state veterans' cemeteries funded under the grant program. This provision would authorize the Secretary to grant up to 100 percent of the cost of improvements to the land to be purchased and up to 100 percent of the initial equipment costs. For existing cemeteries, the Secretary would be authorized to grant up to 100 percent of the cost of the improvements made to any additional land purchased for expansion or 100 percent of the cost of improvements to existing cemetery land. Compromise agreement The compromise bill contains no provision relating this subject.

### NOTICE
Incomplete record of House proceedings. Except for concluding business which follows, today's House proceedings will be continued in the next issue of the Record.

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### CONFERENCE REPORT ON S. 830, FOOD AND DRUG ADMINISTRATION MODERNIZATION ACT OF 1997

Mr. BLILEY submitted the following conference report and statement on the Senate bill (S. 830) to amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to improve the regulation of food, drugs, devices, and biological products, and for other purposes:

**CONFERENCE REPORT (H. Rept. 105-399)**

The Committee of conference on the disagreeing votes of the two Houses on the amendments of the House to the bill (S. 830) to amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to improve the regulation of food, drugs, devices, and biological products, and for other purposes, having met, after full and free conference, have agreed to recommend and do recommend to their respective Houses as follows:

That the Senate recede from its disagreement to the amendment of the House to the text of the bill and agree to the same with an amendment as follows:

In lieu of the matter proposed to be inserted by the House amendment, insert the following:

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

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

(b) **REFERENCES—**Except as otherwise specified, whenever in this Act an amendment or repeal is expressed in terms of an amendment to or a repeal of a section or other provision, the reference shall be considered to be made to that section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

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

**Sec. 1. SHORT title; references; table of contents.**

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**TITLE I—IMPROVING REGULATION OF DRUGS**

**Subtitle A—Fees Relating to Drugs**

Sec. 101. Findings.

Sec. 102. Definitions.

Sec. 103. Authority to assess and use drug fees.

Sec. 104. Annual reports.

Sec. 105. Savings.

Sec. 106. Effective date.

Sec. 107. Termination of effectiveness.

**Subtitle B—Other Improvements**

Sec. 111. Pediatric studies of drugs.

Sec. 112. Expediting study and approval of fast track drugs.

Sec. 113. Information program on clinical trials for serious or life-threatening diseases.

Sec. 114. Health care economic information.

Sec. 115. Clinical investigations.

Sec. 116. Modifications for changes for drugs.

Sec. 117. Streamlining clinical research on drugs.

Sec. 118. Data requirements for drugs and biologics.

Sec. 119. Content and review of applications.

Sec. 120. Scientific advisory panels.

Sec. 121. Positron emission tomography.

Sec. 122. Requirements for radiopharmaceuticals.

Sec. 123. Modernization of regulation.

Sec. 124. Pilot and small scale manufacture.

Sec. 125. Insulin and antibiotics.

Sec. 126. Elimination of certain labeling requirements.

Sec. 127. Application of Federal law to practice of pharmacy compounding.

Sec. 128. Reauthorization of clinical pharmacology program.

Sec. 129. Regulations for sunscreen products.

Sec. 130. Reports of postmarketing approval studies.

Sec. 131. Notification of discontinuance of a life saving product.

**TITLE II—IMPROVING REGULATION OF DEVICES**

Sec. 201. Investigational device exemptions.

Sec. 202. Special review for certain devices.

Sec. 203. Expanding humanitarian use of devices.

Sec. 204. Device standards.

Sec. 205. Scientific review; collaborative determinations of device data requirements.

Sec. 206. Premarket notification.

Sec. 207. Evaluation of automatic class III designation.

Sec. 208. Classification panels.

Sec. 209. Certainty of review timelines; collaborative review process.


Sec. 211. Device tracking.

Sec. 212. Postmarket surveillance.

Sec. 213. Reports.

Sec. 214. Practice of medicine.

Sec. 215. Noninvasive blood glucose meter.

Sec. 216. Use of humans and disease.

**TITLE III—IMPROVING REGULATION OF FOOD**

Sec. 301. Flexibility for regulations regarding claims.

Sec. 302. Petitions for claims.

Sec. 303. Health claims for food products.

Sec. 304. Nutrient content claims.

Sec. 305. Referral statements.

Sec. 306. Disclosure of irradiation.

Sec. 307. Irradiation petition.

Sec. 308. Glass and ceramic ware.

Sec. 309. Food contact substances.

**TITLE IV—GENERAL PROVISIONS**

Sec. 401. Dissemination of information on new uses.

Sec. 402. Expanded access to investigational therapies and diagnostics.

Sec. 403. Approval of supplemental applications for approved products.

Sec. 404. Dispute resolution.

Sec. 405. Informal agency statements.

Sec. 406. Food and Drug Administration mission and annual report.

Sec. 407. Information system.

Sec. 408. Education and training.

Sec. 409. Centers for education and research on therapeutics.

Sec. 410. Mutual recognition agreements and global harmonization.

Sec. 411. Environmental impact review.

Sec. 412. National uniformity for nonprescription methamphetamines.

Sec. 413. Food and Drug Administration study of mercury compounds in drugs and food.

Sec. 414. Interagency collaboration.

Sec. 415. Contracts for expert review.

Sec. 416. Product classification.

Sec. 417. Registration of foreign establishments.

Sec. 418. Clarification of seizure authority.

Sec. 419. Interstate commerce.

Sec. 420. Safety report disclaimers.

Sec. 421. Labeling and advertising regarding comparing with statutory requirements.

Sec. 422. Rule of construction.

**TITLE V—EFFECTIVE DATE**

Sec. 501. Effective date.

**SEC. 2. DEFINITIONS.**

In this Act, the terms "drug", "device", "food", and "dietary supplement" have the meaning given such terms in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

**TITLE I—IMPROVING REGULATION OF DRUGS**

**Subtitle A—Fees Relating to Drugs**

**SEC. 101. FINDINGS.**

Congress finds that—

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

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

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

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

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

(4) the fees authorized by amendments made in this subtitle will be dedicated toward expediting the drug development process and the review of human drug applications as set forth in the goals identified, for purposes of part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, in the letters from the Secretary of Health and Human Services to the chairman of the Committee on Commerce of the House of Representatives and the chairman of

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**CONGRESSIONAL RECORD — HOUSE**

November 9, 1997
the Committee on Labor and Human Resources of the Senate, as set forth in the Congressional Record.

SEC. 102. DEFINITIONS.

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

(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 license of a biological product for further manufacturing use only, and does not include an application or supplement submitted by a State or Federal Government entity for a drug that is not distributed commercially. Such term does include an application or supplement as described in subparagraph (D), of a large volume biological product intended for single dose injection for intravenous use or infusion;"

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

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

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

(iii) by striking "section 254(d)" and inserting "section 254(c)"; and

(iv) by amending the first sentence of paragraph (1)—

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

(B) by striking "and committees," and inserting "and committees and to contracts with such contractors" shall be assessed only one fee per calendar year. The establishment fee shall be payable on the date or after the application or supplement was filed. The Secretary shall have the sole discretion to refund a fee or a portion of the fee under this subparagraph. A determination by the Secretary concerning a refund under this paragraph shall not be reviewable."

(ii) by striking paragraph (2) and inserting the following:

(2) PRESCRIPTION DRUG ESTABLISHMENT FEE.—(A) IN GENERAL.—Except as provided in subparagraph (B), each person that—

(i) is named as the applicant in a human drug application; and

(ii) applied, on or before December 1, 1992, had pending before the Secretary a human drug application or supplement, shall be assessed an annual fee established in subsection (b) for each prescription drug establishment listed in its approved human drug application as an establishment that manufactures the prescription drug product named in the application. The annual establishment fee shall be assessed each year for which the prescription drug product named in the application is assessed a fee under paragraph (3) unless the prescription drug establishment listed in the application does not engage in the manufacture of the prescription drug product during the fiscal year. The establishment fee shall be payable on or before January 31 of each year. Each such establishment shall be assessed only one fee per establishment, notwithstanding the number of prescription drug products manufactured at the establishment. In the event an establishment is listed in its approved human drug application for more than one product, each product shall be assessed an establishment fee for the fiscal year in which such fee is payable."

(3) total fee revenues for product establishment fees.ÐThe total fee revenues collected in product fees under subsection (a) for each fiscal year shall be equal to the total fee revenues collected in establishment fees under subsection (a) for that fiscal year.

(4) increases and adjustments.ÐSection 736(c) (21 U.S.C. 379c(a)) is amended—

(A) by striking "(1) that did not manufacture the product in the previous fiscal year; and

B) by striking "September 1, 1992," and all that follows through "such section.'';

(iii) by striking "subparagraph (B)(i)" and in-
(3) by striking paragraph (3) and inserting the following:

(3) AUTHORIZATION OF APPROPRIATIONS.—There are 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.

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

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

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

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

(ii) Written Requests for Waivers, Reductions, and Refunds.—To qualify for consideration for a waiver or reduction under subsection (d), or for a refund of any fee collected in accordance with subsection (a), the person shall submit to the Secretary a written request for such waiver, reduction, or refund not later than 180 days after such fee is due.

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

(i) ASSESSMENT OF FEES.—The Secretary shall provide such methods of assessment of fees as the Secretary determines to be necessary to achieve uniformity of such fees.

(2) by striking paragraph (2)(A) and inserting the following:

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

(iii) in paragraph (3), by striking "or" and inserting a comma;

(iv) in paragraph (4)(C), by striking "(E) shall retain the authority to assess and collect fees for the review of human drug applications." and inserting the following:

(E) the applicant involved is a small business or its affiliate shall pay—

(A) an application fee for the first human drug application that the small business or its affiliate submits to the Secretary for review;

(B) an application fee for the first human drug application that is submitted to the Secretary for review in the same manner as an entity that does not qualify as a small business; and

(C) any fee required by part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h) that is due prior to the date of enactment of this Act.

(j) REQUIREMENT FOR WRITTEN REQUESTS FOR PEDIATRIC REPORTS.—Section 505 (21 U.S.C. 355) is amended—

(1) by adding at the end the following:

A report concerning the progress of the Food and Drug Administration in achieving goals identified in the letters described in section 1014 during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals identified in such letters is required to be submitted to the Committee on Labor and Human Resources of the Senate concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 1014 during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals identified in such letters.

(k) EFFECTIVE DATE.—(1) In general.—This section shall take effect October 1, 1997.

(2) Secrecy.—Nothing in this section shall be construed to require the disclosure of proprietary information.

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

(A) $110,100,000 for fiscal year 1998;

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

(C) $110,100,000 for fiscal year 2002.

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

(l) FISCAL REPORT.—Beginning with fiscal year 1998, not later than 120 days after the end of each fiscal year during which fees are collected under this part of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act for a human drug application or supplement accepted for filing prior to October 1, 1997, and to assess and collect any product or establishment fee required by such Act for a fiscal year prior to fiscal year 1998.

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

(n) TERMINATION OF EFFECTIVENESS.—The amendments made by sections 102 and 103 cease to be effective October 1, 2002, and section 104 ceases to be effective 120 days after such date.
Congressional Record — House H4055

November 9, 1997

SEC. 112. EXPANDING STUDY AND APPROVAL OF FAST TRACK DRUGS.

(a) IN GENERAL.—Chapter V (21 U.S.C. 351 et seq.) is amended by inserting before section 525 the following:

``(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 the Food and Drug Administration Modernization Act of 1997, the Secretary, after consultation with experts in pediatric research shall develop, prioritize, and publish an initial list of approved drugs for which additional pediatric information may produce health benefits in the pediatric population. The Secretary shall annually update the list.

(c) REVISED EXCLUSIVITY FOR ALREADY-MARKETED DRUGS.—If the Secretary makes a written request to the holder of an approved application under section 505(b)(1) for pediatric studies under paragraph (1) and the period for filing a written request referred to in paragraph (1) has not been conducted in accordance with and the original written request and the written agreement referred to in paragraph (1) have not been conducted in accordance with clause (viii) of section 505(j)(2)(A)(vii)(II) or section 505(j)(2)(A)(vii)(IV) of section 505, and in the patent infringement litigation resulting from the submission of a request for filing 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. The Secretary shall conduct such studies in accordance with the requirements of this section.

(d) CONDUCT OF PEDIATRIC STUDIES.—(1) AGREEMENT FOR STUDIES.—The Secretary may, pursuant to a written request from the Secretary under subsection (a) or (c), after consultation with—

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

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

(C) the holder of an approved application for a drug under section 505(c)(3) or section 505(b)(2) that may result in the approval of pediatric studies under subsection (a) or (c), after consultation with—

(1) the sponsor or holder for the conduct of pediatric studies for such drug. Such agreement shall be in writing and shall include a timeframe for conducting such studies.

(2) WRITTEN PROTOCOLS TO MEET THE STUDIES REQUIREMENT.—If the sponsor or holder agree upon written protocols for the studies, the studies shall be conducted in accordance with the requirements of this section. The Secretary may, if the studies are not conducted in accordance with the written request and the written agreement referred to in paragraph (1), not later than 90 days after the submission of the report of the studies, the Secretary shall accept or reject such reports and so notify the sponsor or holder.

(3) OTHER METHODS TO MEET THE STUDIES REQUIREMENT.—If the sponsor or holder and the Secretary agree to conduct the protocols for the studies, the Secretary shall conduct such studies. If the studies are not conducted in accordance with the written request and the written agreement referred to in paragraph (1), the Secretary shall accept or reject such reports and so notify the sponsor or holder.

(4) DELAY OF EFFECTIVE DATE FOR CERTAIN APPLICATION.—If the Secretary determines that the acceptance or approval of an application under section 505(b)(1) for a new drug may occur after submission of reports of pediatric studies under this section, which were submitted prior to the expiration of the patent in question under section 505(c)(2)(A)(ii) or section 505(c)(2)(A)(iv) of section 505(j)(2)(A)(vii)(II) or section 505(j)(2)(A)(vii)(IV) of section 505, the period of delay shall be deemed to have been running during the period of delay.

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

(6) 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.

(7) LIMITATIONS.—A drug to which the six-month period under subsection (a) or (c) shall be deemed to have been running during the period of delay.

(8) LIMITATION.—Approval of a fast track drug under section 505(b)(2) or 505(j) until the determination under subsection (d) is made, but any such delay shall not exceed 90 days. In the event that requirements of this section are satisfied, the applicable six-month period under subsection (a) or (c) shall be deemed to have been running during the period of delay.

(6) REQUEST FOR DESIGNATION.—The sponsor of a new drug may request the Secretary to designate the drug as a fast track product. A request for designation may be made concurrent with the filing of an application for the investigation of the drug under section 505(i) or section 351(a)(3) of the Public Health Service Act.

(7) TERMINATION.—Within 60 calendar days after the receipt of a request under paragraph (2), the Secretary shall determine whether the drug that is the subject of the request meets the criteria described in subsection (1). If the Secretary finds that the drug meets the criteria, the Secretary shall designate the drug as a fast track product and shall take such actions as are appropriate to expedite the development and review of the application for approval of such product.

(8) APPROVAL OF APPLICATION FOR A FAST TRACK PRODUCT.—(1) IN GENERAL.—The Secretary may approve an application for a fast track product under section 505(c) or section 505 of the Public Health Service Act upon a determination that the product has an effect on a clinical endpoint or on a surrogate endpoint that is reasonably likely to predict clinical benefit.

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

(A) that the sponsor conduct appropriate pediatric studies under subsection (b) or (c) to demonstrate or confirm the effect of the clinical endpoint and otherwise confirm the effect on the clinical endpoint; and

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

(3) Expedited Withdrawal of Approval.—The Secretary may withdraw approval of a fast track product using expedited procedures (as prescribed by the Secretary in regulations which shall include an opportunity for an informal hearing thereon).

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

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

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

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

(c) Review of Incomplete Applications for Approval of a Fast Track Product.—

(1) In General.—If the Secretary determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product meets the definition of a fast track product under section 736 to expedite the drug development process and the review of human drug applications (as defined in section 736) shall not apply to an application submitted under subsection (k) or (l), respectively; and

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

SEC. 112. INFORMATION PROGRAM ON CLINICAL TRIALS OF SERIOUS OR LIFE-THREATENING DISEASES.

SEC. 113. INFORMATION PROGRAM ON CLINICAL TRIALS OF SERIOUS OR LIFE-THREATENING DISEASES.

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

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

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

(1) streamlined conditions that may be available—

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

(3) by inserting after subsection (i) the following:

SEC. 114. HEALTH CARE ECONOMIC INFORMATION.

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

SEC. 115. CLINICAL INVESTIGATIONS.

(a) Clarification of the Number of Required Clinical Investigations for Approval.—Section 505(d) (21 U.S.C. 355(d)) is amended by adding at the end the following:

SEC. 116. MANUFACTURING CHANGES FOR DRUGS.

(a) In General.—Chapter V, as amended by section 112, is hereby amended by inserting after section 506 the following:

SEC. 506A. MANUFACTURING CHANGES.

(a) In General.—With respect to a drug for which an approval has been granted under section 505 or 512 or a license under section 351 of the Public Health Service Act, a change from the manufacturing process approved pursuant to such application or license may be made, and the drug as made with the change may be distributed, if—

(1) the holder of the approved application or license (referred to in this section as the ‘‘holder’’) has validated the effects of the change in accordance with the holder’s procedures.
"(2)(A) in the case of a major manufacturing change, the holder has complied with the requirements of subsection (c); or

(b) in the case of a change that is not a major manufacturing change, the holder may make such change if the Secretary determines that such change complies with the applicable requirements of subsection (d).

(b) **Validation of Effects of Changes.**—For purposes of subsection (a)(1), a drug made with a manufacturing change (whether a major manufacturing change or otherwise) may be distributed only if, before the distribution of the drug as so made, the holder involved submits to the Secretary a supplemental application for such change and the Secretary approves the application. The application shall contain such information as the Secretary determines to be appropriate, and shall include the information developed under subsection (b) by the holder in validating the effects of the change.

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

(d) **Other Manufacturing Changes.**—For purposes of subsection (a)(2)(A), a major manufacturing change is a manufacturing change that is determined by the Secretary to have the potential to adversely affect the identity, strength, quality, purity, or potency of the drug as they may relate to the safety or effectiveness of the drug. Such a change includes a change that:

(A) is made in the qualitative or quantitative formulation of the drug involved or in the specifications in the approved application or license referred to in section 351 of the Public Health Service Act (42 U.S.C. 262) for certain types of studies. Such guidance shall describe the kinds of studies for which abbreviated reports are appropriate and the appropriate abbreviated report formats.

(b) Transition Rule.—The amendment made by subsection (a)(3) shall apply to amendments of the effective date of regulations promulgated by the Secretary of Health and Human Services to implement such amendment, or upon the expiration of the 24-month period beginning on the date of enactment of this Act, whichever occurs first.

**SEC. 117. STREAMLINING CLINICAL RESEARCH.**

Section 505(i)(2) (21 U.S.C. 355(i)) is amended—

(1) by redesignating paragraphs (1) through (3) as subparagraphs (A) through (C), respectively;

(2) by inserting "(1)" after "(2)"; and

(3) by striking the last two sentences; and

(I) by inserting a new paragraph (1) (as designated by paragraph (2) of this section) following new paragraph (2): Subject to paragraph (3), a clinical investigation of a new drug may begin 30 days after the Secretary has received from the manufacturer or sponsor of the investigation a submission containing such information about the drug and the clinical investigation, including—

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

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

(3) At any time, the Secretary may prohibit the conduct of the investigation from conducting the investigation (referred to in this paragraph as a 'clinical hold') if the Secretary determines that such a hold is necessary to protect human beings or to protect the best interests of such human beings. Nothing in this subsection shall be construed to require such exemption shall be conditioned upon the manufacture, or the sponsor of the investigation, requiring that experts using such drugs for investigational purposes certify to such manufacturer or sponsor that they will not use such drugs, or that any controls used in connection therewith, are designed or administered by the Secretary or its representatives, so that such drugs are being used for investigational purposes and will obtain the consent of such human beings or their representatives, except where it is necessary to protect the best interests of such human beings. Nothing in this subsection shall be construed to require any clinical investigator to submit directly to the Secretary reports on the investigational use of drugs."

**SEC. 118. DATA REQUIREMENTS FOR DRUGS AND BIOLOGICS.**

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

**SEC. 119. CONTENT AND REVIEW OF APPLICATIONS.**

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

"(d)(A) The Secretary shall issue guidance for the individuals who review applications submitted under paragraph (1) or under section 351 of the Public Health Service Act, which shall relate to the promptness in conducting the review, technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards, and which shall apply equally to all individuals who make such determinations.

(b) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this subsection or section 351 of the Public Health Service Act if the sponsor or applicant makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size of clinical trials intended to form the primary basis of an effectiveness claim. The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of the clinical trials, and shall provide to the sponsor or applicant upon request.

(c) Any agreement regarding the parameters of the design and size of clinical trials that is to be submitted with an application for a new drug under this paragraph is reached between the Secretary and a sponsor or applicant.
shall be reduced to writing and made part of the administrative record by the Secretary. Such agreement shall not be changed after the testing begins, except—

(i) pursuant to a decision, made in accordance with subparagraph (D) by the director of the reviewing division, that a substantial scientific or effective issue or effectiveness of the drug has been identified after the testing has begun.

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

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

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

(G) For purposes of this paragraph, the reviewing division is the division responsible for the review of an application for approval of a drug under this subsection (including scientific matters, chemistry, manufacturing, and controls).

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

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

(B) in paragraph (4) (as redesignated in paragraph (3)), by striking ``(4)'' and inserting ``(5)'';

(C) in paragraph (4)(I) (as redesignated in paragraph (3)), by striking ``(5)'' and inserting ``(6)'';

(D) in paragraph (7)(C) (as redesignated in paragraph (3)), by striking ``(5)'' each place it occurs and inserting ``(6)'';

(E) in paragraph (7)(D), by striking ``(6)'' each place it occurs and inserting ``(7)'';

(F) by adding after paragraph (7) the following:

``(8) As paragraphs (4) through (9), respectively;

``(G) (1) For the purpose of providing expert scientific advice and recommendations to the Secretary regarding a clinical investigation of a drug or the approval for marketing of a drug under section 505 or section 351 of the Public Health Service Act, the Secretary shall establish panels of experts or use panels of experts established before the date of enactment of the Food and Drug Administration Modernization Act of 1992, or both.

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

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

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

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

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

Scientific, trade, and consumer organizations shall be afforded an opportunity to nominate individuals for appointment to the panels. No individual who is in the regular full-time employ of the United States and engaged in the administrative or regulatory functions of the Secretary, or any member of the Secretary's immediate family, may be appointed to serve as a member of any panel. The Secretary shall designate one of the members of each panel to serve as chairman thereof.

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

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

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

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

(8) Within 90 days after a scientific advisory panel makes recommendations on any matter under review, the Food and Drug Administration official responsible for the matter shall review the conclusions and recommendations of the panel, and notify the affected persons of the final decision on the matter, or of the reasons that no such decision has been reached. Each such final decision shall be documented including the rationale for the decision.

SEC. 120. SCIENTIFIC ADVISORY PANELS.

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

``(n) For the purpose of providing expert scientific advice and recommendations to the Secretary regarding a clinical investigation of a drug or the approval for marketing of a drug under section 505 or section 351 of the Public Health Service Act, the Secretary shall establish panels of experts or use panels of experts established before the date of enactment of the Food and Drug Administration Modernization Act of 1992, or both.

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

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

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

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

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

Scientific, trade, and consumer organizations shall be afforded an opportunity to nominate individuals for appointment to the panels. No individual who is in the regular full-time employ of the United States and engaged in the administrative or regulatory functions of the Secretary, or any member of the Secretary's immediate family, may be appointed to serve as a member of any panel. The Secretary shall designate one of the members of each panel to serve as chairman thereof.

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

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

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

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

(8) Within 90 days after a scientific advisory panel makes recommendations on any matter under review, the Food and Drug Administration official responsible for the matter shall review the conclusions and recommendations of the panel, and notify the affected persons of the final decision on the matter, or of the reasons that no such decision has been reached. Each such final decision shall be documented including the rationale for the decision.

SEC. 121. POSITRON EMISSION TOMOGRAPHY.

(a) REGULATION OF COMPOUNDED POSITRON EMISSION TOMOGRAPHY DRUGS.—Section 201 (21 U.S.C. 321) is amended by adding at the end the following:

``(j) The term 'compounded positron emission tomography drug'—

(1) means a drug that—

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

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

(b) ADULTERATION.—

(1) In general.—Section 501(a) (21 U.S.C. 351(a)) is amended by striking "; or (3)" and inserting "; or (3) or (4)".

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

``(4) The term 'compounded positron emission tomography drug'—

(1) means a drug that—

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

(b) ADULTERATION.—
standards and the official monographs of the United States Pharmacopoeia to assure that such drug meets the requirements of this Act as to safety and has the identity, strength, and purity, and包装, and that it purports or is represented to possess; or
(3) the property of the biological product contained in the package; and
(iii) the expiration date of the biological product;
(ii) on the basis of a demonstration that—
\(\text{(i)}\) the biological product that is the subject of the application is safe, pure, and potent; and
\(\text{(ii)}\) the facility in which the biological product is manufactured, processed, packed, or held by the manufacturer is designed to assure that the biological product continues to be safe, pure, and potent; and
(iii) if the applicant (or other appropriate person) consents to the inspection of the facility that is the subject of the application, in accordance with subsection (c), the Secretary shall prescribe requirements under which a biological product undergoing investigation shall be exempt from the requirements of paragraph (1).

(a) REQUIREMENTS.—
(1) REGULATIONS.—
(A) PROPOSED REGULATIONS.—Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services, after consultation with patient advocacy groups, professional associations, manufacturers, scientists licensed to make or use positron emission tomography drugs, and the special techniques and requirements required to produce these drugs, not later than 2 years after the date of enactment of this Act, the Secretary of Health and Human Services shall consult with patient advocacy groups, professional associations, manufacturers, and scientists licensed to make or use positron emission tomography drugs.

(b) DEFINITION.—In this section, the term "radiopharmaceutical" means—
(1) an article that is intended for use in the diagnosis or monitoring of a disease or a manifestation of a disease in human beings; and
(2) in subparagraph (A), the name, address, and applicable license number of the manufacturer of the biological product.

(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."
SEC. 124. PHARMACY AND SMALL SCALE MANUFACTURE.

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

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"(2)(A) is by a licensed pharmacist or licensed physician in limited quantities before the receipt of a valid prescription order for such individual patient; and

"(B) is based on a history of the licensed pharmacist or licensed physician receiving valid prescription orders for the compounding of the drug product, which orders have been generated solely within an established relationship between—

"(i) the licensed pharmacist or licensed physician; and

"(ii)(I) such individual patient for whom the prescription order will be provided; or

"(II) the physician or other licensed practitioner to whom write such prescription order.

"(2) Compounded Drug.—

"(1) Licensed Pharmacist and Licensed Physician—This may be compounded under subsection (a) if the licensed pharmacist or licensed physician—

"(A) compounds the drug product using bulk drug substances, as defined in regulations issued by the Secretary published at section 207.3(a)(4) of title 21 of the Code of Federal Regulations—

"(i) comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and

"(ii) that is in accordance with the United States Pharmacopoeia chapter on pharmacy compounding;

"(ii) if such a monograph does not exist, is a drug substance that are components of drugs approved by the Secretary, or

"(III) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, that appear on a list developed by the Secretary through regulations issued by the Secretary under subsection (d); and

"(iii) that are manufactured by an establishment that is registered under section 510(i); and

"(iii) that are accompanied by valid certificates that such bulk drug substance is manufactured by an establishment that is registered under section 510(i);

"(B) compounds the drug product using ingredients (other than bulk drug substances) that comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and

"(C) does not compound a drug product that appears on a list published by the Secretary in the Federal Register of drug products that have been withdrawn or removed from the market because of serious or life-threatening adverse reactions or components of drug products have been found to be unsafe or not effective; and

"(D) a drug product not compounded regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product.

"(2) Definition.—For purposes of paragraph (1)(D), the term 'essentially a copy of a commercially available drug product' does not include a drug product in which there is a change, made for an identified individual patient, which produces for that patient a significant difference, as determined by the prescribing practitioner, between the compounded drug and the comparable drug that is commercially available by prescription.

"(3) Drug Product.—A drug product may be compounded under subsection (a) only if—

"(A) the compounded drug product is not a drug product identified by the Secretary by regulation as a drug product that presents demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of the drug product; and

"(B) such drug product is compounded in a State—

"(i) that has entered into a memorandum of understanding with the Secretary which addresses the distribution of inordinate amounts of compounded drug products interstate and provides for the investigation and prosecution of the State agency of complaints relating to compounded drug products distributed outside such State; or

"(ii) that has not entered into the memorandum of understanding described in clause (i) and the licensed pharmacist, licensed physician, or licensed physician distributes (or causes to be distributed) compounded drug products outside the State in which they are compounded in quantities that do not exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacist, physician, or licensed physician.

The Secretary shall, in consultation with the National Association of Boards of Pharmacy, develop a standard memorandum of understanding for use by the States in complying with subparagraph (B).

"(4) Advertising and Promotion.—A drug product may be compounded under subsection (a) only if the licensed pharmacist or licensed physician does not advertise or promote the compounding of any particular drug, class of drug, or type of drug. The pharmacy, licensed pharmacist, or licensed physician may advertise and promote the compounding service provided by the licensed pharmacist or licensed physician.

"(d) Regulations.—

"(1) In General.—The Secretary shall issue regulations to implement this section. Before issuing regulations to implement subsections It and (ii) of subsection (a), the Secretary shall convene and consult an advisory committee on compounding unless the Secretary determines that the issuance of such regulations before the completion of the public health. The advisory committee shall include representatives from the National Association of Boards of Pharmacy, the United States Pharmacopoeia and National Formulary, the United States Pharmacopoeia Convention, Incorporated, and the United States Pharmacopoeia, or National Formulary, and other compounding pharmacist, or licensed physician may advertise

"(2) Limiting Compounding.—The Secretary, in consultation with the United States Pharmacopoeia Convention, Incorporated, shall promulgate regulations identifying drug substances that may be used in compounding under subsection (a)(I), (II), or (III) for which a monograph does not exist or which are not components of drug products approved by the Secretary. The Secretary shall include in the regulation the criteria for such substances, which shall include historical use, reports in peer reviewed medical literature, or other criteria the Secretary may identify.

"(e) Application.—This section shall not apply to—

"(1) compounded positron emission tomography drugs as defined in section 201(iii); or

"(2) radiopharmaceuticals.

"(f) Definition.—As used in this section, the term 'compounding' does not include mixing, reconstituting, or other such acts that are performed in accordance with an approved labeling provided by the product manufacturer or other manufacturer directions consistent with that labeling.

"(1) Effective Date.—Section 503A of the Federal Food, Drug, and Cosmetic Act, added by subsection (a), shall take effect upon the expiration of the 1-year period beginning on the date of the enactment of this Act.

"(2) Postmarketing Study.—A postmarketing study of a drug shall be subject to the provisions of section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act, and

"(3) Postmarketing Study.—Any agreement entered into between the Secretary and a sponsor of a drug that has entered into an agreement with the Secretary to conduct a postmarketing study of a drug shall submit to the Secretary, within 1 year after the approval of such drug and annually throughout the study, a report of the progress of the study or the reasons for the failure of the sponsor to conduct the study. The report shall be submitted in such form as is prescribed by the Secretary in regulations issued by the Secretary.

"(g) Agreements Prior to Effective Date.—Any agreement entered into between the Secretary and a sponsor of a drug, prior to the date of enactment of the Food and Drug Administration Modernization Act of 1997, to conduct a postmarketing study of a drug shall be subject to the provisions of section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act, and

"(h) Consideration of Information as Public Information.—Any information pertaining to a report described in subsection (a) shall be considered to be public information to the extent that the information is necessary—

"(1) to identify the sponsor; and

"(2) to establish the status of a study described in subsection (a) and the reasons, if any, for any failure to carry out the study.

"(i) Status of Studies and Reports.—The Secretary shall annually publish in the Federal Register a report containing—

"(1) a summary of the reports submitted under section 506B of the Federal Food, Drug, and Cosmetic Act; and

"(2) an evaluation of—

"(A) the performance of the sponsors described in subsection (a) and the reasons, if any, for any failure to carry out the study; and

"(B) the timeliness of the Secretary's review of the postmarketing studies; and

"(J) any legislative recommendations respecting the postmarketing studies.

"(k) Notification of Discontinuance of a Life Saving Product.—

"(1) In General.—A manufacturer that is the sole manufacturer of a drug—

"(i) that is—

"(I) life-saving;

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

"(2) for which an application has been approved under section 505(b) or 505(j); and

"(3) for which the product that was originally derived from human tissue and was replaced by a recombinant product,
shall notify the Secretary of a discontinuance of the manufacture of the drug at least 6 months prior to the date of the discontinuance.

(b) Reduction in Notification Period.—The 6-month period required under subsection (a) for a manufacturer to submit to the Secretary an order to cease or modify the manufacture of a drug under subsection (a) may be reduced by the Secretary if the Secretary determines that such a reduction is in the public interest.

(c) Distribution.—To the maximum extent practicable, the Secretary shall distribute information concerning a drug that is subject to subsection (a) to appropriate physicians and patient organizations.

SEC. 201. INVESTIGATIONAL DEVICE EXEMPTIONS.

(a) In General.—Section 520(g) (21 U.S.C. 360j(g)) is amended by adding at the end the following: """
(1) in paragraph (2), by adding after and before such paragraph the following:
(2) by adding the following:
(3) by inserting after such paragraph the following:
(4) by adding the following:
(5) by inserting after such paragraph the following:
(6) by amending paragraph (5) to read as follows:
"""

(b) Action on Application.—Section 513(d)(1)(B) (21 U.S.C. 360e(d)(1)(B)) is amended by adding at the end the following:

(6) The Secretary may suspend or withdraw an exemption from the effectiveness requirements of sections 514 and 515 for a humanitarian device under this section if—
(A) the sponsor or applicant for the purpose of reaching agreement with the Secretary or to an institutional review committee of such use. Such notification shall include the identification of the procedure described in subparagraph (b) in which a physician uses a device without an approval from an institutional review committee.

(c) Distribution.—To the maximum extent practicable, the Secretary shall distribute information concerning a device under subsection (a) to appropriate physicians and patient organizations.

SEC. 202. SPECIAL REVIEW FOR CERTAIN DEVICES.

Section 515(d) (21 U.S.C. 360e(d)) is amended—
(1) by redesignating paragraph (3) as paragraph (4); and
(2) by adding at the end the following:

(5) In order to provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human diseases or conditions, the Secretary shall provide priority review for devices—
(A) representing breakthrough technologies,
(B) for which no approved alternatives exist,
(C) which offer significant advantages over existing approved alternatives, or
(D) the availability of which is in the best interest of the patients.

SEC. 203. EXISTING HUMANITARIAN USE OF DEVICES.

Section 520(m) (21 U.S.C. 360m) is amended—
(1) by redesignating paragraph (2) as paragraph (3); and
(2) by adding at the end the following:

(4) The Secretary may request, at any time, the data or information provided to the Secretary under subsection (a) to submit to the Secretary, for review, an investigational plan (including a clinical protocol). If the Secretary determines that such a review is necessary, the Secretary shall prepare an investigational plan which shall include an order approving or denying the application.

(5) The Secretary may submit an order approving or denying the application for review by the Secretary, for review, an investigational plan (including a clinical protocol). If the Secretary determines that such a review is necessary, the Secretary shall prepare an investigational plan which shall include an order approving or denying the application.

(6) The Secretary may require a person making a declaration of conformity to the Secretary, for review, an investigational plan (including a clinical protocol). If the Secretary determines that such a review is necessary, the Secretary shall prepare an investigational plan which shall include an order approving or denying the application.
and information demonstrating conformity of the device to the standard for a period of two years after the date of the classification or approval of the device by the Secretary or a period equal to the expected design life of the device, whichever is longer."

(b) Section 510—Section 510 (21 U.S.C. 3511) is amended by adding at the end the following:

"(c) (1) In making a determination of a reasonable assurance of the effectiveness of a device for which an application under section 515 has been submitted, the Secretary shall consider whether the extent of data of that otherwise would be required for approval of the application with respect to effectiveness can be reduced through reliance on postmarket controls.

"(d) (1) The Secretary, upon the written request of any person submitting an application under section 515, may permit a person to determine the type of valid scientific evidence (within the meaning of subparagraphs (A), (B), and (C)) that will be necessary to demonstrate for purposes of approval of an application the effectiveness of a device for the conditions of use proposed by such person. The written request shall include a detailed description of the device, a detailed description of the proposed conditions of use of the device, a proposed plan for determining whether there is a reasonable assurance of effectiveness, and, if applicable, information regarding the expected performance from the device. Within 30 days after such meeting, the Secretary shall specify in writing the evidence (within the meaning of subparagraphs (A), (B), and (C)) that will be necessary to demonstrate at the time postmarket controls may expedite the review of the Secretary for demonstrating a reasonable assurance of the effectiveness of a device under section (f)(1) of this section.

"(2) Whenever the Secretary requests information that is necessary to making a determination that a proposed conditions of use of the device, a proposed plan for determining whether there is a reasonable assurance of the effectiveness of a device under section (f)(1) of this section, the Secretary shall specify in writing the least burdensome means of demonstrating substantial equivalence and request information accordingly.

"(e) (i) Any determination by the Secretary of the intended use of a device shall be based upon the proposed labeling submitted in a report for the device under section 510(k). However, if determining that a device can be found substantially equivalent to a legally marketed device, the director of the organizational unit responsible for regulating this device (referred to as the 'Director') may require a statement in labeling that provides appropriate information regarding a use of the device that is not identified in the proposed labeling.

"(ii) If, upon providing an opportunity for consultation with the person who submitted such report, the Director determines and states in writing that (I) there is a reasonable likelihood that the device will be used for an intended use not identified in the proposed labeling for the device; and (II) that such use could cause harm, (iii) Such determination shall—

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

"(II) find the device substantially equivalent if the requirements of subparagraph (A) are met and if the labeling for such device conforms to the limitations specified in subclause (II).

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

"(iv) This section has no legal effect with respect to a medical device that is exempted from the requirements of this subparagraph.

"(v) This section has no legal effect with respect to a medical device if the proposed labeling is neither false nor misleading. In determining whether a device is false or misleading, the Secretary shall fairly evaluate all material facts pertinent to the proposed labeling.

"(vi) If the Secretary notifies the holder that the notice is not adequate, the holder of the initial application, for an application for approval supplements, may distribute the device 30 days after the date that is required for acceptance of such change.

"(vii) If the holder of a supplemental application refers to the Secretary to exempt the device, or of the petition, and provide a 30-day period for public comment. Within 120 days after the issuance of the notice, the Secretary shall publish in the Federal Register an order that sets forth the final determination of the Secretary that the change has been made under the requirements of section 520(f).

"(viii) The holder of an approved application who submits a request under clause (i) with respect to a manufacturing change of a device that affects safety or effectiveness, the Secretary shall review the supplement within 135 days after the receipt of the supplement. The time used by the Secretary to review the notice of the manufacturing change shall be deducted from the 135-day review period if the notification meets appropriate content requirements for premarket approval supplements.

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

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

"(ii) clinical data from the approved application and any supplement to the approved application provide a reasonable assurance of safety and effectiveness for the changes described in the supplement.

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

SEC. 205. SCOPE OF REVIEW; COLLABORATIVE DETERMINATIONS OF DEVICE DATA REQUIREMENTS.

(a) Section 513(a) is amended—

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

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

SEC. 206. PREMARKET NOTIFICATION.

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

"(B) In making the determination whether to approve a device intended for human use that is exempted from the requirements of this subsection under subsection (m) or is within a type that has been classified into class II under section 510(m), the Secretary shall consider whether the preexisting evidence under clauses (i) and (ii) shall be binding upon the Secretary, unless such determina-
regarding the exemption of the device that was the subject of the notice. If the Secretary fails to respond to a petition within 180 days of receiving it, the petition shall be deemed to be granted.

(b) Section 513(f).—Section 513(f)(2) (21 U.S.C. 360c(f)) is amended by adding at the end the following:

"(5) The Secretary may not withhold a determination of the initial classification of a device under paragraph (1) because of a failure to comply with all the requirements of this Act to determine substantial equivalence, including a finding that the facility in which the device is manufactured is not in compliance with good manufacturing practices, or the failure to provide any regulations of the Secretary under section 520(f) (other than a finding that there is a substantial likelihood that the failure to comply with such regulations will potentially present a serious risk to human health)."

(c) Section 513(b).—Section 513(b)(2) (21 U.S.C. 360c(b)), as amended by section 205(b), is amended—

(1) in subparagraph (A)(ii)—

(A) in clause (i), by striking "clinical data" and inserting "clinical or scientific data" and by inserting "or a person accredited under section 523" after "Secretary"; and

(B) in clause (ii), by striking "efficacy" and inserting "effectiveness"; and

(2) by adding to the end the following:

"(F) Not later than 60 days after the date of the enactment of the Food and Drug Administration Modernization Act of 1997, the Secretary shall, upon the written request of a device manufacturer, provide a decision regarding the initial classification under this paragraph of a device that is required to be classified as a class II device by law or regulation, but was not previously classified under this paragraph."

SEC. 207. EVALUATION OF AUTOMATIC CLASS III DESIGNATION.

Section 513(f)(2) (21 U.S.C. 360c(f)), as amended by section 206(b), is amended—

(1) in paragraph (1)—

(A) in subparagraph (B), by striking "paragraph (2)" and inserting "paragraphs (2) and (3)"; and

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

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

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

"(2)(A)(i) 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 applied for into class III under paragraph (1), may request, within 30 days after receiving written notice of such a classification, the Secretary to classify the device under the criteria set forth in subparagraphs (A) through (C) of subsection (a)(1). The person may, in the request, recommend to the Secretary a classification for the device. Any such request shall describe the device and provide detailed information and reasons for the recommended classification.

(B)(i) Not later than 60 days after the date of the submission of the request under subparagraph (A), the Secretary shall, by written order classify the device involved. Such classification shall be the initial classification of the device for purposes of paragraphs (1) and any device classified under this paragraph shall be a predicate device for determining substantial equivalence under paragraph (1).

(ii) A device that remains in class III under subsection (c), to discuss the review standards and the reasons for the classification.

(iii) The Secretary shall, promptly, after the receipt of the application, provide the applicant with a written description of any deficiencies in the application, that, at that point, have been identified by the Secretary, based on its review of the entire application and identify the information that is required to correct those deficiencies.

(iv) The Secretary shall notify the applicant promptly of—

(A) any additional deficiency in the application, or

(B) any additional information required to achieve completion of the review and final action on the application, that was not described as a deficiency in the written description provided by the Secretary under clause (ii).

(B) The Secretary and the applicant may, by mutual consent, establish a different schedule for a meeting required under this paragraph.

SEC. 208. CLASSIFICATION PANELS.

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

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

(A) Any person whose device is specifically the subject of review by a classification panel shall have—

(i) the same access to data and information submitted to a classification panel (except for data and information that are not available for public disclosure under section 522 of title 5, United States Code) as the Secretary;

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

(iii) the same opportunity as the Secretary to participate in meetings of the panel.

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

(7) After receiving a classification panel the conclusions and recommendations of the panel on the matter that has been reviewed by the Secretary shall review the conclusions and recommendations, shall make a final decision on the matter in accordance with section 515(d)(2), and shall notify the persons of the decision in writing and, if the decision differs from the conclusions and recommendations of the panel, shall include the reasons for the difference.

(C) A classification panel under this subsection shall not be subject to the annual chartering and annual report requirements of the Federal Advisory Committee Act."

SEC. 209. CERTAINTY OF REVIEW TIMEFRAMES; COLLABORATIVE REVIEW PROCESS.

(a) CERTAINTY OF REVIEW TIMEFRAMES.—Section 510(b) (21 U.S.C. 360b), as amended by section 206(a)(2), is amended—

(1) by adding at the end the following:

"In the event that the Secretary has not made a determination within 60 days of the receipt of the request, the Secretary shall notify the applicant within 60 days of the receipt of the request.

(2) REQUIREMENTS REGARDING REVIEW.—

(A) In general.—In making a recommendation to the Secretary under paragraph (1), an accredited person shall notify the Secretary in writing of the reasons for the recommendation.

(B) TIME PERIOD FOR REVIEW.—Not later than 30 days after the date on which the Secretary is notified under subparagraph (A) by an accredited person with respect to a recommendation of an initial classification of a device, the Secretary shall make a determination with respect to the initial classification of the device.

(C) SPECIAL RULE.—The Secretary may change the initial classification under section 513(f)(1) that is recommended under paragraph (3) of an accredited person's case only if the case shall provide to such person, and the person who submitted the report under section 510(k) for the device, a statement explaining in detail the reasons for the change.

(3) CERTAIN DEVICES.—

(A) In general.—An accredited person may not be used to perform a review of—

(i) a class III device; and

(ii) a class II device which is intended to be permanently implantable or life sustaining or life supporting.

(iii) a class II device which requires clinical data in the report submitted under section 510(k) for the device, except that the number of class II devices to which the Secretary applies this clause for a year, less the number of such reports to which clauses (i) and (ii) apply, may not exceed 6 percent of the number that is equal to the total number of reports submitted to the Secretary under such section for such year less the number of such reports to which such clauses apply for such year.

(B) ADJUSTMENT.—In determining for a year the ratio described in subparagraph (A)(iii), the Secretary shall not include in the numerator class III devices that the Secretary rescinded on the basis of section 510(m)(1), and the Secretary shall not include in the denominator class II devices for which reports under section 510(k) were not required to be submitted by reason of the operation of section 510(m).

(C) ACCREDITATION.—

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

(2) ACCREDITATION.—

(A) In general.—Not later than 180 days after the date of the enactment of the Food and Drug Administration Modernization Act of 1997, the Secretary shall establish and publish in the Federal Register criteria to accredit or deny accreditation to persons who request to perform the duties specified in subsection (a). The Secretary shall respond to a request for accreditation within 60 days of the receipt of the request.

The accreditation of such person shall specify the particular activities under subsection (a) for which the person is accredited.

(B) WITHDRAWAL OF ACCREDITATION.—The Secretary may suspend or withdraw accreditation of any person accredited under this paragraph upon providing the person with an opportunity for an informal hearing, when such person is substantially not in compliance with the
requirements of this section or poses a threat to public health or failure to act in a manner that is consistent with the purposes of this section.

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

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

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

(D) ANNUAL REPORT.—The Secretary shall include in the annual report required under section 903(g) the names of all accredited persons included in the program for that year (as such program may be amended pursuant to the amendment made by subsection (a)) with respect to a device, of any complaint regarding its activities for which it is accredited; and

(E) Audit.—Each person accredited under subsection (b) shall make available the records of the person and the employees of the person, and annually make available to the public documentation of the procedures used by the person to identify and avoid conflicts of interest. Upon the request of an officer or employee designated by the Secretary, the person shall permit the officer or employee, at all reasonable times, to have access to, to copy, and to verify, the records.

(2) Within 15 days after the receipt of a written request from the Secretary to a person accredited under section 523 for copies of records described in paragraph (1), the person shall produce the copies of the records at the place designated by the Secretary.

(F) CONFORMING AMENDMENT.—Section 301 (21 U.S.C. 331), as amended by section 204(b), is amended by adding at the end the following:

``(y) In the case of a drug, device, or food, the following:

(i) the support or recommendation by a person accredited under section 523 that is false or misleading in any material respect;

(ii) the disclosure by a person accredited under section 523 of confidential commercial information or any trade secret without the express written consent of the person who submitted such information or secret to such person;

(iii) the receipt by a person accredited under section 523 of a bribe in any form or the doing of any corrupt act by such person associated with a responsibility delegated to such person under this Act.

(G) REPORTS ON PROGRAM OF ACCREDITATION.—

(I) COMPTROLLER GENERAL.—

(A) IMPLEMENTATION OF PROGRAM.—Not later than 5 years after the date of the enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report describing the extent to which the Secretary has implemented the amendment made by subsection (a) has been implemented.

(B) EVALUATION OF PROGRAM.—Not later than 6 months prior to the date on which, pursuant to subsection (c) of section 523 of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)), the authority provided under subsection (c) in paragraph (1) of subsection (b) of section 562 (as added by subsection (a)) is implemented, the Comptroller General shall submit to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report describing the use of accredited persons under such section 523, including an evaluation of the extent to which such use assisted the Secretary in carrying out the duties of the Secretary under such Act with respect to devices, and the extent to which such use promoted actions which are contrary to the purposes of such Act.

(II) CERTAIN DEVICES WITHIN PROGRAM.—Not later than 3 years after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report providing a description of the Secretary of Health and Human Services' and the Comptroller General's efforts, in the period during which devices were accredited pursuant to the amendment made by subsection (a), the limitation established in clause (iii) of section 523(a)(1)(A) of the Federal Food, Drug, and Cosmetic Act, to the procedures for devices for which clinical data are required in reports under section 510(k) should be removed.

SEC. 211. DEVICE TRACKING.

Effective 90 days after the date of the enactment of this Act, section 519(e) (21 U.S.C. 360i) is amended to read as follows:

``Device Tracking

(1) The Secretary may order a manufacturer to adopt a method of tracking a class I or class III device—

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

(B) which is—

(i) intended to be implanted in the human body for more than one year; or

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

(2) Any patient receiving a device subject to tracking under paragraph (1) may refuse to receive the device, request that the manufacturer or importer cease to reissue the device, or refuse permission to release, the patient's name, address, social security number, or other identifying information for the purpose of tracking.

SEC. 222. POSTMARKET SURVEILLANCE.

Effective 90 days after the date of the enactment of this Act, section 522 (21 U.S.C. 360i) is amended to read as follows:

``SEC. 522. (a) IN GENERAL.—The Secretary may by order require a manufacturer to conduct postmarket surveillance for any device of the manufacturer which is a class I or class III device—

(1) whose failure would be reasonably likely to have serious adverse health consequences; or

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

(b) SURVEILLANCE APPROVAL.—Each manufacturer subject to an order under paragraph (1) may by order require a manufacturer to conduct postmarket surveillance for any device of the manufacturer which is a class I or class III device—

(1) whose failure would be reasonably likely to have serious adverse health consequences; or

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

(c) REPORTS.—

(I) A manufacturer, importer, or distributor of a device subject to an order under subsection (a) shall submit, for the approval of the Secretary, a plan for the required surveillance. The Secretary, within 30 days of the receipt of such plan, shall determine if the person/designated to conduct the surveillance has appropriate qualifications and experience to undertake such surveillance and if the plan will result in the collection of useful data that can reasonably be expected to reduce adverse events or other information necessary to protect the public health.

(II) In consultation with the manufacturer of such device, the Secretary may by order extend the surveillance period of up to 36 months. Any determination by the Secretary that a longer period is necessary shall be made by mutual agreement between the Secretary and the manufacturer or, if no agreement can be reached, after the completion of a dispute resolution process as described in section 562.''

SEC. 233. REPORTS.

(a) REPORTS.—Section 539 (21 U.S.C. 360) is amended—

(1) in subsection (a)—

(A) by striking manuÒfacturer, importer, or distributor and inserting manufacturer or importer; or

(B) in paragraph (4), by striking manuÒfacturer, importer, or distributor and inserting manufacturer or importer; or

(C) in paragraph (7), by adding and after the semicolon at the end,

(D) in paragraph (8)—

(I) by striking manuÒfacturer, importer, or distributor each place such term appears and inserting manufacturer or importer; and

(II) by striking the semicolon at the end and inserting a period.

(E) by striking paragraph (9); and

(F) by inserting at the end the following sentence: The Secretary shall by regulation require a manufacturer, importer, or distributor to disclose such records available to the Secretary upon request.

Paragraphs (4) and (8) are amended to apply to distributors to
the same extent and in the same manner as such paragraphs apply to manufacturers and importers;"; (2) by striking subsection (d); and (3) in subsection (f), by striking "exporter, or distributor" each place it appears and inserting "or importer".

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

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

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

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

and

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

"In this subsection, the term `wholesale distributor' means any person (other than the manufacturer or the initial importer) who distributes a device from the original place of manufacture to the person who makes the final delivery or sale of the device to the ultimate consumer or user.".

(c) DEVICE USER FACILITIES.—

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

(A) in paragraph (1)(C)—

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

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

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

(B) in paragraph (2)—

(i) in subparagraph (A), by striking "or" after the comma at the end;

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

(iii) by striking subparagraph (C).

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

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

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

"(5) With respect to device user facilities:

"(A) The Secretary shall by regulation plan and implement a program under which the Secretary limits user reporting under paragraphs (1) through (4) to a subset of user facilities that constitutes a representative profile of user reports for device deaths and serious illnesses or serious injuries by adding after the comma the following: "or the petition is

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

(C) In the event that the Secretary is providing for a transition to the full implementation of the program, paragraphs (1) through (4) apply except to the extent that the Secretary determines otherwise.

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

(E) Not later than 2 years after the date of the enactment of the Food and Drug Administration Reorganization Act of 1997, the Secretary shall submit to the Committee on Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report describing the plan developed by the Secretary under subparagraph (A) and the progress that has been made toward the implementation of the plan.

SEC. 214. PRACTICE OF MEDICINE.

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

"SEC. 906. PRACTICE OF MEDICINE.

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

SEC. 215. NONINVASIVE BLOOD GLUCOSE METER.

(a) APPROVAL.—The Secretary finds that—

(1) diabetes and its complications are a leading cause of death by disease in America;

(2) diabetes affects approximately 16,000,000 Americans and another 650,000 will be diagnosed in 1997;

(3) the total health care-related costs of diabetesc total nearly $100,000,000,000 per year;

(4) diabetes is a disease that is managed and controlled on a daily basis by the patient;

(5) the failure to properly control and manage diabetes results in costly and often fatal complications including but not limited to blindness, coronary artery disease, and kidney failure;

(6) blood testing devices are a critical tool for the control and management of diabetes, and existing blood testing devices require repeated piercing of the skin;

(7) the pain associated with existing blood testing devices creates a disincentive for people with diabetes to test blood glucose levels, particularly children;

(8) a safe and effective noninvasive blood glucose meter would likely improve control and management of diabetes by increasing the number of tests conducted by people with diabetes, particularly children;

(9) the Food and Drug Administration is responsible for regulating new medical devices in the United States.

(b) SENSE OF CONGRESS. — It is the sense of the Congress that the availability of a safe, effective, noninvasive blood glucose meter would greatly enhance the health and well-being of all people with diabetes across America and the world.

SEC. 216. USE OF DATA RELATING TO PREMARKET APPROVAL; PRODUCT DEVELOPMENT PROTOCOL.

(a) USE OF DATA RELATING TO PREMARKET APPROVAL.—

(1) IN GENERAL.—Section 520(h)(4) (21 U.S.C. 360(h)(4)) is amended to read as follows:

"(4)(A) Any information contained in an application submitted with a request for approval by the Secretary pursuant to section 515(c) (including information from clinical and preclinical tests or studies that demonstrate the safety and effectiveness of a device, but excluding the results of any combination of methods of manufacture and product composition and other trade secrets) shall be available, 6 years after the application has been approved by the Secretary, for use by the Secretary in—

"(i) approving another device; and

"(ii) determining whether a product development protocol has been completed, under section 515 for another device; and

"(ii) establishing a performance standard or special control under this Act; or

"(iii) classifying another device under section 513 and subsection (I)(2).

(B) The publicly available detailed summaries of information respecting the safety and effectiveness of a device, as described in paragraph (1)(A) shall be available for use by the Secretary as the evidentiary basis for the agency actions described in subparagraph (A).

(2) CONFIRMING AMENDMENTS.—Section 517(a) (21 U.S.C. 360(a)) is amended—

(A) in paragraph (8), by adding "or" at the end;

(B) in paragraph (9), by striking "or" and inserting a comma; and

(C) by striking paragraph (10).
authorized and may be made with respect to a food if—

(ii) a scientific body of the United States Government with official responsibility for public health protection or research directly relating to human nutrition (such as the National Institutes of Health or the Centers for Disease Control and Prevention) or the National Academy of Sciences or any of its subdivisions has published an authoritative statement, which is currently in effect, about the relationship between a nutrient and a disease or health-related condition to which the claim refers; 

(iii) a person has submitted to the Secretary, at least 120 days (during which the Secretary may notify any person who is making a claim as authorized by clause (C) that such person has not submitted all the information required by such clause) before the first introduction into interstate commerce of the food with a label containing the claim, (i) a notice of the claim, which shall include the exact words used in the claim and shall include a concise description of the basis upon which such person relied for determining that the requirements of subclause (i) have been satisfied, (ii) a copy of the statement referred to in subclause (i) upon which such person relied in making the claim, and (iii) a balanced representation of the scientific literature relating to the nutrient level to which the claim refers; 

(iv) the claim is made in compliance with clauses (A), (B), and (C) of section 201(n); and 

(v) the claim is stated in a manner so that the claim is an accurate representation of the authoritative statement referred to in subclause (i) and so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet.

For purposes of this clause, a statement shall be regarded as an authoritative statement of a scientific body described in subclause (i) only if the scientific body made in the individual capacity the scientific body described in subclause (i) only if the scientific body made in the individual capacity of the claim and the reader had no reason to doubt the reliability of the statement.

SEC. 305. REFERRAL STATEMENTS.
Section 403(r)(2)(B) (21 U.S.C. 343(r)(2)(B)) is amended—

(B) if a claim described in subparagraph (A)(i) is made with respect to a nutrient in a food and the Secretary makes a determination that the claim, or any claim that is similar to the claim and that increases to persons in the general population the risk of a disease or health-related condition that is diet related, the label or labeling of such food shall contain, in an immediate proximity to such claim, the following statement: `See nutrition information for the context. The blank shall identify the nutrient associated with the increased disease or health-related condition risk. In making the determination described in this clause, the Secretary shall take into account the significance of the food in the total daily diet.

SEC. 306. DISCLOSURE OF IRRADIATION.
Chapter IV (21 U.S.C. 341 et seq.) is amended by inserting after section 403B the following:

"DISCLOSURE
"SEC. 403C. (a) In elaboration of section 201(n), 403(a), or 409 shall be construed to require on the label or labeling of a food a separate radio- disclosure statement that is more prominent than any other name or claim of ingredients required by section 403C(2).

"(b) In this section, the term `radiation disclosure statement' means a written statement that discloses that a food has been intentionally subject to radiation.

SEC. 307. IRRADIATION PETITION.
Not later than 60 days following the date of the enactment of this Act, the Secretary of Health and Human Services shall take such action as is necessary for the final determination on any petition pending with the Food and Drug Administration that would permit the irradiation of red meat under section 409(b)(1) of the Federal Food, Drug, and Cosmetic Act. If the Secretary does not make such determination, the Secretary shall, not later than 60 days following the enactment of this Act, provide the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate with a report of the action taken by the Secretary and the reasons on which the action was based.

SEC. 308. GLASS AND CERAMIC WARE.
(a) In General.—The Secretary may not implement any requirement which would ban, as unsafe, the use of any glass or ceramic ware, lead and cadmium based enamel on such glass and ceramic ware before the expiration of one year after the date such requirement is published in the Federal Register.

(b) Lead and Cadmium Based Enamel.—Unless the Secretary determines, based on available data, that lead and cadmium based enamel on glass and ceramic ware—

(1) which has less than 60 millimeters of decorating area below the external rim, and 

(2) which is not, by design, representation, or customary use intended for use by children, is unsafe, the Secretary shall not take any action before January 1, 2003, to ban lead and cadmium based enamel on such glass and ceramic ware upon which such person relied for determining that the requirements of subclause (i) have not been met, including finding that the requirements of clause (G) have not been met.

SEC. 309. FOOD CONTACT SUBSTANCES.
(a) FOOD CONTACT SUBSTANCES.—Section 409(a) (21 U.S.C. 349(a)) is amended—

(1) by redesignating subsections (h) and (i), as so redesignated, the reasons action on the petition was delayed, (I) a notice of the claim, and the reasons action on the petition was delayed.

(2) which is not, by design, representation, or customary use intended for use by children, is unsafe, the Secretary shall not take any action before January 1, 2003, to ban such enamel on such glass and ceramic ware as an unapproved food additive.

SEC. 310. LEAD AND CADMIUM BASED ENAMEL.
(a) Not later than 60 days following the date of the enactment of this Act, the Secretary of Health and Human Services shall make a final determination on any food additive which is not, by design, representation, or customary use intended for use by children, is unsafe, the Secretary shall not take any action based on available data, that lead and cadmium based enamel on glass and ceramic ware—

(b) LEAD AND CADMIUM BASED ENAMEL.—Unless the Secretary determines, based on available data, that lead and cadmium based enamel on glass and ceramic ware—

(1) which has less than 60 millimeters of decorating area below the external rim, and 

(2) which is not, by design, representation, or customary use intended for use by children, is unsafe, the Secretary shall not take any action before January 1, 2003, to ban such enamel on such glass and ceramic ware before the expiration of one year after the date such requirement is published in the Federal Register.

SEC. 311. FOOD CONTACT SUBSTANCES.
For purposes of this Act, the term `radiation disclosure statement' means a written statement that discloses that a food has been intentionally subject to radiation.

"(a) In General.—The Secretary may not implement any requirement which would ban, as unsafe, the use of any glass or ceramic ware, lead and cadmium based enamel on such glass and ceramic ware before the expiration of one year after the date such requirement is published in the Federal Register.

(b) Lead and Cadmium Based Enamel.—Unless the Secretary determines, based on available data, that lead and cadmium based enamel on glass and ceramic ware—

(1) which has less than 60 millimeters of decorating area below the external rim, and 

(2) which is not, by design, representation, or customary use intended for use by children, is unsafe, the Secretary shall not take any action before January 1, 2003, to ban lead and cadmium based enamel on such glass and ceramic ware before the expiration of one year after the date such requirement is published in the Federal Register.

SEC. 312. FOOD CONTACT SUBSTANCES.
(a) FOOD CONTACT SUBSTANCES.—Section 409(a) (21 U.S.C. 349(a)) is amended—

(1) by redesignating subsections (h) and (i), as so redesignated, the reasons action on the petition was delayed, (I) a notice of the claim, and the reasons action on the petition was delayed.

(2) which is not, by design, representation, or customary use intended for use by children, is unsafe, the Secretary shall not take any action before January 1, 2003, to ban such enamel on such glass and ceramic ware as an unapproved food additive.

SEC. 313. LEAD AND CADMIUM BASED ENAMEL.
(a) Not later than 60 days following the date of the enactment of this Act, the Secretary of Health and Human Services shall make a final determination on any food additive which is not, by design, representation, or customary use intended for use by children, is unsafe, the Secretary shall not take any action based on available data, that lead and cadmium based enamel on glass and ceramic ware—

(b) LEAD AND CADMIUM BASED ENAMEL.—Unless the Secretary determines, based on available data, that lead and cadmium based enamel on glass and ceramic ware—

(1) which has less than 60 millimeters of decorating area below the external rim, and 

(2) which is not, by design, representation, or customary use intended for use by children, is unsafe, the Secretary shall not take any action before January 1, 2003, to ban such enamel on such glass and ceramic ware as an unapproved food additive.
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 conditions of use described in subsection (c)(3)(A). The notification shall contain the information that forms the basis of the determination and all information required to be submitted by regulations promulgated by the Secretary.

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

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

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

"(3)(A) The process in this subsection shall be utilized for the notification of a food contact substance except where the Secretary determines in the notification that the provision of notification under subsection (b) is necessary to provide adequate assurance of safety, or where the Secretary and any manufacturer or supplier agree that such notification or filing under subsection (b) and the consideration criteria specified in the notification represent a substantial burden on the notification proceeding.

"(B) The Secretary is authorized to promulgate regulations to identify the circumstances in which a notification or filing 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 the 120-day period that the information is available to any interested party except for any matter in the notification that is a trade secret or confidential commercial information.

"(5) Provided in clause (ii), the notification program established under this subsection shall not operate in any fiscal year unless:

"(I) an appropriation equal to or exceeding the applicable amount under clause (ii) is made for such fiscal year for carrying out such program in such fiscal year; and

"(II) the Secretary certifies that the amount appropriated for such fiscal year for the Center for Food Safety and Applied Nutrition of the Food and Drug Administration (exclusive of the amounts described in the notification) equals or exceeds the amount appropriated for such center for fiscal year 1997, excluding any amount appropriated for new programs.

"(II) the Secretary certifies that the amount appropriated for such fiscal year for the Center for Food Safety and Applied Nutrition of the Food and Drug Administration (exclusive of the appropriation referred to in subsection (I)) equals or exceeds an amount equal to one-half the amount appropriated for the Center for fiscal year 1999, excluding any amount appropriated for new programs.

"(iii) For the last six months of fiscal year 1999, the applicable amount under this clause is $1,500,000, or the amount specified in the budget request of the President for the six-month period involved in the notification program in fiscal year 1999, whichever is less.

"(iv) For fiscal year 2000 and subsequent fiscal years, the applicable amount under this clause is the amount specified in the budget request of the President for the fiscal year involved in the notification program under this subsection, whichever is less.

"(B) For purposes of carrying out the notification program under this subsection, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1999 through fiscal year 2003, except that such authorization of appropriations is not effective for a fiscal year for any amount that is less than the amount specified under clause (ii) or (iv) of subparagraph (A), whichever is applicable.

"(C) Not later than April 1 of fiscal year 1998 and February 1 of each subsequent fiscal year, the Secretary shall submit a report to the Committees on Appropriations of the House of Representatives and the Senate, the Committee on Commerce of the Senate, and the Committee on Labor and Human Resources of the Senate that provides an estimate of the Secretary of the costs of carrying out the notification program under this subsection for the next fiscal year.

"(D) In this section, the term `food contact substance' means any substance intended for use as a coating, immobilizer, stabilizer, sequestering agent, or other substance intended to have any technical effect in such food.'';

"(vi) the identification of any person that has solicited for other manufacturer to use a similar or identical substance or substance, or who has a significant financial or other interest in the manufacturer;

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

"(vi) the identification of any person that has provided funding for the conduct of a study relating to the new use of a drug or device for which such information is being disseminated.

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

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

"(i) additional objective and scientifically sound information that pertains to the safety or effectiveness of the use and is necessary to provide data, analyses, and other written matter that is necessary to provide information that the Secretary may require a manufacturer to disseminate on the safety or effectiveness of the new use of the drug or device.
"SEC. 552. INFORMATION AUTHORIZED TO BE DISSEMINATED.

(a) AUTHORIZED INFORMATION.—A manufacturer may disseminate information under section 551 on the information—

(1) is in the form of an unabridged—

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

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

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

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

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

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

(3) does not focus on any particular drug or device of a manufacturer that disseminates information under section 551, and does not have a primary focus on new uses of drugs or devices that are marketed or under investigation by a manufacturer supporting the dissemination of information; and

(4) presents materials that are not false or misleading.

SEC. 553. ESTABLISHMENT OF LIST OF ARTICLES AND PUBLICATIONS DISSEMINATED AND LIST OF PROVIDERS THAT RECEIVED ARTICLES AND REFERENCE PUBLICATIONS.

(a) IN GENERAL.—A manufacturer may disseminate information under section 551 on a new use only if the manufacturer prepares and submits to the Secretary a written request for the extension of the period of 36 months established for dissemination of the information.

(b) A list that identifies the categories of providers (as described in section 551(a)) that received the articles and reference publications for the 6-month period described in paragraph (1) and on a supplemental application for the new use have been completed;

(2) the supplemental application will be submitted to the Secretary not later than 6 months after the date of the initial dissemination of the information under section 551;

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

(1) I N GENERAL.—For purposes of subsection (a)(1)(B), a manufacturer may disseminate information on a new use if the manufacturer has submitted to the Secretary an application containing a certification that—

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

(ii) the supplemental application will be submitted to the Secretary not later than 6 months after the date of the initial dissemination of the information under section 551;

(iii) the certification that the supplemental application will be submitted to the Secretary not later than 6 months after the date of the initial dissemination of the information under section 551.

(2) T ERM INATION OF DEEMED APPROVAL.—Applications under this section shall be submitted in the form and manner prescribed by the Secretary.

SEC. 554. REQUIREMENT REGARDING SUBMISSION OF SUPPLEMENTAL APPLICATION FOR NEW USE; EXEMPTION FROM REQUIREMENT.

(a) IN GENERAL.—A manufacturer may disseminate information under section 551 on a new use only if the information—

(1) a list containing the titles of the articles and reference publications relating to the new use of drugs or devices that were disseminated by the manufacturer that supports the information does not constitute a minor violation of this subchapter, the Secretary shall consider (in addition to any other considerations the Secretary finds appropriate)—

(i) the lack of the availability under law of an approved new use; or

(ii) the size of the population expected to benefit from approval of the supplemental application.

(b) The Secretary makes a determination that, for reasons defined by the Secretary, it would be unethical to conduct the studies necessary for the approval of the supplemental application. In making such determination, the Secretary shall consider (in addition to any other considerations the Secretary finds appropriate) whether the new use involved is the standard of medical care for a health condition.

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

(1) A manufacturer may disseminate information under section 551 on a new use only if—

(A) the manufacturer disseminates written information under section 551 on the new use, the Secretary may at any time terminate such application under section 555(a) and order the manufacturer to cease disseminating the information.

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

SEC. 555. CORRECTIVE ACTIONS; CESSION OF DISSEMINATION.

(a) POSTDISSEMINATION DATA REGARDING SAFETY AND EFFECTIVENESS.—

(1) CORRECTIVE ACTIONS.—With respect to data received by the Secretary under section 551, the dissemination of information under section 551 by a manufacturer has begun (whether received pursuant to paragraph (2) or otherwise), if the Secretary determines that the data indicate that the new use involved may not be effective or may present a significant risk to public health, the Secretary shall, after consultation with the manufacturer, take such action as is necessary to cease the dissemination of the information as the Secretary determines to be appropriate for the protection of the public health, which may include ordering that the manufacturer cease the dissemination of the information.

(2) RESPONSIBILITIES OF MANUFACTURERS TO SUBMIT DATA.—After a manufacturer disseminates information under section 551, the manufacturer shall submit to the Secretary a notification of any additional knowledge of the manufacturer on clinical research or other data that relate to the safety or effectiveness of the new use involved. If the manufacturer is in possession of the data, the notification shall include the data. The Secretary shall by regulation establish the scope of the responsibilities of manufacturers under this paragraph, including such limits on the responsibilities as the Secretary determines to be appropriate.

(3) FAILURE OF MANUFACTURER TO COMPLY WITH REQUIREMENTS.—The Secretary may order a manufacturer to cease the dissemination of information pursuant to section 551 if the Secretary determines that the information being disseminated does not comply with the requirements established in this subchapter. Such an order may be issued only if the Secretary has provided notice to the manufacturer of the intent of the Secretary to issue the order and (unless paragraph (2)(B) applies) has provided an opportunity for a meeting with respect to such intent. If the failure of the manufacturer constitutes a minor violation of this subchapter, the
Secretary shall delay issuing the order and provide to the manufacturer an opportunity to correct the violation.

(2) Supplemental Applications.—The Secretary may require the manufacturer to cease the dissemination of information pursuant to section 551 if—

(A) in the case of a manufacturer that has submitted a supplemental application for a new use pursuant to section 554(a)(1), the Secretary determines that the supplemental application does not contain adequate information for approval, or new use for which the application was submitted;

(B) in the case of a manufacturer that has submitted a certification under section 554(b), the manufacturer has not, within the 6-month period involved, submitted the supplemental application referred to in the certification; or

(C) in the case of a manufacturer that has submitted a certification under section 554(c)(1) but has not yet submitted the supplemental application referred to in the certification, the Secretary determines, after an informal hearing, that the manufacturer is not acting with due diligence to complete the studies involved.

(3) Termination of Deemed Approval of Exemption Regarding Supplemental Applications.—In the case of an order under subsection (b)(3) to cease disseminating information, the Secretary may order the manufacturer involved to cease disseminating the information. A manufacturer may appeal from an order under the preceding sentence not later than 60 days after the receipt of the order.

(4) Corrective Actions by Manufacturers.—

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

(B) Termination of Deemed Approval of Exemption Regarding Supplemental Applications.—In the case of an order under subsection (b)(3) to cease disseminating information, the Secretary may order the manufacturer involved to take action to correct the information that has been disseminated unless the Secretary determines that the new use described in the information would pose a significant risk to the public health.

Section 556. Definitions.

For purposes of this chapter—

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

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

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

(4) Subchapter—

(A) with respect to a drug, means a use that is not included in the labeling of the approved drug, and

(B) with respect to a device, means a use that is not included in the labeling for the approved or cleared device.

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

(A) that is published by an organization—

(i) that has an editorial board;

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

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

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

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

(6) The term 'The Index Medicus of the National Library of Medicine of the National Institutes of Health'; and

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

Section 557. Rules of Construction.

(a) Unsolicited Request.—Nothing in section 551 shall be construed as prohibiting a manufacturer from disseminating information in response to an unsolicited request from a health care practitioner.

(b) Dissemination of Information on Drugs or Devices Not Evidence of Intended Use.—Notwithstanding subsection (a), (f), or (o) of section 502, or any other provision of law, the dissemination of information relating to a new use of a drug or device, in accordance with section 551, shall not be construed by the Secretary as evidence of a new intended use of the drug or device that is different from the intended use of the drug or device for the official labeling of the drug or device. Such dissemination shall not be considered by the Secretary as evidence of adulteration, or misbranding of the drug or device.

(c) Patent Protection.—Nothing in section 551 shall affect patent rights in any manner.

(d) Authorization for Dissemination of Articles and Fees for Reprints of Articles.—Nothing in section 551 shall be construed as prohibiting an entity that publishes a scientific journal, as defined in section 556(f)(4), from requiring authorization from the entity to disseminate an article published by such entity or charging fees for the purchase of reprints of published articles.

(e) Prohibited Act.—Section 301 (21 U.S.C. 331), as amended by section 210, is amended by adding at the end the following:

'"THERAPIES AND DIAGNOSTICS."

(a) Authorization for Dissemination of Information on Drugs or Devices Not Evidence of Intended Use.—Notwithstanding subsection (a), (f), (o), or (p) of section 502, or any other provision of law, the dissemination of information relating to a new use of a drug or device, in accordance with section 551, shall not be construed by the Secretary as evidence of a new intended use of the drug or device that is different from the intended use of the drug or device for the official labeling of the drug or device. Such dissemination shall not be considered by the Secretary as evidence of adulteration, or misbranding of the drug or device.

(f) Patent Protection.—Nothing in section 551 shall affect patent rights in any manner.

(g) Authorization for Dissemination of Articles and Fees for Reprints of Articles.—Nothing in section 551 shall be construed as prohibiting an entity that publishes a scientific journal, as defined in section 556(f)(4), from requiring authorization from the entity to disseminate an article published by such entity or charging fees for the purchase of reprints of published articles.'.

(h) Prohibited Act.—Section 301 (21 U.S.C. 331), as amended by section 210, is amended by adding at the end the following:

'"A review of the results of the study required by paragraph (2). The Secretary, after the completion of the review, shall make the report available to the public.

Section 502. Expanded Access to Investigational Therapies and Diagnostics.

Chapter V (21 U.S.C. 351 et seq.), as amended in section 401, is further amended by adding at the end the following:

"SUBCHAPTER E—GENERAL PROVISIONS RELATING TO DRUGS AND DEVICES"

"SEC. 561. Expanded Access to Unapproved Therapies and Diagnostics."

(a) Emergency Situations.—The Secretary may, under appropriate conditions, authorize by the Secretary, the shipment of investigational drugs or investigational devices for the diagnosis, monitoring, or treatment of a serious disease or condition in emergency situations.

(b) Individual Patient Access to Investigational Products Intended for Serious or Unmet Medical Needs.—Any person, acting through a physician licensed in accordance with State law, may request from a manufacturer or distributor, and any manufacturer or distributor may, after complying with the provisions of this subsection, provide to such physician an investigational drug or investigational device for the diagnosis, monitoring, or treatment of a serious disease or condition in emergency situations.

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

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

(3) The Secretary determines that provision of the investigational drug or investigational device would not interfere with the manufacture, development, and commercialization of a product, or completion of clinical investigations to support marketing approval; and
SEC. 406. FOOD AND DRUG ADMINISTRATION MIS-
SION AND ANNUAL REPORT.

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

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

(2) by inserting after subsection (a) the follow-
ing:

"(2) with respect to such products, protect the public health by ensuring that—

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

(2) drugs are safe and effective;

(3) human and veterinary drugs are safe and effective;

(4) there is reasonable assurance of the safety
and effectiveness of devices intended for human use;"

``(i)(A) The Secretary shall develop guid-
ance documents with public participation and
ensure that information identifying the exist-
ence of such documents and the documents
themselves are made available to the public in
written form and, as feasible, through elec-
tronic means. Such documents shall not create
or confer any rights for or on any person, al-
though they present the views of the Secre-
tary on matters under the jurisdiction of the Food
and Drug Administration.

(2) Although guidance documents shall not be
binding on the Secretary, the Secretary shall
ensure that employees of the Food and Drug
Administration do not deviate from such guid-
ances without appropriate justification and su-
icient documentation. The Secretary shall pro-
vide training to employees in how to develop
and use guidance documents and shall monitor
the development and issuance of such docu-
ments.

(3) For guidance documents that set forth
initial interpretations of a statute or regulation,
changing in interpretation or policy that are of
more than a minor nature, complex scientific is-
ues, or highly controversial issues, the Secre-
tary shall ensure public participation prior to
issuance of guidance documents. In such cases,
the Secretary shall provide for public comment
and take such comment into account.

(4) In developing guidance documents, the Secre-
tary shall ensure uniform nomenclature for such
documents and uniform procedures for approval
of such documents. The Secretary shall pro-
vide guidance documents and revisions of such
documents are properly drafted and indicate the nonbinding nature of the
documents. The Secretary shall periodically re-
view all guidance documents and, where appro-
riate, revise such documents.

(5) The Secretary, acting through the Com-
mis sioner, shall maintain electronically and up-
date and publish periodically in the Federal
Register a list of guidance documents. All such
documents shall be made available to the public.

(6) The Secretary shall ensure that an effec-
tive appeals mechanism is in place to address
complaints that the Food and Drug Administra-
tion is not developing and using guidance docu-
ments in accordance with this subsection.

(7) Not later than July 1, 2000, the Secretary
shall promulgate a regulation consistent with this
subsection specifying the policies and procedures of the Food and Drug Administration for the
development, issuance, and use of guidance docu-
ments."
(D) cosmetics are safe and properly labeled; and
(E) public health and safety are protected from electronic product radiation;
(3) establish, in consultation with representatives of other countries to reduce the burden of regulation, harmonize regulatory requirements, and achieve appropriate reciprocal recognition of products, and
(4) as determined to be appropriate by the Secretary, carry out paragraphs (1) through (3) in consultation with experts in science, medicine, and public health, and in cooperation with consumers, users, manufacturers, importers, packers, distributors, and retailers of regulated products.

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

"SEC. 274. EDUCATION AND TRAINING.
(1) The Secretary shall conduct training and education programs for the employees of the Food and Drug Administration relating to the regulatory responsibilities and policies established by this Act, including programs for—
(A) scientific training;
(B) training to improve the skill of officers and employees authorized to conduct inspections under section 704;
(C) training to achieve product specialization in such inspections; and
(D) training in administrative process and procedure and integrity issues.

(b) INTRAMURAL AND OTHER TRAINING PROGRAMS.—The Secretary, acting through the Commissioner, may, through fellowships and other training programs, conduct and support intramural research training for predoctoral and postdoctoral scientists and physicians.

(2) CEN TRS FOR DISEASE CONTROL AND PREVENTION.—
(A) IN GENERAL.—The Secretary shall carry out the activities specified in subsection (a) through the Centers for Disease Control and Prevention, including objectives related to—
(i) the availability and clarity of information about the process for review of applications and submissions (including petitions, notifications, and any other similar forms of request for review) made under this Act;
(ii) the prevention of adverse effects of drugs, biological products, and devices; and
(iii) such harmonization continues consumer protection, while reducing the cost of health care through—
(A) new uses of drugs, biological products, and devices; and
(B) the development of good manufacturing practices, and global harmonization.

Title IX of the Public Health Service Act (42 U.S.C. 383) is amended by adding at the end the following:

"SEC. 317G. FELLOWSHIP AND TRAINING PROGRAMS.
The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish fellowship and training programs to be conducted by such Centers to train individuals to develop skills in epidemiology, surveillance, laboratory analysis, and other disease detection and prevention methods. Such programs shall be designed to enable health professionals and health personnel trained under such programs to work, after receiving such training, in local, State, national, and international efforts toward the prevention and control of diseases, injuries, and disabilities. Such fellowships and training may be administered through the use of any appointment or nonappointment procedures.

(2) EFFECTIVE DATE.—The amendment made by this subsection is deemed to have taken effect July 1, 1995.

SEC. 409. CENTERS FOR EDUCATION AND RESEARCH ON THERAPEUTICS.
Title IX of the Public Health Service Act (42 U.S.C. 299 et seq.) is amended by adding at the end of title IX the following:

"SEC. 905. DEMONSTRATION PROGRAM REGARDING THERAPEUTIC RESEARCH AND RESEARCH ON THERAPEUTICS.
(1) IN GENERAL.—The Secretary, acting through the Administrator and in consultation with the Commissioner of Food and Drugs, shall establish a demonstration program for the purpose of making one or more grants for the establishment and operation of one or more centers to carry out the activities specified in subsection (b).

(b) REQUIRED ACTIVITIES.—The activities referred to in subsection (a) are the following:
(1) The development of a state-of-the-art clinical and laboratory research for the following purposes:
methods and approaches to harmonize regulatory requirements.

"(4) The Secretary shall, not later than 180 days after the date of enactment of the Food and Drug Administration Modernization Act of 1997, make public a plan that establishes a framework for achieving mutual recognition of good manufacturing practices inspections.

"(5) Paragraph (2) shall not apply with respect to products defined in section 210(f)."

SEC. 411. ENVIRONMENTAL IMPACT REVIEW.

Chapter 121 of title 21, section 371 et seq., as amended by section 407, is further amended by adding at the end the following:

"SUBCHAPTER E—ENVIRONMENTAL IMPACT REVIEW

"SEC. 746. ENVIRONMENTAL IMPACT.

"Notwithstanding any other provision of law, an environmental impact statement prepared in accordance with the regulations published in part 25 of title 21, Code of Federal Regulations (as in effect on August 31, 1997) in connection with an action carried out under (or as a recommendation or report relating to) this Act, shall be provided to the Secretary of the Interior, and shall be considered to be part of the action.

"(a) NONPRESCRIPTION DRUGS. Chapter VII of title 21, sections 371 et seq., as amended by section 412, is further amended by adding the following:

"(b) EXEMPTION. Upon application of a State or political subdivision thereof, the Secretary may modify or otherwise affect any action or accompanying statement of a State or political subdivision thereof, or any required recordkeeping or reporting, or any enforcement action, or any State requirement relating to public information or any other form of public communication.

"(c) SCOPE. For purposes of subsection (a), a reference to a State requirement that relates to the packaging or labeling of a cosmetic means any specific requirement relating to the same aspect of such cosmetic as a requirement specifically applicable to that cosmetic.

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

"SEC. 752. PREEMPTION FOR LABELING OR PACKAGING OF COSMETICS.

"(a) IN GENERAL. Except as provided in subsection (b), (d), or (e), no State or political subdivision of a State may establish or continue in effect a requirement that would otherwise be unprotected, including the establishment and execution of a requirement for written and oral presentation of views, except that the Secretary may by regulation, after notice and opportunity for written and oral presentation of views, or, in subsection (a), under such conditions as may be prescribed in such regulation, a State or political subdivision requirement that (A) protects an important public interest that would otherwise be unprotected, including the health and safety of children; (B) would not cause a drug to be in violation of any applicable requirement or prohibition under Federal law; (C) would not unduly burden interstate commerce.

"(2) TIMELY ACTION. The Secretary shall make a decision on the exemption of a State or political subdivision requirement under paragraph (1) not later than 120 days after receiving the application of the State or political subdivision requirement under paragraph (1).

"(3) SCOPE. (1) In general. This section shall not apply to—

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

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

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

"(3) Exceptions. (1) In general. In the case of a drug described in subsection (a)(1) that is not the subject of an application approved under section 505 or section 507 (as in effect on the day before the enactment of the Food and Drug Administration Modernization Act of 1997) or a final regulation promulgated by the Secretary establishing conditions under which the drug is generally recognized as safe and effective and not misbranded, subsection (a) shall apply only with respect to a requirement that relates to the same subject as is different from, in addition to, or that is otherwise not identical with—

"(A) a regulation for written and oral presentation of views, except that the Secretary may by regulation, after notice and opportunity for written and oral presentation of views, or, in subsection (a), under such conditions as may be prescribed in such regulation, a State or political subdivision requirement that (A) protects an important public interest that would otherwise be unprotected; (B) would not cause a drug to be in violation of any applicable requirement or prohibition under Federal law; and (C) would not unduly burden interstate commerce.

"(b) EXCEPTIONS. (1) In general. This section shall not apply to a State requirement adopted by a State public initiative or referendum enacted prior to September 1, 1997.

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

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

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

"SEC. 413. FOOD AND DRUG ADMINISTRATION STUDY OF MERCURY COMPOUNDS IN DRUGS AND FOOD.

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

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

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

"(b) STUDY. The Secretary of Health and Human Services, acting through the Food and
Drug Administration, shall conduct a study of the effect on humans of the use of mercury compounds in nasal sprays. Such study shall include data from other studies that have been made or conducted. Such study shall be conducted by the Secretary or under contract with the Secretary, shall be completed, and shall be submitted to Congress within 60 days of the date of enactment of this Act. Such study shall be conducted in cooperation with the Food and Drug Administration, the Consumer Product Safety Commission, the Environmental Protection Agency, and the Department of Transportation.

(c) STUDY OF MERCURY SALES.—
(1) Study.—The Secretary of Health and Human Services, acting through the Food and Drug Administration, and subject to the approval of the Secretary of Health and Human Services or the Administrator of the Food and Drug Administration, shall conduct, or shall contract with the National Academy of Sciences to conduct, a study of the effect on human health of the use of elemental, organic, or inorganic mercury when offered for sale as a drug or dietary supplement. Such study shall, among other things, evaluate:

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

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

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

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

SEC. 414. INTERAGENCY COLLABORATION.
Section 903 (21 U.S.C. 393), as amended by section 406, is further amended by inserting after subsection (b) the following:

``(c) INTERAGENCY COLLABORATION.—The Secretary shall implement programs and policies that will foster collaboration between the Administration, the National Institutes of Health, and other Federal agencies. The Department shall enhance the scientific and technical expertise available to the Secretary in the conduct of the duties of the Secretary with respect to the development, approval, evaluation, and postmarket monitoring of emerging medical therapies, including complementary therapies, and advise on legislation and policy.``

SEC. 415. CONTRACTS FOR EXPERT REVIEW.
Chapter IX (21 U.S.C. 391 et seq.), as amended by section 214, is further amended by adding at the end the following:

``SEC. 907. CONTRACTS FOR EXPERT REVIEW.

(a) Authority.—The Secretary may enter into a contract with any organization or individual who has the technical expertise that is necessary to review or evaluate new therapies and technologies.

(b) Review of Expert Review.—

(1) IN GENERAL.—Subject to paragraph (2), the Secretary may enter into a contract with any organization or individual who has the technical expertise that is necessary to review or evaluate new therapies and technologies. Such contract shall be designed to protect the health of children and other sensitive populations from adverse effects resulting from, or due to, or ingestion or inhalation of mercury when so used.

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

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

``SEC. 416. PRODUCT CLASSIFICATION.

Subchapter E of chapter V, as amended by section 404, is further amended by adding at the end the following:

``SEC. 906. CLASSIFICATION OF PRODUCTS.

(a) Authority.—The Secretary, after considering the results of the study required by section 905, shall make a final determination regarding the classification of the product for the purpose of this Act. The Secretary shall make such determination after consultation with the Secretary of Transportation, the Administrator of the Federal Aviation Administration, and the Administrator of the Federal Highway Administration.

(b) Review of Expert Review.—

(1) General.—Subject to section 907, the Secretary may enter into a contract with any organization or any individual who has the technical expertise that is necessary to review or evaluate new therapies and technologies.

(2) Review of Expert Review.—

(a) Authority.—The Secretary, after considering the results of the study required by section 905, shall make a final determination regarding the classification of the product for the purpose of this Act. The Secretary shall make such determination after consultation with the Secretary of Transportation, the Administrator of the Federal Aviation Administration, and the Administrator of the Federal Highway Administration.

(b) Review of Expert Review.—

(1) IN GENERAL.—Subject to paragraph (2), the Secretary may enter into a contract with any organization or individual who has the technical expertise that is necessary to review or evaluate new therapies and technologies.

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

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

``SEC. 417. CONTRACTS FOR EXPERT REVIEW.

Chapter IX (21 U.S.C. 391 et seq.), as amended by section 214, is further amended by adding at the end the following:

``SEC. 908. CONTRACTS FOR EXPERT REVIEW.

(a) Authority.—The Secretary may enter into a contract with any organization or individual who has the technical expertise that is necessary to review or evaluate new therapies and technologies.

(b) Review of Expert Review.—

(1) IN GENERAL.—Subject to paragraph (2), the Secretary may enter into a contract with any organization or individual who has the technical expertise that is necessary to review or evaluate new therapies and technologies.

(2) Review of Expert Review.—

(a) Authority.—The Secretary, after considering the results of the study required by section 905, shall make a final determination regarding the classification of the product for the purpose of this Act. The Secretary shall make such determination after consultation with the Secretary of Transportation, the Administrator of the Federal Aviation Administration, and the Administrator of the Federal Highway Administration.

(b) Review of Expert Review.—

(1) General.—Subject to section 907, the Secretary may enter into a contract with any organization or any individual who has the technical expertise that is necessary to review or evaluate new therapies and technologies.

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

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

``SEC. 418. CLARIFICATION OF SECRECY AUTHORITY.

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

``SEC. 420. SAFETY REPORT DISCLAIMERS.

Chapter VII (21 U.S.C. 371 et seq.), as amended by section 412, is further amended by adding at the end the following:

``SEC. 756. SAFETY REPORT DISCLAIMERS.

With respect to any entity that submits or is required to submit a safety report or other information in connection with the safety of a product (including a product that is a food, drug, device, dietary supplement, or cosmetic) under this Act (and any release by the Secretary of the report or information), such report or information shall not be construed to reflect necessarily a conclusion by the entity or the Secretary that the report or information constitutes an admission that the product involved malfunctioned, caused or contributed to an adverse experience, or otherwise caused or contributed to a death, serious injury, or serious illness. Such an entity need not admit, and may deny, that the report or information submitted by the entity constitutes an admission that the product involved malfunctioned, caused or contributed to an adverse experience, or otherwise caused or contributed to a death, serious injury, or serious illness."

``SEC. 421. LABELING AND ADVERTISING REGARDING COMPLIANCE WITH STATUTORY REQUIREMENTS.

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

``SEC. 422. RULE OF CONSTRUCTION.

Nothing in this Act or the amendments made by this Act shall be construed to affect the question of whether the Secretary of Health and Human Services has any authority to regulate any tobacco product, tobacco ingredient, or tobacco additive. Such authority, if any, shall be exercised under the Federal Food, Drug, and Cosmetic Act as in effect on the day before the date of the enactment of this Act."

``TITLE V—EFFECTIVE DATE

SEC. 501. EFFECTIVE DATE.

Except as otherwise provided in this Act, this Act and the amendments made by this Act, other than the provisions of sections 601 through 607, made by sections 111, 121, 125, and 307, shall take effect 45 days after the date of enactment of this Act. And the House agree to the same.

That the House recede from its amendment to the title of the bill.
The managers on the part of the House and the Senate at the conference on the disagreeing votes of the two Houses on the amendments of the House to the bill (S. 830) to amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to improve the regulation of food, drugs, devices, and biological products, and for other purposes, submit the following joint statement to the House and the Senate in explanation of the effect of the substitute agreed to in the accompanying conference report:

The House amendment to the text of the bill struck all of the Senate bill after the enacting clause and inserted a substitute text.

The Senate recedes from its disagreement to the amendment of the House with an amendment which substitutes for the Senate bill the House amendment. The differences between the Senate bill, the House amendment, and the substitute agreed to in conference are noted below, except for clerical corrections, conforming changes made necessary by agreements reached by the conference, and minor drafting and clerical changes.

The conference agreement on S. 830, the Food and Drug Administration Modernization Act of 1997, provides for (1) the reauthorization of the Prescription Drug User Fee Act of 1992; (2) the improvement of regulation of drugs through such reforms as those pertaining to pediatric studies, drugs that are subject to postmarket surveillance, and accredited party review; (3) the improvement of regulation of medical devices through such reforms as those pertaining to device standards and data requirements, procedures relating to humanitarian and breakthrough devices, tracking and postmarket surveillance, and accredited party review; (4) the improvement of food through such reforms as those pertaining to the timetable and regulatory authority of the Secretary in processing health and nutrition content claims, postmarket substance notifications, and information relating to irradiation treatment; and (5) general provisions pertaining to the dissemination of information about clinical trials of investigational therapies, and consumer access to information about clinical trials of investigational therapies.

Certain matters agreed to in conference are noted below:

**Title I—Improving Regulation of Drugs**

The conference believes it is important to place the PDUFA reauthorization provisions of the Senate bill in the House bill in the context of the legislative agreements which have been put into place by the 1997 Balanced Budget Agree-
Application of Federal law to practice of pharmacy compounding (Sec. 127)

The conference report includes provisions on pharmacy compounding that reflect the conferences extensive work with the Food and Drug Administration, other federal agencies and other interested parties to reach consensus. It is the intent of the conferences to ensure continued availability of compounded drug products as a component of alternative and other therapies, while limiting the scope of compounding so as to prevent manufacturing under the guise of compounding. Section 503A establishes parameters of compounding that are appropriate and lawful. The conditions set forth in Section 503A should be used by the state boards of pharmacy and medicine for proper regulation of pharmacy compounding in addition to existing state-specific regulations.

The conferences intend that, as defined in subparagraph (b)(2), copies of commercially available drug products do not include drug products in which the change from the commercially available drug product produces a "significant difference" for the particular patient. For example, the removal of a dye from a commercially available drug product for a particular patient who is allergic to such dye shall be presumed to be a "significant difference." The conferences further intend that FDA and the courts will accord great deference to the licensed prescribers judgment in determining whether the changed product produces a "significant difference." However, where it is readily apparent, based on the circumstances, the "significant difference" is a mere rearrangement of products that are essentially copies of commercially available products, such compounding would be considered copying of commercially available products and would not qualify for the compounding exemptions if it is done regularly or in inordinate amounts. Such circumstances may include, for example, instances in which minor changes in strength (such as from 0.8% to 0.9%) are made that are not known to be significant or instances in which the prescribing physician is receiving remuneration or other financial incentives to write prescription for compounded products.

The conferences also expect that the Secretary will specifically list bulk drug substances in subsection (b)(1)(A)(i)(III) within one year from the date of enactment. It is the intent of the conferences to require the Secretary, in consultation with the United States Pharmacopeia, to provide guidance on the meaning of inordinate amounts, including any circumstances under which the compounding of drug products for interstate shipments would be consistent with the longest statutes of limitations. The total prescription order would be included in a "safe harbor" of interstate shipments of compounded drug products for any such practice that is done pursuant to a manufacturers approved labeling, and other directions from such manufacturer that are consistent with that labeling. In general, such practices would be considered valid practice for an identification individual patient, are appropriately regulated by state boards of pharmacy. The conferences intend that facilities required to register with the FDA, including those which are engaged in non-patient specific compounding and reconstitution activities, are appropriately regulated under the Federal Food, Drug and Cosmetic Act.

Finally, with regard to the effective date described in paragraph (b), the conferences expect the FDA to work diligently to consult with necessary parties to promulgate the required regulations and lists. Nothing in paragraph (b) is intended to abrogate the Secretarys responsibility to promulgate such regulations through the notice and comment rulemaking process.

Reauthorization of the Clinical Pharmacology Program (Sec. 128)

The conference agreement extends through fiscal year 2002 the authorization of appropriations of the Clinical Pharmacology Training Program, a program originally authorized under P.L. 102-506. Nothing in this section of the agreement prohibits the Secretary from continuing the awarding of grants to the original and current grantees. The conferees strongly recommend that the Secretary continue the development of the clinical pharmacology programs at the colleges and universities originating in the original legislation. Regulations for sunscreen products (Sec. 129)

The conference agreement includes a provision requiring FDA to continue diligently with its work to complete its rulemaking process on sunscreen products and to issue regulations within 18 months. The conferences recognize that various technical and scientific issues may take longer to resolve than other aspects of the rulemaking. The conferences intend that the regulation in this area be complete or comprehensive by a specified date.

Title II—Improving Regulation of Devices Scope of review (Sec. 205)

The conference agreement addresses the issue of regulation by ensuring that the impact of the Secretaries necessary review, approval, and oversight functions is not inappropriate. This assurance is achieved by requiring the Secretary to consider, in consultation with an applicant for device approval, the method for evaluating the device's effectiveness, whether it would be appropriate least burdensome and reasonably likely to result in the devices approval. The conferences believe that this language is necessary to and consistent with improving communications between FDA and regulated persons, increasing regulatory efficiency, and decreasing the length of product review and approval.

Premature notification (Sec. 206)

The conference agreement exempts class I devices from premarket notification under section 510(k), except those types that present a potential unreasonable risk of illness or injury, or that contain substantial importance in preventing impairment of human health. The agreement also requires the Secretary to publish a notice listing the types of class I devices for which such exemption applies. The Secretary must publish this initial list within 60 days.

Thereafter, class II devices may be exempted by the Secretary on the Secretarys own initiative or through a petition process. The agreement provides that the Secretary must respond to any such petition within 30 days and that the petition will be deemed granted.

The conferences do not intend by this provision that the Secretaries classification decision will expire unless it is renewed and the duration of the pilot program specify that an accredited person may not review a class III device, a class I device that is permanently implantable, life-sustaining, or a class II device for which clinical data are required. The latter category is limited in size to not more than six manufacturers, all 510(k) submissions. The agreement provides for the termination of the pilot program after the Secretary has met specified targets for inclusion of eligible devices.

Reports (Sec. 213)

The conference agreement amends Section 529 of the Federal Food, Drug and Cosmetic Act to reduce the reporting requirements for distribution of devices by distributors and importers, however, are required to comply with the existing requirements for medical device reporting. The amendment to section 513(a)(9) requires distributors to keep records and make them available to the Secretary on request. Because distributors will no longer be submitting reports to the Secretary, copies of the reports would not be required from the manufacturers. This is not intended to provide the FDA with any new statutory authority to require distributors to keep additional records. Thereafter, class II devices may be exempted by the Secretary on the Secretarys own initiative or through a petition process. The agreement provides that the Secretary must respond to any such petition within 30 days and that the petition will be deemed granted.

The conferences do not intend by this provision that the Secretaries classification decision will expire unless it is renewed and the duration of the pilot program specify that an accredited person may not review a class III device, a class I device that is permanently implantable, life-sustaining, or a class II device for which clinical data are required. The latter category is limited in size to not more than six manufacturers, all 510(k) submissions. The agreement provides for the termination of the pilot program after the Secretary has met specified targets for inclusion of eligible devices.
that the reports under this section are not required from any manufacturer, importer, or distributor who also is regulated and required to make such reports under the Radiation Emission Control Act of 1968 (21 U.S.C. 3601).

Practice of medicine (Sec. 214)

The conference agreement includes a provision intended by the conferees to emphasize that when a drug is being marketed, its labeling is determined by the American Health Protection Agency and when to use the medical product for the care of a particular patient is not the province of the FDA. It is the intent of the conferees that the label must be construed to affect medical professional liability.

TITLE III—IMPROVING REGULATION OF FOOD

Flexibility for regulations regarding claims (Sec. 301)

The conference agreement clarifies the parameters within which the Secretary may use the authority granted to the Secretary to approve and authorize, under this section, the publication for public comment of proposed regulations. The conference agreement directs the Secretary promptly to ensure the intended effect of this provision, and to publish for public comment proposed regulations that are to be utilized for such labeling. To this end, the Americans with Disabilities Act mandates that a bibliography of such literature be maintained. The conference agreement clarifies the parameters within which the Secretary may use the authority granted to the Secretary to approve and authorize, under this section, the publication for public comment of proposed regulations. The conference agreement directs the Secretary promptly to ensure the intended effect of this provision, and to publish for public comment proposed regulations that are to be utilized for such labeling. To this end, the Americans with Disabilities Act mandates that a bibliography of such literature be maintained.

Health and nutrient content claims (Sec. 303, 304)

The conference agreement makes streamlined procedures available for the Secretaries to permit more scientifically sound nutrition information to be provided to consumers through health and nutrient content claims. The conferees note that the dietary recommendations are authoritative statements of entities such as the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC). The conferees wish to commend the FDA and the Environmental Protection Agency (EPA) for developing an Administration policy on the question of returning from FDA to EPA regulatory authority over antimicrobials used as food contact substances. This policy addresses the uncertainty unintentionally created by the Food Quality Protection Act of 1996 (FQPA) over the authority for regulating antimicrobials used as food contact substances. Although the legislative language effectively intended to be triggered only when the FDA receives an appropriation sufficient to fund the program, the conferees strongly encourage the House and Senate to appropriate funds to this authority. The conferees also urge the Committee of jurisdiction, when reauthorizing the notification program, to reevaluate fully its appropriateness of its timeframes, the adequacy of funding, and its protection of the public health.

On the subject of food contact substances, the conferees wish to commend the FDA and the Environmental Protection Agency (EPA) for developing an Administration policy on the question of returning from FDA to EPA regulatory authority over antimicrobials used as food contact substances. This policy addresses the uncertainty unintentionally created by the Food Quality Protection Act of 1996 (FQPA) over the authority for regulating antimicrobials used as food contact substances. Although the legislative language effectively intended to be triggered only when the FDA receives an appropriation sufficient to fund the program, the conferees strongly encourage the House and Senate to appropriate funds to this authority. The conferees also urge the Committee of jurisdiction, when reauthorizing the notification program, to reevaluate fully its appropriateness of its timeframes, the adequacy of funding, and its protection of the public health.

The conferees recognize that there may be cases where the size of the patient population may be cause for concern. To determine that a supplemental application should not be filed. However, this is intended to be the exception, rather than the rule, in the case of populations suffering from orphan disease disorders. In these cases, the conferees note that they purposely used the term “orphan” to emphasize that the Secretary may consider, among other factors, the rareness of a disease or disorder, the size of the patient population, and the expected duration of treatment. The conferees note that they purposely used the term “orphan” to emphasize that the Secretary may consider, among other factors, the rareness of a disease or disorder, the size of the patient population, and the expected duration of treatment. The conferees note that they purposely used the term “orphan” to emphasize that the Secretary may consider, among other factors, the rareness of a disease or disorder, the size of the patient population, and the expected duration of treatment.

Expanded access to investigational therapies and diagnostics (Sec. 402)

The conference report provides statutory direction to expand access programs and emphasizes that opportunities to participate in expanded access programs are available to everyone without regard to financial status or seriousness of illness. The conference report emphasizes the importance of these programs because they allow patients to have access to experimental drugs that may be new uses or new uses for which there is not an effective, approved therapy. The conferees note that they purposely used broad language in this section relating to “serious” conditions, without attempting to define them, in order to permit wide flexibility in implementation. Illnesses that do not cause death, or are not otherwise serious, nonetheless destroy the lives of both patients and their families. The conferees therefore intend that the seriousness of an illness be defined according to the particular circumstances when it is appropriate to exempt a particular substance from the notification process for the regulation of antimicrobials used as food contact substances. This policy addresses the uncertainty unintentionally created by the Food Quality Protection Act of 1996 (FQPA) over the authority for regulating antimicrobials used as food contact substances. Although the legislative language effectively intended to be triggered only when the FDA receives an appropriation sufficient to fund the program, the conferees strongly encourage the House and Senate to appropriate funds to this authority. The conferees also urge the Committee of jurisdiction, when reauthorizing the notification program, to reevaluate fully its appropriateness of its timeframes, the adequacy of funding, and its protection of the public health.

Disclosure of irradiation (Sec. 306)

The conference agreement clarifies that no existing law and no section of the Federal Food, Drug, and Cosmetic Act will be considered to require the disclosure of any information about a new use must either certify that it will file a supplemental application or must submit a proposed protocol and related regulatory information to the necessary study and a certification that a supplemental application will be filed.

Although the conferees intend to ensure that the research is undertaken to get new uses on product labels, the conferees also recognize that there may be limited circumstances when it is appropriate to exempt a manufacturer from the requirement to file a supplemental application. In making the determination of whether to grant an exemption, the Secretary may consider, among other factors, whether the new use meets the requirements of section 186(t)(2)(B) of the Social Security Act. The conferees note that the off-label use of a medical device by a physician using his or her best medical judgment in determining how and when to use the medical product for the care of a particular patient is not the province of the FDA. It is the intent of the conferees that the label must be construed to affect medical professional liability.

Food contact substances (Sec. 309)

The conference agreement establishes a notification process for the regulation of compounds and devices that are not included in the approved labeling of drugs, biological products, and devices. The conferees wish to encourage the Secretary to ensure that the research is undertaken to get new uses on product labels, the conferees also recognize that there may be limited circumstances when it is appropriate to exempt a manufacturer from the requirement to file a supplemental application.
patients who have failed existing approved therapies. Information system (Sec. 407) The conference intend that the information system shall provide access to the information by the under consideration by the Secretary, except that access shall not be provided under any particular form of information system to any applicants until appropriate procedures in place to ensure that integrity and confidentiality of the information for which access is provided.

Education and training (Sec. 408) The conference agreement authorizes the Centers that conduct intramural research to provide fellowships and training to appropriate undergraduate, pre-doctoral, and post-doctoral candidates. In the past, FDA's Centers provided for a limited number of scientific training positions through Full Time Equivalent programs or interagency agreements with other federal agencies which have the statutory authority to hire trainees through third parties. However, many of the benefits of the training program have been reduced because FDA has not specified the authority to conduct and support them. In light of the additional overhead costs, reduced training flexibility, increased paperwork, and hiring delays that have occurred, it is increasingly difficult and impractical for FDA to hire trainees as FTE Service Fellows. As a result, the Intramural Research and Training Authorization is not provided here in order to avoid unnecessary duplication, which deals both with cosmetic products and packaging. Therefore, under these provisions, manufacturers of such OTC products will be subject to records inspection by FDA. It is expected that OTC drug firms would be subject to the same provisions as prescription drug firms. Thus, during routine inspections of OTC drug establishments, FDA would not be expected to request or to review or copy reports and records that result from the firm's own audits and inspections of its operations to assure compliance with applicable FDA requirements such as good manufacturing practice (GMP) regulations. FDA would reserve the right to review such audits in certain limited circumstances as outlined in the compliance guide.

OTC and cosmetics inspection The conferences intend that FDA exercise its new records inspection powers fairly and carefully, especially with regard to inspections at facilities that manufacture products that are both cosmetics and over-the-counter drugs. Cosmetic products that are also OTC drugs will, under the provisions of this bill, benefit from full national uniformity relating to all regulatory requirements, including those associated with ingredients, labeling, and packaging. Therefore, under these provisions, manufacturers of such OTC products will be subject to records inspection by FDA. The conferences intend to make clear that any records inspection applies only to those products for which there is full national uniformity. This new records inspection authority applies only to products determined to be over-the-counter drugs. It does not apply to products that are solely cosmetics.

In the case of an inspection at a facility which produces both cosmetic products that are OTC drugs and those that are not, FDA inspectors do not have access to any records relating to the cosmetic products. Furthermore, the convey that there are no records inspection authority under these provisions for facilities dealing exclusively with cosmetics.

Finally, the conferees wish to note that FDA will provide sufficient time and guidance to the over-the-counter drug industry prior to initiating any program of records inspection in the early stages of implementing this new requirement.

Effect of national uniformity on state enforcement "little FTC" laws All states have laws prohibiting false and misleading advertising, modeled on the Federal Trade Commission Act. These laws have been applied to prohibit unsubstantiated claims for non-prescription drugs and cosmetics, and to require corrective advertising. This provision is not intended to preempt the application of these laws under such circumstances. The Conference Committee intends to make clear that "little FTC" laws, as they have historically been written and applied, are not preempted. The scope of national uniformity is modified to only apply to state requirements that relate to labeling and packaging or, if they go beyond labeling and packaging, to requirements relating to warnings. Thus, advertising issues relating to claims substantiation, fair balance, and misleading or deceptive claims are outside the scope of preemption.

Effect of national uniformity on state food labeling laws This provision is not intended to pre-empt or prohibit States from applying the labeling of food which derives from animals treated with non-prescription drugs. Nor are these provisions intended to void State regulations on the use of these drugs.

Product classification (Sec. 416) Subsections (b) and (c) have been amended to make clear that FDA may only modify product classifications for public health reasons based on scientific information.