissions described in clause (ii) and submitted after the date of enactment of this paragraph; and

''(vi) reduce backlogs in the review of all applications and submissions described in clause (ii) for any article with the objective of eliminating all backlogs in the review of the applications and submissions by January 1, 2000.

''(5) ANNUAL REPORT.—

''(A) CONTENTS.—The Secretary shall prepare and publish in the Federal Register and solicit public comment on an annual report that—

''(i) provides detailed statistical information on the performance of the Secretary under the plan described in paragraph (4);

''(ii) compares such performance of the Secretary with the objectives of the plan and with the statutory obligations of the Secretary;

"(iii) analyzes any failure of the Secretary to achieve any objective of the plan or to meet any statutory obligation;

"(iv) identifies any regulatory policy that has a significant impact on compliance with any objective of the plan or any statutory obligation; and

"(v) sets forth any proposed revision to any such regulatory policy, or objective of the plan that has not been met.

"(B) STATISTICAL INFORMATION.—The statistical information described in subparagraph (A)(i) shall include a full statistical presentation relating to all applications and submissions (including petitions, notifications, and any other similar forms of request) made under this Act and approved or subject to final action by the Secretary during the year covered by the report. In preparing the statistical presentation, the Secretary shall take into account the date of—

"(i) the submission of any investigational application;

"(ii) the application of any clinical hold;

''(iii) the submission of any application or submission (including a petition, notification, and any other similar form of request) made under this Act for approval or clearance;

''(iv) the acceptance for filing of any application or submission described in clause (iii) for approval or clearance;

''(v) the occurrence of any unapprovable action;

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

''(vii) the approval or clearance of any application or submission described in clause (iii).''.

TITLE VI—INCREASING RESOURCES BY SETTING PRIORITIES

SEC. 601. MINOR MODIFICATIONS.

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

''(6)(A) The Secretary shall, not later than 120 days after the date of enactment of this paragraph, by regulation modify parts 812 and 813 of title 21, Code of Federal

Regulations to update the procedures and conditions under which a device intended for human use may, upon application by the sponsor of the device, be granted an exemption from certain requirements under this Act.

''(B) The regulation shall 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 such application, if the sponsor of the investigation determines, prior to making any changes, that the changes—

''(i) do not affect the scientific soundness of an investigational plan submitted under paragraph (3)(A) or the rights, safety, or welfare of the human subjects involved in the investigation; and

''(ii) do not constitute a significant change in design, or a significant change in basic principles of operation, of the device.''.

(b) ACTION ON APPLICATION.—Section 515(d)(1)(B) (21 U.S.C. 360e(d)(1)(B)) is amended by adding at the end the following:

''(iii) The Secretary shall accept and review data and any other information from investigations conducted under the authority of regulations required by section

520(g) to make a determination of whether there is a reasonable assurance of safety and effectiveness of a device subject to a pending application under this section if—

''(I) the data or information is derived from investigations of an earlier version of the device, the device has been modified during or after the investigations (but prior to submission of an application under section 515(c)) and such a modification of the device does not constitute a significant change in the design or in the basic principles of operation of the device that would invalidate the data or information; or

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

(c) ACTION ON SUPPLEMENTS.—Section 515(d) (21 U.S.C. 360e(d)), as amended by section 302, is further amended by adding at the end the following:

''(6)(A) A supplemental application shall be required for any change to a device subject to an approved application under this subsection that affects safety or effectiveness, unless such change is a modification in a manufacturing procedure or method of manufacturing and the

holder of an approved application submits a written notice to the Secretary that describes the change and informs the Secretary that the change has been made under the requirements of section 520(f).

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

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

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

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

SEC. 602. ENVIRONMENTAL IMPACT REVIEW.

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

''SEC. 742. ENVIRONMENTAL IMPACT REVIEW.

''Notwithstanding any other provision of law, 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 Secretary 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. 603. EXEMPTION OF CERTAIN CLASS DEVICES FROM PREMARKET NOTIFICATION REQUIREMENT.

Section 510 (21 U.S.C. 360) is amended inserting after subsection (k) the following:

''(l)(1) Not later than 30 days after the date of enactment of this subsection, the Secretary shall publish in the Federal Register a list of each type of class II device that does not require a notification under subsection (k) to provide reasonable assurance of safety and effectiveness. Each type of class II device identified by the Secretary not to require the notification shall be exempt from the requirement to provide notification under subsection (k)

as of the date of the publication of the list in the Federal Register.

''(2) Beginning on the date that is 1 day after the date of the publication of a list under this subsection, any person may petition the Secretary to exempt a type of class II device from the notification requirement of subsection (k). The Secretary shall publish notice of the petition in the Federal Register and provide a 30-day period for public comment. The Secretary shall respond to the petition within 120 days after the receipt of the petition and determine whether or not to grant the petition in whole or in part.''.

SEC. 604. REVIEW OF CLASS I AND CLASS II DEVICES.

(a) EXEMPTION FROM PREMARKET NOTIFICATION.—Section 510(k) (21 U.S.C. 360(k)) is amended by striking ''intended for human use'' and inserting ''intended for human use (except a device that is classified into class I under section 513 or 520 unless such device is intended for a use which is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury, or a device that is classified into class II under section 513 or 520 and is exempt from the requirements of this subsection under subsection (l))''.

SEC. 605. EVALUATION OF AUTOMATIC CLASS III DESIGNATION.

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

(1) in paragraph (1) in the last sentence, by striking ''paragraph (2)'' and inserting ''paragraph (2) or (3)'';

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

(3) by inserting after paragraph (1) the following:

''(2)(A) Any person who submits a report under section 510(k) for a type of device that has not been previously classified under this Act, and which is classified into class III under paragraph (1), may request, within 30 days after receiving written notice of such a classification, the Secretary to classify the device into class I or II under the criteria set forth in subsection (a)(1). The person may, in the request, recommend to the Secretary the classification for the device. The request shall describe the device and provide detailed information and reasons for the recommended classification.

''(B)(i) Not later than 60 days after the date of the request under subparagraph (A) for classification of a device under the criteria set forth in subparagraphs (A) through (C) of section 513(a)(1), the Secretary shall by written order classify the device. Such classification shall

be the initial classification of the device for purposes of paragraph (1) and any device classified under this paragraph into class I or II shall be a predicate device for determining substantial equivalence under paragraph (1).

''(ii) A device that remains in class III under this subparagraph shall be deemed adulterated within the meaning of section 501(f)(1)(B) until approved under section 515 or exempted from such approval under section 520(g).

''(C) Following the issuance of an order classifying a device under this paragraph, the Secretary shall, within 30 days after the date of the issuance of the order, publish a notice in the Federal Register announcing such classification.''.

SEC. 606. SECRETARY'S DISCRETION TO TRACK DEVICES.

(a) RELEASE OF INFORMATION.—Section 519(e) (21 U.S.C. 360i(e)) is amended by adding at the end the following flush sentence:

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

(b) PUBLICATION OF CERTAIN DEVICES.—Not later than 180 days after the date of enactment of this Act,

the Secretary shall develop and publish in the Federal Register a list that identifies each type of device subject to tracking under section 519(e)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i(e)). Each device not identified by the Secretary under this subsection shall be deemed to be exempt from the mandatory tracking requirement under section 519 of such Act.

SEC. 607. SECRETARY'S DISCRETION TO CONDUCT POSTMARKET SURVEILLANCE.

(a) IN GENERAL.—Section 522 (21 U.S.C. 360*l*) is amended by striking ''SEC. 522.'' and all that follows through ''(2) DISCRETIONARY SURVEILLANCE.—The'' and inserting the following:

''SEC. 522. (a) DISCRETIONARY SURVEILLANCE.—The''.

(b) SURVEILLANCE APPROVAL.—Section 522(b) (21 U.S.C. 360*l*(b)) is amended to read as follows:

''(b) SURVEILLANCE APPROVAL.—

''(1) IN GENERAL.—Each manufacturer required to conduct a surveillance of a device under subsection (a) shall, not later than 30 days after 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 plan for the required surveillance.

''(2) DETERMINATION.—Not later than 60 days after the receipt of the plan, the Secretary shall determine if a person proposed to be used to conduct the surveillance has sufficient qualifications and experience to conduct the surveillance and if the plan will result in the collection of useful data that can reveal unforeseen adverse events or other information necessary to protect the public health and to provide safety and effectiveness information for the device.

''(3) LIMITATION ON PLAN APPROVAL.—The Secretary may not approve the plan until the plan has been reviewed by a qualified scientific and technical review committee established by the Secretary.''.

(c) DURATION OF SURVEILLANCE.—Section 522 (21 U.S.C. 360*l*), as amended by subsection (b), is further amended by adding at the end the following:

''(c) DURATION OF SURVEILLANCE.—

''(1) IN GENERAL.—Each manufacturer required to conduct a surveillance of a device under subsection (a) shall be required to conduct such surveillance for not longer than 24 months.

''(2) EXTENSION OF THE PERIOD OF SURVEILLANCE.—If the Secretary determines that additional

surveillance is needed to identify the incidence of adverse events documented during the initial period of surveillance that were not foreseen at the time of approval or classification of the device, the Secretary may extend the period of surveillance for such time as may be necessary after providing the person required to conduct such surveillance an opportunity for an informal hearing to determine whether or not additional surveillance is appropriate and to determine the appropriate period, if any, for such surveillance.''.

SEC. 608. 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 and inserting ''; and'';

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

(C) by striking paragraph (9); and

(3) by striking subsection (d).

SEC. 609. PILOT AND SMALL-SCALE MANUFACTURE.

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

''(4) An application shall be approved based on information obtained from products manufactured in a pilot or other small facility so long as the commercial manufacturing process is validated prior to product distribution pursuant to a protocol submitted with the application, unless the Secretary specifies in writing the reasons why information from a full scale production facility is necessary to ensure the safety or effectiveness of the drug.''.

SEC. 610. REQUIREMENTS FOR 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 radiopharmaceutical articles designed for diagnosis and monitoring of diseases and conditions. The regulations shall provide that the safety and effectiveness of a radiopharmaceutical shall be evaluated taking into account the appropriate use of radiopharmaceutical in the practice of medicine, the pharmacological and toxicological activity of the radiopharmaceutical, and the estimated absorbed ra-

diation dose of the radiopharmaceutical. Not later than 1 year after the date of enactment of this Act, the Secretary shall promulgate the final regulations governing the approval of the radiopharmaceutical.

(2) SPECIAL RULE.—In the case of a radiopharmaceutical intended to be used for diagnostic purposes, the indications for which such radiopharmaceutical is approved for marketing 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) DEFINITION.—In this section, the term ''radiopharmaceutical'' means—

(1) an article—

(A) 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

(B) that exerts its primary effect through its pharmacokinetics and 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.

SEC. 611. MODERNIZATION OF REGULATION OF BIOLOGICAL PRODUCTS.

(a) LICENSES.—

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

REGULATION OF BIOLOGICAL PRODUCTS

''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 biologics 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 in the package, the name, address, and applicable license number of the manufacturer of the biological product, and the expiration date of the biological product.

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

''(B) A biologics license application shall be approved based upon a demonstration that—

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

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

''(3) A demonstration under paragraph (2)(B)(i) may be made on the basis of 1 or more clinical trials, or other requirements established by the Secretary under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355).

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

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

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

(B) in paragraph (2),

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

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

(C) in paragraph (2), (as so redesignated by subparagraph (B)(ii)), by striking ''subparagraph (A)'' and inserting ''paragraph (1)''.

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

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

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

(d) DEFINITION; APPLICATION.—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 the following:

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

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

(1) in subparagraph (A), by striking ''section 351(a)'' and inserting ''section 351(i)''; and

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

(f) SPECIAL RULE.—The Secretary of Health and Human Services shall take measures to minimize differences in the review and approval of products required to have biological license applications under section 351 of the Public Health Service Act (42 U.S.C. 262) and products required to have full new drug applications under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355).

SEC. 612. SUPPLEMENTAL NEW DRUG APPLICATIONS.

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

''(7) The Secretary may approve a supplement to an approved application for an additional use for the drug on the basis of literature reports, reliable clinical experience, or persuasive scientific evidence, the totality of which is sufficient to demonstrate the effectiveness of the drug for the use involved.''.

SEC. 613. HEALTH CARE ECONOMIC INFORMATION.

Section 502 (21 U.S.C. 352) is amended by adding at the end the following:

''(u) In the case of a health care economic statement that is included in labeling or advertising provided to a formulary committee, managed care organization, or similar entity with responsibility for drug selection decisions (other than the label or approved physician package insert relating to an indication approved under section 505 or 351 of the Public Health Service Act) if the health care economic statement is not competent and reliable. Any such statement shall be subject solely to this paragraph. In this paragraph, the term 'health care economic statement' means any statement that identifies, measures, or compares the costs (direct, indirect, and intangible) and health care consequences of a drug to another drug or to another health care intervention for the same indication, or to no intervention, where the primary endpoint is an economic outcome.''.

SEC. 614. EXPEDITING STUDY AND APPROVAL OF FAST TRACK DRUGS.

(a) IN GENERAL.—Chapter V (21 U.S.C. 351 et seq.), as amended by section 102, is further amended by adding at the end the following:

''SUBCHAPTER E—FAST TRACK DRUGS

''SEC. 561. FAST TRACK DRUGS.

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

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

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

''(3) DESIGNATION.—Within 30 calendar days after the receipt of a request under paragraph (2), the Secretary shall determine whether the drug that is the subject of the request is being, or will be, investigated for treatment of a condition described in paragraph (1). If the Secretary finds that the drug is intended for such treatment, the Secretary shall

designate the drug as a fast track drug and shall take such actions as are appropriate to expedite the development and review of the drug.

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

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

''(2) LIMITATION.—Approval under this subsection may be subject to the requirement that the sponsor conduct appropriate post-approval studies to validate the surrogate endpoint or otherwise confirm the clinical benefit of the drug.

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

''(1) IN GENERAL.—The Secretary shall, after completion of the pivotal clinical trial for a fast track drug under investigation, accept for filing and commence review of an incomplete application for the drug's approval if the application includes a schedule for submission of information necessary to

make the application complete and any fee that may be required under section 736.

''(2) EXCEPTION.—Any time period for review of human drug applications agreed to by the Secretary under section 736 shall not apply to applications submitted under paragraph (1) until a completed application is submitted.

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

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

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

(b) REGULATIONS.—Within 90 days after the date of enactment of this Act, the Secretary shall issue guidelines for fast track drugs that implement the requirements of section 561 of the Federal Food, Drug, and Cosmetic Act.

SEC. 615. MANUFACTURING CHANGES FOR DRUGS AND BIOLOGICS.

Chapter VII (21 U.S.C. 371 et seq.), as amended by section 602, is further amended by adding at the end the following:

''SUBCHAPTER E—MANUFACTURING CHANGES

''SEC. 751. MANUFACTURING CHANGES.

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

''(b) CHANGES.—

''(1) VALIDATION.—Before distributing a drug made after a change in the manufacture of the drug from the manufacturing process established in the approved new drug application under section 505, or license application under section 351 of the Public Health Service Act, the applicant shall validate the effect of the change on the identity, strength, quality, purity, and potency as the identity, strength, quality, purity, and potency may relate to the safety or effectiveness of the drug.

''(2) REPORTS.—The applicant shall report a change described in paragraph (1) to the Secretary and may distribute a drug made after the change as follows:

''(A)(i) Major manufacturing changes, which are of a type determined by the Secretary to have a substantial potential to adversely affect the identity, strength, quality, purity, and potency as the identity, strength, quality, purity, and potency may relate to the safety or effectiveness of a drug, shall be submitted to the Secretary in a supplemental application and drugs made after such changes may not be distributed until the Secretary approves the supplemental application.

''(ii) In this subparagraph, the term 'major manufacturing changes' means—

''(I) changes in the qualitative or quantitative formulation or the specifications in the approved marketing application (unless exempted by the Secretary);

''(II) changes which the Secretary determines by regulation or guidance require completion of an appropriate human study demonstrating equivalence to the drug manufactured before such changes; and

''(III) other changes which the Secretary determines by regulation or guidance have a substantial potential to ad-

versely affect the safety or effectiveness of the drug.

''(B)(i) As determined by the Secretary, manufacturing changes other than major manufacturing changes shall—

''(I) be made at any time and reported annually to the Secretary, with supporting data; or

''(II) be reported to the Secretary in a supplemental application.

''(ii) In the case of changes made in accordance with clause (i)(II);

''(I) the applicant may distribute the drug 30 days after the supplemental application is received by the Secretary unless the Secretary notifies the applicant within such 30-day period that prior approval of such supplemental application is required; and

''(II) the Secretary shall, after the notification to an applicant under subclause (I), approve or disapprove each such supplemental application.

''(ii) The Secretary may determine types of manufacturing changes after which distribution

of a drug may commence at the time of submission of such supplemental application.''.

(b) EXISTING LAW.—The requirements of the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act in effect on the date of enactment of this Act with respect to manufacturing changes shall remain in effect for—

(1) a period of 24 months after the date of the enactment of this Act; or

(2) until the effective date of regulations promulgated by the Secretary implementing section 751 of the Federal Food, Drug, and Cosmetic Act,

whichever is sooner.

SEC. 616. DATA REQUIREMENTS FOR DRUGS AND BIOLOGICS.

Within 12 months after the date of enactment of this Act, the Secretary, through the Commissioner of Food and Drugs, shall issue guidance that describes when abbreviated study reports in lieu of full reports may be submitted with a new drug application for certain types of studies. Such guidance will describe the kinds of studies for which abbreviated reports are appropriate and the appropriate abbreviated report formats.

SEC. 617. FOOD CONTACT SUBSTANCES.

(a) FOOD CONTACT SUBSTANCES.—Section 409(a) (21 U.S.C. 348(a)) is amended—

(1) in paragraph (1), by striking at the end ''or'';

(2) by striking the period at the end of paragraph (2) and inserting ''; or'';

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

''(3) in the case of a food additive as defined in this Act that is a food contact substance, there is—

''(A) in effect, and such substance and the use of such substance are in conformity with, a regulation issued under this section prescribing the conditions under which such additive may be safely used; or

''(B) a notification submitted under subsection (h) which is effective.''; and

(4) by striking the matter following paragraph (3) (as added by paragraph (2)) and inserting the following flush sentence:

''While such a regulation relating to a food additive, or such a notification under subsection (h) relating to a food additive that is a food contact substance , is in effect, and has not been revoked pursuant to subsection (j), a food

shall not, by reason of bearing or containing such a food additive in accordance with the regulation or notification, be considered adulterated under section 402(a)(1).''.

(b) NOTIFICATION FOR FOOD CONTACT SUBSTANCES.—Section 409 (21 U.S.C. 348), as amended by subsection (a), is further amended—

(1) by redesignating subsections (h) and (i), as subsections (i) and (j), respectively;

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

''NOTIFICATION RELATING TO A FOOD CONTACT SUBSTANCE

''(h)(1) Subject to such regulations as may be promulgated under paragraph (3), a manufacturer or supplier of a food contact substance may, at least 120 days prior to the introduction or delivery for introduction into interstate commerce of the food contact substance, notify the Secretary of the identity and intended use of the food contact substance, and of the determination of the manufacturer or supplier that the intended use of such food contact substance is safe under the standard described in subsection (c)(3)(A). The notification shall contain the information that forms the basis of the determination, the fee required under paragraph (5), and all information re-

quired to be submitted by regulations promulgated by the Secretary.

''(2)(A) A notification submitted under paragraph (1) shall become effective 120 days after the date of receipt by the Secretary and the food contact substance may be introduced or delivered for introduction into interstate commerce, unless the Secretary makes a determination within the 120-day period that, based on the data and information before the Secretary, such use of the food contact substance has not been shown to be safe under the standard described in subsection (c)(3)(A), and informs the manufacturer or supplier of such determination.

''(B) A decision by the Secretary to object to a notification shall constitute final agency action subject to judicial review.

''(C) For purposes of this paragraph, 'food contact substance' means the substance that is the subject of a notification submitted under paragraph (1), and does not include a similar or identical substance manufactured or prepared by a person other than the manufacturer identified in the notification.

''(3)(A) The process in this subsection shall be utilized for authorizing the marketing of a food contact substance except where the Secretary determines that submission and review of a petition under subsection (b) is nec-

essary to provide adequate assurance of safety, or where the Secretary and any manufacturer or supplier agree that such manufacturer or supplier may submit a petition under subsection (b).

''(B) The Secretary is authorized to promulgate regulations to identify the circumstances in which a petition shall be filed under subsection (b), and shall consider criteria such as the probable consumption of such food contact substance and potential toxicity of the food contact substance in determining the circumstances in which a petition shall be filed under subsection (b).

''(4) The Secretary shall keep confidential any information provided in a notification under paragraph (1) for 120 days after receipt by the Secretary of the notification. After the expiration of such 120 days, the information shall be available to any interested party except for matters in the notification that is a trade secret or confidential commercial information.

''(5)(A) Each person that submits a notification regarding a food contact substance under this section shall be subject to the payment of a reasonable fee. The fee shall be based on the resources required to process the notification including reasonable administrative costs for such processing.

''(B) The Secretary shall conduct a study of the costs of administering the notification program established under this section and, on the basis of the results of such study, shall, within 18 months after the date of enactment of this subsection, promulgate regulations establishing the fee required by subparagraph (A).

''(C) A notification submitted without the appropriate fee is not complete and shall not become effective for the purposes of paragraph (3) until the appropriate fee is paid.

''(D) Fees collected pursuant to this subsection—

''(i) shall not be deposited as an offsetting collection to the appropriations for the Department of Health and Human Services;

''(ii) shall be credited to the appropriate account of the Food and Drug Administration; and

''(iii) shall be available in accordance with appropriation Acts until expended, without fiscal year limitation.

''(6) In this section, the term 'food contact substance' means any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food.'';

(3) in subsection (i), as so redesignated by paragraph (1), by adding at the end the following: ''The Secretary shall by regulation prescribe the procedure by which the Secretary may deem a notification under subsection (h) to no longer be effective.

(4) in subsection (j), as so redesignated by paragraph (1), by striking ''subsections (b) to (h)'' and inserting ''subsections (b) to (i)''.

(c) EFFECTIVE DATE.—Notifications under section 409(h) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (b), may be submitted beginning 18 months after the date of the enactment of this Act.

SEC. 618. HEALTH CLAIMS OF FOOD PRODUCTS.

Section 403(r)(3) (21 U.S.C. 343(r)(3)) is amended by adding at the end the following:

''(C) Notwithstanding the provisions of clauses (A)(i) and (B), a claim of the type described in subparagraph (1)(B) which is not authorized by the Secretary in a regulation promulgated in accordance with clause 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.''.

SEC. 619. 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:

''SEC. 505A. PEDIATRIC STUDIES OF DRUGS.

''(a) MARKET EXCLUSIVITY FOR NEW DRUGS.—If, prior to approval of an application that is submitted under section 505(b)(1) the Secretary determines that information relating to the use of a drug in the pediatric popu-

lation may produce health benefits in that population, the Secretary makes a written request for pediatric studies (which may include a time frame for completing such studies), and such studies are completed within any such time frame and the reports thereof submitted in accordance with subsection (d)(2) or completed within any such time frame and the reports thereof are accepted in accordance with subsection (d)(3)—

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

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

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

''(i) a listed patent for which a certification has been submitted under section 505(b)(2)(A)(ii) or section (j)(2)(A)(vii)(II) and

for which pediatric studies were submitted prior to the expiration of the patent (including any patent extensions), or

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

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

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

"(b) SECRETARY TO DEVELOP LIST OF DRUGS FOR WHICH ADDITIONAL PEDIATRIC INFORMATION MAY BE

BENEFICIAL.—Not later than 180 days after the date of enactment of this section, the Secretary, after consultation with experts in pediatric research (such as the American Academy of Pediatrics, the Pediatric Pharmacology Research Unit Network, and the United States Pharmacopoeia) shall develop and publish an initial list of approved drugs for which additional pediatric information may produce health benefits in the pediatric population. The Secretary shall annually update the list.

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

''(1)(A) the period during which an application may not be submitted under subsections (c)(3)(D)(ii) and (j)(4)(D)(ii) of section 505 shall be five years and six months rather than five years, and the references in subsections (c)(3)(D)(ii) and

(j)(4)(D)(ii) of section 505 to four years, to forty-eight months, and to seven and one-half years shall be deemed to be four and one-half years, fifty-four months, and eight years, respectively; or

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

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

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

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

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

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

''(d) CONDUCT OF PEDIATRIC STUDIES.—

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

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

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

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

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

''(2) WRITTEN PROTOCOLS TO MEET THE STUDIES REQUIREMENT.—If the sponsor or holder

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

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

respond to the written request, whether such studies have been conducted in accordance with commonly accepted scientific principles and protocols, and whether such studies have been reported in accordance with the requirements of the Secretary for filing.

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

''(f) NOTICE OF DETERMINATIONS ON STUDIES REQUIREMENT.—The Secretary shall publish a notice of any

determination that the requirements of subsection (d) have been met and that submissions and approvals under section 505(b)(2) or (j) for a drug will be subject to the provisions of this section.

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

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

''(i) SUNSET.—No period of market exclusivity shall be granted under this section based on studies commenced after January 1, 2004. The Secretary shall conduct a study and report to Congress not later than January 1, 2003 based on the experience under the program. The study and report shall examine all relevant issues, including—

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

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

''(3) the economic impact of the program; and

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

TITLE VII—FEES RELATING TO DRUGS

SEC. 701. SHORT TITLE.

This title may be cited as the ''Prescription Drug Users Fee Reauthorization Act of 1997''.

SEC. 702. FINDINGS.

Congress finds that—

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

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

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

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

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

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

SEC. 703. DEFINITIONS.

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

(1) in paragraph (1)—

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

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

(2) in paragraph (3)—

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

(B) by striking ''September 1, 1992.'' and inserting the following: ''September 1, 1992, does not include a biological product that is licensed for further manufacturing use only, and does not include a biological product that is not distributed commercially and is the subject of a supplement or application submitted by a State

or Federal Government entity. Such term does include a large volume biological product intended for single dose injection for intravenous use or infusion.'';

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

(4) in paragraph (7)(A), by striking ''employees under contract'' and all that follows through ''Administration,'' and inserting ''contractors of the Food and Drug Administration,'';

(5) in paragraph (8)—

(A) in subparagraph (A)—

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

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

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

''(B) the total percentage increase for such fiscal year since fiscal year 1997 in basic pay under the General Schedule in accordance with section 5332 of title 5, United States Code, as adjusted by any locality-based comparability payment pursuant to section 5304 of such title

for Federal employees stationed in the District of Columbia.''; and

(6) by adding at the end the following:

''(9) The term 'affiliate' means, directly or indirectly,—

''(A) 1 business entity controls, or has the power to control, the other business entity; or

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

SEC. 704. AUTHORITY TO ASSESS AND USE DRUG FEES.

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

(1) in paragraph (1)—

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

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

(B) in subparagraph (D)—

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

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

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

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

(C) by adding at the end the following:

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

''(F) EXCEPTION FOR APPLICATIONS AND SUPPLEMENTS FOR PEDIATRIC INDICATIONS.—A human drug application or supplement that includes an indication for use in pediatric populations shall be assessed a fee under subparagraph (A) only if—

''(i) the application is for initial approval for use in a pediatric population; or

''(ii) the application or supplement is for approval for use in pediatric and non-pediatric populations.

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

(2) in paragraph (2)(A), by striking ''505(j), and'' and inserting the following: ''505(j) or under an abbreviated new drug application pursuant to regulations in effect prior to the implementation of the Drug Price Competition and Patent Term Restoration Act of 1984, or a product approved under an application under section 507 that is abbreviated, and''; and

(3) in paragraph (3)—

(A) in subparagraph (A)—

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

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

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

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

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

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

''(2) SUPPLEMENT FEE.—The supplement fee under subsection (a)(1)(A)(ii) shall be $125,352 in fiscal year 1998, $128,169 in fiscal years 1999 and 2000, $133,803 in fiscal year 2001, and $129,226 in fiscal year 2002.

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

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

establishment fees under subsection (a)(2) in that fiscal year.''.

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

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

(2) in paragraph (1)—

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

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

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

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

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

(3) in paragraph (2), by striking ''October 1, 1992,'' and all that follows through ''such schedule.''

and inserting the following: ''September 30, 1997, adjust the establishment and product fees described in subsection (b) so that the revenues collected from each such fee category shall be set to be equal to the revenues collected from the application and supplement fee category.''; and

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

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

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

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

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

(3) in subparagraph (C) (as so redesignated by paragraph (1)), by striking '', or'' and inserting a comma;

(4) in subparagraph (D) (as so redesignated by paragraph (1)), by striking the period and inserting '', and'';

(5) by inserting after subparagraph (D) (as so redesignated by paragraph (1)) the following:

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

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

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

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

''(A) DEFINITION.—For the purpose of paragraph (1)(E), a small business is an entity that has fewer than 500 employees, including employees of affiliates.

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

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

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

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

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

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

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

(1) in paragraph (1), by adding at the end the following: ''Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limi-

tation. The sums transferred shall be available solely for the process for the review of human drug applications within the meaning of subsection 735(6).'';

(2) in paragraph (2)—

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

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

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

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

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

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

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

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

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

as adjusted to reflect adjustments in the total fee revenues made under this section and changes in the

total amounts collected by application, supplement, establishment, and products fees.''.

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

(1) redesignating subsection (i) as subsection (j); and

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

''(i) WRITTEN REQUESTS FOR WAIVERS AND REFUNDS.—To qualify for consideration for a waiver under subsection (d), or for a refund of any fee collected in accordance with subsection (a), a person must submit to the Secretary a written request for such waiver or refund not later than 180 days after such fee is due. Any requests for waivers, refunds, or exceptions must be submitted in writing to the Secretary within 1 year after the date of enactment of this subsection.''.

SEC. 705. ANNUAL REPORTS.

(a) FIRST REPORT.—Not later than 60 days after the end of each fiscal year during which fees are collected under part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g et seq.), the Secretary of Health and Human Services shall prepare and submit to the Committee on Commerce of the House

of Representatives and the Committee on Labor and Human Resources of the Senate a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letter described in section 702(4) during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals.

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

SEC. 706. EFFECTIVE DATE.

The amendments made by this title shall take effect October 1, 1997.

SEC. 707. TERMINATION OF EFFECTIVENESS.

The amendments made by sections 703 and 704 cease to be effective October 1, 2002 and section 4 ceases to be effective 120 days after such date.

TITLE VIII—MISCELLANEOUS

SEC. 801. REGISTRATION OF FOREIGN ESTABLISHMENTS.

Section 510(i) (21 U.S.C. 360(i)) is amended to read as follows:

''(i)(1) Any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs or a device or devices that are imported or offered for the import into the United States shall register with the Secretary the name and place of business of the establishment and the name of the United States agent for the establishment.

''(2) The establishment shall also provide the information required by subsection (j).

''(3) The Secretary is authorized to enter into cooperative arrangements with foreign countries to ensure that adequate and effective means are available for purposes of determining, from time to time, whether drugs or devices manufactured, prepared, propagated, compounded, or processed in an establishment in paragraph (1), if imported or offered for import into the United States, shall be refused admission on any of the grounds set forth in section 801(a) of this Act.

SEC. 802. ELIMINATION OF CERTAIN LABELING REQUIREMENTS.

(a) PRESCRIPTION DRUGS.—Section 503(b)(4) (21 U.S.C. 353(b)(4)) is amended to read as follows:

''(4)(A) A drug which is subject to paragraph (1) shall be deemed to be misbranded if at any time prior to dispensing the label of the drug fails to bear, at a minimum, the symbol 'Rx only'.''

''(B) A drug to which paragraph (1) does not apply shall be deemed to be misbranded if at any time prior to dispensing the label of the drug bears the symbol described in subparagraph (B).

(b) MISBRANDED DRUG.—Section 502(d) (21 U.S.C. 352(d)) is repealed.

SEC. 803. CLARIFICATION OF SEIZURE AUTHORITY.

Section 304(d)(1) (21 U.S.C. 334(d)(1)) is amended—

(1) in paragraph (1), in the fifth sentence, by striking ''paragraphs (1) and (2) of section 801(e)'' and inserting ''subparagraphs (A) and (B) of section 801(e)(1)''; and

(2) by inserting after the fifth sentence the following: ''Any person seeking to export an imported article pursuant to any of the provisions of this subsection shall establish that the article was intended for export at the time the article entered commerce.''

SEC. 804. INTRAMURAL RESEARCH TRAINING AWARD PROGRAM.

Chapter IX (21 U.S.C. 391 et seq.), as amended by section 206, is further amended by adding at the end the following:

"SEC. 908. RESEARCH TRAINING AWARD PROGRAM.

''(a) IN GENERAL.—The Secretary, acting through the Commissioner of Food and Drugs, may, directly or through grants, contracts, or cooperative agreements, conduct and support research training in regulatory scientific programs by predoctoral and postdoctoral scientists and physicians, including the use of fellowships.

''(b) LIMITATION ON PARTICIPATION.—A recipient of a fellowship under subsection (a) may not be an employee of the Federal Government.

''(c) SPECIAL RULE.—The Secretary, acting through the Commissioner of Food and Drugs, may support the provision of assistance for fellowships through a Cooperative Research and Development Agreement.''.

SEC. 805. ENFORCEMENT AUTHORITY FOR SPECIAL CONTROLS.

(a) ADULTERATED PROVISIONS.—Section 501(e) as amended by section 205, is amended by striking subparagraph (1) and inserting the following: ''(1) If it is, or purports to be or is represented as, a device which is subject to a performance standard or a special control estab-

lished under section 514, unless such device is in all respects in conformity with such standard or special control.''.

(b) MISBRANDED PROVISIONS.—Section 502(s) (21 U.S.C. 352(s)) is amended to read as follows:

''(s) If it is a device subject to a performance standard or a special control established or recognized under section 514, unless the device bears such labeling as may be prescribed in such standard or special control.''.

SEC. 806. DEVICE SAMPLES.

(a) RECALL AUTHORITY.—

(1) IN GENERAL.—Section 518(e)(2) (21 U.S.C. 360h(e)(2)) is amended by adding at the end the following:

''(C) If the Secretary issues an amended order under subparagraph (A), the Secretary may require the person subject to the order to submit samples of such device and of components of the device as the Secretary may reasonably require, except that where the submission of such samples is impracticable or unduly burdensome, the requirement of this subparagraph may be met by the submission of complete information concerning the location of 1 or more such devices readily available for examination and testing.''.

(2) TECHNICAL AMENDMENT.—Section 518(e)(2)(A)) is amended by striking ''subparagraphs (B) and (C)'' and inserting ''subparagraph (B)''.

(b) RECORDS AND REPORTS ON DEVICES.—Section 519(a) (21 U.S.C. 360(a)) is amended—

(1) in paragraph (8), by striking ''; and'' and inserting a semicolon;

(2) in paragraph (9), by striking ''made.'' and inserting ''made; and'';

(3) by inserting after paragraph (9) the following:

''(10) may reasonably require a manufacturer, importer, or distributor to submit samples of a device and of components of the device that may have caused or contributed to a death or serious injury, except that where the submission of such samples is impracticable or unduly burdensome, the requirement of this paragraph may be met by the submission of complete information concerning the location of 1 or more such devices readily available for examination and testing.''.

SEC. 807. INTERSTATE COMMERCE.

(a) FINDINGS.—Congress finds that—

(1) in order to make effective the regulation of interstate commerce involving devices, foods, drugs, and cosmetics, it is necessary to impose equivalent requirements on intrastate commerce involving adulterated and misbranded devices, foods, drugs, and cosmetics as imposed on interstate commerce in such articles;

(2) without the presumption of a connection with interstate commerce, intrastate commerce involving adulterated and misbranded devices, foods, drugs, and cosmetics would discriminate against and depress interstate commerce in devices, foods, drugs, and cosmetics, and adversely burden, obstruct, and affect such interstate commerce; and

(3) transactions involving adulterated and misbranded devices, foods, drugs, and cosmetics constitute a class of activities that have a deleterious effect on the public health and welfare.

(b) DEFINITION.—Section 201(b) (21 U.S.C. 321(b)) is amended—

(1) by striking ''and (2) commerce'' and inserting ''(2) commerce'';

(2) by inserting before the period the following: '', and (3) commerce involving any article or class of

activities that directly or indirectly affects interstate commerce pursuant to section 709''.

(c) SEIZURE.—Section 304(a)(2)(D) (21 U.S.C. 334(a)(2)(D)) is amended to read as follows: ''(D) Any adulterated or misbranded device, food, drug, or cosmetic.''.

(d) PRESUMPTION.—Section 709 (21 U.S.C. 379a) is amended by striking ''a device'' and inserting ''a device, food, drug, or cosmetic''.

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