



FOOD AND DRUG ADMINISTRATION MODERNIZATION ACT  
OF 1997

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NOVEMBER 9, 1997.—Ordered to be printed

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Mr. BLILEY, from the committee of conference,  
submitted the following

CONFERENCE REPORT

[To accompany S. 830]

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.

Sec. 2. Definitions.

**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. *Manufacturing 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. *Scope of 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 timeframes; collaborative review process.*
- Sec. 210. *Accreditation of persons for review of premarket notification reports.*
- 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 data relating to premarket approval; product development protocol.*
- Sec. 217. *Clarification of the number of required clinical investigations for approval*

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

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

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

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

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

(4) the fees authorized by amendments made in this 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

duced by a micro-organism and which has the capacity to inhibit or destroy micro-organisms in dilute solution (including a chemically synthesized equivalent of any such substance) or any derivative thereof.”.

**SEC. 126. ELIMINATION OF CERTAIN LABELING REQUIREMENTS.**

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

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

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

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

(c) **CONFORMING AMENDMENTS.**—

(1) Section 503(b)(1) (21 U.S.C. 353(b)(1)) is amended—

(A) by striking subparagraph (A); and

(B) by redesignating subparagraphs (B) and (C) as subparagraphs (A) and (B), respectively.

(2) Section 503(b)(3) (21 U.S.C. 353(b)(3)) is amended by striking “section 502(d) and”.

(3) Section 102(9)(A) of the Controlled Substances Act (21 U.S.C. 802(9)(A)) is amended—

(A) in clause (i), by striking “(i)”; and

(B) by striking “(ii)” and all that follows.

**SEC. 127. APPLICATION OF FEDERAL LAW TO PRACTICE OF PHARMACY COMPOUNDING.**

(a) **AMENDMENT.**—Chapter V is amended by inserting after section 503 (21 U.S.C. 353) the following:

**“SEC. 503A. PHARMACY COMPOUNDING.**

“(a) **IN GENERAL.**—Sections 501(a)(2)(B), 502(f)(1), and 505 shall not apply to a drug product if the drug product is compounded for an identified individual patient based on the unsolicited receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient, if the drug product meets the requirements of this section, and if the compounding—

“(1) is by—

“(A) a licensed pharmacist in a State licensed pharmacy or a Federal facility, or

“(B) a licensed physician,

on the prescription order for such individual patient made by a licensed physician or other licensed practitioner authorized by State law to prescribe drugs; or

“(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 who will write such prescription order.

"(b) COMPOUNDED DRUG.—

"(1) LICENSED PHARMACIST AND LICENSED PHYSICIAN.—A drug product 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 of the Secretary published at section 207.3(a)(4) of title 21 of the Code of Federal Regulations—

"(i) that—

"(I) comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;

"(II) if such a monograph does not exist, are drug substances 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);

"(ii) that are manufactured by an establishment that is registered under section 510 (including a foreign establishment that is registered under section 510(i)); and

"(iii) that are accompanied by valid certificates of analysis for each bulk drug substance;

"(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 the United States Pharmacopoeia chapter on pharmacy compounding;

"(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 such drug products or components of such drug products have been found to be unsafe or not effective; and

"(D) does not compound 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 pre-

scribing practitioner, between the compounded drug and the comparable commercially available drug product.

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

"(A) such 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 that 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 appropriate investigation by a 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 pharmacy, or licensed physician distributes (or causes to be distributed) compounded drug products out of 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 pharmacy or 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)(i).

"(c) ADVERTISING AND PROMOTION.—A drug may be compounded under subsection (a) only if the pharmacy, 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 (b)(1)(A)(i)(III), (b)(1)(C), or (b)(3)(A), the Secretary shall convene and consult an advisory committee on compounding unless the Secretary determines that the issuance of such regulations before consultation is necessary to protect the public health. The advisory committee shall include representatives from the National Association of Boards of Pharmacy, the United States Pharmacopoeia, pharmacy, physician, and consumer organizations, and other experts selected by the Secretary.

"(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 (b)(1)(A)(i)(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(ii); 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 directions contained in approved labeling provided by the product’s manufacturer and other manufacturer directions consistent with that labeling.”

(b) 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.

**SEC. 128. REAUTHORIZATION OF CLINICAL PHARMACOLOGY PROGRAM.**

Section 2 of Public Law 102-222 (105 Stat. 1677) is amended—

(1) in subsection (a), by striking “a grant” and all that follows through “Such grant” and inserting the following: “grants for a pilot program for the training of individuals in clinical pharmacology at appropriate medical schools. Such grants”; and

(2) in subsection (b), by striking “to carry out this section” and inserting “, and for fiscal years 1998 through 2002 \$3,000,000 for each fiscal year, to carry out this section”.

**SEC. 129. REGULATIONS FOR SUNSCREEN PRODUCTS.**

Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services shall issue regulations for over-the-counter sunscreen products for the prevention or treatment of sunburn.

**SEC. 130. REPORTS OF POSTMARKETING APPROVAL STUDIES.**

(a) IN GENERAL.—Chapter V, as amended by section 116, is further amended by inserting after section 506A the following:

**“SEC. 506B. REPORTS OF POSTMARKETING STUDIES.**

“(a) SUBMISSION.—

“(1) IN GENERAL.—A sponsor of a drug that has entered into an agreement with the Secretary to conduct a postmarketing study of a drug shall submit to the Secretary, within 1 year after the approval of such drug and annually thereafter until the study is completed or terminated, a report of the progress of the study or the reasons for the failure of the sponsor to conduct the study. The report shall be submitted in such form as is prescribed by the Secretary in regulations issued by the Secretary.

“(2) 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 requirements of paragraph (1). An initial report for such an agreement

The agreement requires the Secretary, in two years, to establish procedures for approving PET products, including compounded PET products, and good manufacturing practices for such products, taking account of relevant differences between commercial manufacturers and non-profit organizations and in consultation with patient groups, physicians, and others. The Secretary may not require NDAs or ANDAs for these products for four years (or two years after the procedures mentioned above are established).

A compounded PET drug, by definition, must be compounded pursuant to a valid prescription order and in accordance with state law, among other requirements. A PET drug that fails to meet these requirements is not a "compounded PET drug" and therefore is not exempt from section 501(a)(2)(B) (21 USC 351(a)(2)(B)) or from subsections (b) and (j) of section 505 (21 USC 355). PET drugs that fail to meet the definition of a "compounded PET drug" shall be subject to the procedures and requirements established by the Secretary under subsection (c)(1).

*Application of Federal law to practice of pharmacy compounding  
(Sec. 127)*

The conference report includes provisions on pharmacy compounding that reflect the conferees' extensive work with the Food and Drug Administration and other interested parties to reach consensus. It is the intent of the conferees to ensure continued availability of compounded drug products as a component of individualized therapy, while limiting the scope of compounding so as to prevent manufacturing under the guise of compounding. Section 503A establishes parameters under which compounding is 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 conferees 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 conferees expect that FDA and the courts will accord great deference to the licensed prescriber's judgement in determining whether the change produces a "significant difference." However, where it is readily apparent, based on the circumstances, the "significant difference" is a mere pretext to allow compounding 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 .08% to .09%) are made that are not known to be significant or instances in which the prescribing physician is receiving financial remuneration or other financial incentives to write prescriptions for compounded products.

The conferees also expect that the Secretary will develop the list of bulk drug substances described in subsection (b)(1)(A)(i)(III) within one year from the date of enactment. It is the intent of the conferees that the criteria used to develop the list of bulk drug substances and the list itself are to be developed in consultation with the United States Pharmacopeia. The conferees further intend that where evidence relating to an approval under Section 505 does not exist, the Secretary shall consider other criteria. Finally, the conferees intend that after this list is published, organizations may petition the FDA for inclusion of additional substances on the aforementioned list.

The memorandum of understanding described in Paragraph (b)(3)(B)(i) shall provide guidance on the meaning of inordinate amounts, including any circumstances under which the compounding of drug products for interstate shipment in excess of 5 percent of total prescription orders would be included in a "safe harbor" of interstate shipments of compounded products that shall not be deemed inordinate.

As stated in paragraph (e), nothing in Section 503A is intended to change or otherwise affect current law with respect to radiopharmaceuticals, including PET drugs. Further, as stated in paragraph (f), the term compounding does not include mixing reconstituting or other such acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling. Nothing in this provision is intended to change or otherwise affect the Act with respect to reconstitution or other similar processing that is done pursuant to a manufacturer's approved labeling, and other directions from such manufacturer that are consistent with that labeling. In general, such practices, as performed by a licensed practitioner for an identified individual patient, are appropriately regulated by state boards of pharmacy. The conferees 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 conferees 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 Secretary's 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 section 2(b) of P.L. 102-222. 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 originally selected to participate in the program.