

FOOD AND DRUG ADMINISTRATION MODERNIZATION ACT  
OF 1997

NOVEMBER 9, 1997.—Ordered to be printed

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.

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.