law, for a patient or for research, teaching, or quality control; and

''(2) includes any nonradioactive reagent, reagent kit, ingredient, nuclide generator, accelerator, target material, electronic synthesizer, or other apparatus or computer program to be used in the preparation of such a drug.''.

(b) ADULTERATION.—

(1) IN GENERAL.—Section 501(a)(2) (21 U.S.C. 351(a)(2)) is amended by striking ''; or (3)'' and inserting the following: ''; or (C) if it is a compounded positron emission tomography drug and the methods used in, or the facilities and controls used for, its compounding, processing, packing, or holding do not conform to or are not operated or administered in conformity with the positron emission tomography compounding standards and the official monographs of the United States Pharmacopeia to assure that such drug meets the requirements of this Act as to safety and has the identity and strength, and meets the quality and purity characteristics, that it purports or is represented to possess; or (3)''.

(2) SUNSET.—Sections 201(ii) and 501(a)(2)(C) (21 U.S.C. 321(ii) and 351(a)(2)(C)) shall not apply 4 years after the date of enactment of this Act or 2 years after the date or which the Secretary of Health and Human Services establishes the requirements described in subsection (c)(1)(B), whichever is later.

(c) REQUIREMENTS FOR REVIEW OF APPROVAL PROCEDURES AND CURRENT GOOD MANUFACTURING PRACTICES FOR POSITRON EMISSION TOMOGRAPHY.—

(1) PROCEDURES AND REQUIREMENTS.—

(A) IN GENERAL.—In order to take account of the special characteristics of positron emission tomography drugs and the special techniques and processes 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 establish—

(i) appropriate procedures for the approval of positron emission tomography drugs pursuant to section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355); and

(ii) appropriate current good manufacturing practice requirements for such drugs.

(B) CONSIDERATIONS AND CONSULTATION.—In establishing the procedures and requirements required by subparagraph (A), the Secretary of Health and Human Services shall take due account of any relevant differences between not-for-profit institutions that compound the drugs for their patients and commercial manufacturers of the drugs. Prior to establishing the procedures and requirements, the Secretary of Health and Human Services shall consult with patient advocacy groups, professional associations, manufacturers, and physicians and scientists licensed to make or use positron emission tomography drugs.

(2) SUBMISSION OF NEW DRUG APPLICATIONS AND ABBREVIATED NEW DRUG APPLICATIONS.—

(A) IN GENERAL.—The Secretary of Health and Human Services shall not require the submission of new drug applications or abbreviated new drug applications under subsection (b) or (j) of section 505 (21 U.S.C. 355), for compounded positron emission tomography drugs that are not adulterated drugs described in section 501(a)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351(a)(2)(C)) (as amended by subsection (b)), for a period of 4 years after the date of enactment of this Act, or for 2 years after the date or which the Secretary establishes procedures and requirements under paragraph (1), whichever is later.

(B) CONSTRUCTION.—Nothing in this Act shall prohibit the voluntary submission of such applications or the review of such applications by the Secretary of Health and Human Services. Nothing in this Act shall constitute an exemption for a positron emission tomography drug from the requirements of regulations issued under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) for such drugs.

(d) REVOCATION OF CERTAIN INCONSISTENT DOCUMENTS.—Within 30 days after the date of enactment of this Act, the Secretary of Health and Human Services shall publish in the Federal Register a notice terminating the application of the following notices and rule:

(1) A notice entitled ''Regulation of Positron Emission Tomography Radiopharmaceutical Drug Products; Guidance; Public Workshop'', published in the Federal Register on February 27, 1995, 60 Fed. Reg. 10594.

(2) A notice entitled ''Draft Guideline on the Manufacture of Positron Emission Tomography Radiopharmaceutical Drug Products; Availability'', published in the Federal Register on February 27, 1995, 60 Fed. Reg. 10593.

(3) A final rule entitled ''Current Good Manufacturing Practice for Finished Pharmaceuticals; Positron Emission Tomography'', published in the Federal Register on April 22, 1997, 62 Fed. Reg. 19493 (codified at part 211 of title 21, Code of Federal Regulations).

(e) DEFINITION.—In this section:

(1) COMPOUNDED POSITRON EMISSION TOMOGRAPHY DRUG.—The term ''compounded positron emission tomography drug'' means a positron emission tomography drug that has been compounded by or on the order of a practitioner who is licensed by a State to compound or order compounding for such a drug, and is compounded in accordance with that State's law, for a patient or for research, teaching, or quality control.

(2) DRUG.—The term ''drug'' has the meaning given the term in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.).

(3) POSITRON EMISSION TOMOGRAPHY DRUG.—The term ''positron emission tomography drug'' means a drug that—

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

(B) includes any nonradioactive reagent, reagent kit, ingredient, nuclide generator, accelerator, target material, electronic synthesizer, or other apparatus or computer program to be used in the preparation of such a drug.

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AMENDMENT NO. 1174

On page 30, strike lines 17 through 20, and insert the following:

(c) RULE OF CONSTRUCTION.—Nothing in the amendments made by subsections (a) and (b) shall be construed to alter any authority of the Secretary of Health and Human Services to regulate any tobacco product, or any additive or ingredient of a tobacco product.

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AMENDMENT NO. 1175

Strike section 602 and insert the following:

**SEC. 602. ENVIRONMENTAL IMPACT REVIEW.**

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

**''SEC. 742. ENVIRONMENTAL IMPACT REVIEW.**

''Notwithstanding any other provision of law, 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 a recommendation or report relating to) this Act, shall be considered to meet the requirements for a detailed statement under section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332(2)(c)).''.

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## REED AMENDMENTS NOS. 1176–1177

(Ordered to lie on the table.)

Mr. REED submitted two amendments intended to be proposed by him to the bill, S. 830, supra; as follows:

AMENDMENT NO. 1176

On page 30, line 16, after the first period, insert the following: ''Nothing in the preceding sentence shall be construed to prohibit the Secretary from determining that a new device is not substantially equivalent to a predicate device because changes in the technological characteristics of the new device demonstrate that the device is intended for a different use than the use stated in the labeling of the device.''.

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AMENDMENT NO. 1177

On page 30, line 16, insert before the first period the following: ''if the proposed labeling is neither false nor misleading''.

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## THE DEPARTMENT OF THE INTERIOR AND RELATED AGENCIES APPROPRIATIONS ACT, 1998

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## BROWNBACK AMENDMENT NO. 1178

Mr. BROWNBACK submitted an amendment intended to be proposed by him to the bill (H.R. 2107) making appropriations for the Department of the Interior and related agencies for the fiscal year ending September 30, 1998, and for other purposes; as follows:

At the appropriate place in title I, insert the following:

''SEC. 1 . (a) In this section—

(1) the term ''Huron Cemetery'' means the lands that form the cemetery that is popularly known as the Huron Cemetery, located in Kansas City, Kansas, as described in subsection (b)(4);

(2) the term ''Secretary'' means the Secretary of the Interior; and

(3) the term ''Wyandot Nation'' means the nation of the Wyandot Indians that consists of the descendants of the Wyandott nation described in the treaty between the United States and the Wyandott Indians, done at Washington on January 31, 1855 (10 Stat. 1159 et seq.), and includes—

(A) the Wyandot Nation of Kansas, Inc.; and

(B) the Wayandotte Tribe of Oklahoma.

(b)(1) Subject to subsection (c), the Secretary shall take such action as may be necessary to ensure that the lands comprising the Huron Cemetery (as described in paragraph (4)) are held in trust for the Wyandot Nation to be used only for a burial ground for the Wyandot Nation in accordance with this subsection.

(2) Subject to subsection (c), the Secretary shall take such action as may be necessary to ensure that the lands of the Huron Cemetery are used only—

(A) for religious and cultural uses of the Wyandot Nation that are compatible with the use of the lands as a cemetery; and

(B) as a burial ground for members of the Wyandot Nation.

(3) In carrying out this subsection, the Secretary shall take such action as may be necessary to ensure that members of the Wyandot Nation of Kansas, Inc. may use the

Huron Cemetery for the purposes specified in paragraph (2) on the condition that if space is available in the Huron Cemetery, no member of the Wyandotte Tribe of Oklahoma may be denied the right to be buried in that cemetery.

(4) The description of the lands of the Huron Cemetery is as follows:

The tract of land in the NW ¼ of sec. 10, T. 11 S., R. 25 E., of the sixth principal meridian, in Wyandotte County, Kansas (as surveyed and marked on the ground on August 15, 1888, by William Millor, Civil Engineer and Surveyor), described as follows:

''Commencing on the Northwest corner of the Northwest Quarter of the Northwest Quarter of said Section 10;

''Thence South 28 poles to the 'true point of beginning';

''Thence South 71 degrees East 10 poles and 18 links;

''Thence South 18 degrees and 30 minutes West 28 poles;

''Thence West 11 and one-half poles;

''Thence North 19 degrees 15 minutes East 31 poles and 15 feet to the 'true point of beginning', containing 2 acres or more.''.

## THE FOOD AND DRUG ADMINISTRATION MODERNIZATION AND ACCOUNTABILITY ACT OF 1997 PRESCRIPTION DRUG USERS FEE REAUTHORIZATION ACT OF 1997

### FEINSTEIN AMENDMENTS NOS. 1179–1181

(Ordered to lie on the table.)

Mrs. FEINSTEIN submitted three amendments intended to be proposed by her to the bill, S. 830, supra; as follows:

AMENDMENT NO. 1179

In section 761 of the Federal Food, Drug, and Cosmetic Act, as added by section 807(a), add the following new subsection:

''(g) REGULATIONS.—

''(1) REQUIREMENT.—Not later than 2 years after the date of enactment of the Food and Drug Administration Modernization and Accountability Act of 1997, the Secretary shall promulgate final regulations (after notice and comment) that establish the criteria and conditions under which a State may apply for and receive an exemption under subsection (b).

''(2) EFFECTIVE DATE.—No exemption may be provided under subsection (b) until the date on which the Secretary has promulgated the regulations referred to in paragraph (1).''.

AMENDMENT NO. 1180

At the appropriate place in title VIII, insert the following:

**SEC. . RULE OF CONSTRUCTION REGARDING STATE LAWS.**

Chapter IX (21 U.S.C. 391 et seq.), as amended by section 804, is further amended by adding at the end thereof the following:

**''SEC. 908, RULE OF CONSTRUCTION REGARDING STATE LAWS.**

''Nothing in this Act shall be construed to prohibit any State or political subdivision from imposing any requirements that are more stringent than those imposed by this Act, including, but not limited to, requirements relating to embargoing products, the licensing and inspection of manufacturers' facilities, advertising, labeling, packaging, the regulation of the quality and nature of ingredients, and the provision of warnings or other communications to protect the public health.''.

AMENDMENT NO. 1181

On page 141, after line 24, add the following:

''(8) CONSIDERATION OF INFORMATION AS PUBLIC INFORMATION.—The certification, summary of the proposed protocol, and the schedule for the proposed protocol under this subsection, excluding proprietary information, shall be considered to be public information.

### HATCH AMENDMENTS NOS. 1182–1183

(Ordered to lie on the table.)

Mr. HATCH submitted two amendments intended to be proposed by him to the bill, S. 830, supra; as follows:

AMENDMENT NO. 1182

Beginning on page 4, strike line 11 and all that follows through page 5, line 6, and insert the following:

''(1) IN GENERAL.—The Secretary, acting through the Commissioner, 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, shall protect the public health by taking actions that help ensure that

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

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

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

''(D) cosmetics are safe; and

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

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

AMENDMENT NO. 1183

At the appropriate place, insert the following:

**SEC. . SAFETY REPORT DISCLAIMERS.**

Chapter IX (21 U.S.C. 391 et seq.), as amended by section 804, is further amended by adding at the end the following:

**''SEC. 908. 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 which is a food, drug, new drug, device, dietary supplement, or cosmetic) under this Act (and any release by the Secretary of that report of information), such report or information shall not be construed to necessarily reflect a conclusion by the entity or the Secretary that the report or information constitutes an admission that the product involved caused or contributed to an adverse experience, or otherwise caused or contributed to a death, serious injury, serious illness, or malfunction. 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 caused or contributed to an adverse experience or caused or contributed to a death, serious injury, serious illness, or malfunction.''.

### HUTCHINSON AMENDMENT NO. 1184

(Ordered to lie on the table.)

Mr. HUTCHINSON submitted an amendment intended to be proposed by him to the bill, S. 830, supra; as follows:

Strike section 809 and insert the following:

**SEC. 809. APPLICATION OF FEDERAL LAW TO THE PRACTICE OF PHARMACY COMPOUNDING.**

Section 503 (21 U.S.C. 353) is amended by adding at the end the following:

''(h)(1) Sections 501(a)(2)(B), 502(f)(1), 502(l), 505, and 507 shall not apply to a drug product if—

''(A) the drug product is compounded for an identified individual patient, based on a medical need for a compounded product—

''(i) by a licensed pharmacist in a State licensed pharmacy or a Federal facility, or a licensed physician, or the prescription order of a licensed physician or other licensed practitioner authorized by State law to prescribe drugs; or

''(ii) by a licensed pharmacist or licensed physician in limited quantities, prior to the receipt of a valid prescription order for the identified individual patient, and is compounded based on a history of the licensed pharmacist or licensed physician receiving valid prescription orders for the compounding of the drug product that have been generated solely within an established relationship between the licensed pharmacist, or licensed physician, and—

''(I) the individual patient for whom the prescription order will be provided; or

''(II) the physician or other licensed practitioner who will write such prescription order; and

''(B) the licensed pharmacist or licensed physician—

''(i) compounds the drug product using bulk drug substances—

''(I) that—

''(aa) comply with the standards of an applicable United States Pharmacopeia or National Formulary monograph; or

''(bb) in a case in which such a monograph does not exist, are drug substances that are covered by regulations issued by the Secretary under paragraph (3);

''(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;

''(ii) compounds the drug product using ingredients (other than bulk drug substances) that comply with the standards of an applicable United States Pharmacopeia or National Formulary monograph and the United States Pharmacopeia chapter on pharmacy compounding;

''(iii) only advertises or promotes the compounding service provided by the licensed pharmacist or licensed physician and does not advertise or promote the compounding of any particular drug, class of drug, or type of drug;

''(iv) 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;

''(iv) does not compound a drug product that is identified by the Secretary in regulation as presenting demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product; and

''(vi) does not distribute compounded drugs outside of the State in which the drugs are compounded, unless the principal State agency of jurisdiction that regulates the