AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

I

107TH CONGRESS
1ST SESSION

H. R. 1043

To amend the Federal Food, Drug, and Cosmetic Act to provide the Food and Drug Administration jurisdiction over tobacco.

IN THE HOUSE OF REPRESENTATIVES

MARCH 15, 2001

Mr. WAXMAN (for himself, Mr. HANSEN, Mr. MEEHAN, Mr. GANSKE, Mr. DINGELL, Mrs. MORELLA, Mr. BROWN of Ohio, Mr. DOGGETT, Mr. BONIOR, Ms. DEGETTE, Mrs. CAPPS, Ms. DELAURO, Mr. LANTOS, Mr. MARKEY, Ms. ESHOO, Mr. STARK, Mr. ALLEN, Mr. MCDERMOTT, Mrs. MINK of Hawaii, Ms. SCHAKOWSKY, Mr. OLVER, Mr. HINCHEY, Ms. NORTON, Mrs. TAUSCHER, Mr. OBERSTAR, Mr. GEORGE MILLER of California, Ms. RIVERS, Mr. BALDACCI, Mr. PAYNE, Mr. BORSKI, Ms. ROYBAL-ALLARD, Mr. LAFALCE, Mr. DEFAZIO, Ms. SLAUGHTER, Ms. PELOSI, Mr. COYNE, Mr. BLUMENAUER, Mrs. MALONEY of New York, and Mr. WEXLER) introduced the following bill; which was referred to the Committee on Energy and Commerce

---

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide the Food and Drug Administration jurisdiction over tobacco.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''FDA Tobacco Jurisdiction Act of 2001''.

SEC. 2. REFERENCE.

Whenever in this Act an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

SEC. 3. DEFINITIONS.

(a) DRUG.—Section 201(g)(1) (21 U.S.C. 321(g)(1)) is amended by striking ''; and (D)'' and inserting ''; (D) nicotine in tobacco products; and (E)''.

(b) DEVICES.—Section 201(h) (21 U.S.C. 321(h)) is amended by adding at the end the following: ''Such term includes a tobacco product.''.

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

''(kk) The term 'tobacco product' means any product made or derived from tobacco that is intended for human consumption.''.

SEC. 4. AMENDMENTS TO CHAPTER V.

(a) MISBRANDING.—Section 502 (21 U.S.C. 360) is amended by adding at the end the following:

''(u) In the case of a tobacco product, if it does not comply with a requirement under subchapter F.''.

(b) CLARIFICATION OF AUTHORITY.—Section 520(e) (21 U.S.C. 360j(e)) is amended by adding at the end the following:

''(3) In the case of tobacco products, the restrictions on sale and distribution authorized by paragraph (1) shall include restrictions on advertising and promotion of tobacco products.''.

(c) PREEMPTION.—Section 521(a) (21 U.S.C. 360k(a)) is amended—

(1) by striking ''Except as provided in subsection (b)'' and inserting ''Except in the case of tobacco products and as provided in subsection (b)''; and

(2) by adding at the end the following:

''TOBACCO PRODUCTS

''(c) If the package or advertisement of a tobacco product is required to bear a warning under this Act, no statement relating to the use of the tobacco product and health, other than a statement required under this Act, may be required by any State or local statute or regulation to be included on any package or in any advertisement of such tobacco product.''.

SEC. 5. VALIDATION OF THE FDA RULE.

(a) IN GENERAL.—All provisions of the regulations related to tobacco products promulgated by the Secretary of Health and Human Services on August 28, 1996 (61 Fed. Reg. 44396) shall be considered to be lawful, and to have been lawfully promulgated, under the Federal Food, Drug, and Cosmetic Act.

(b) EFFECTIVE DATE.—All provisions of such regulations shall take effect upon the expiration of 1 year after the date of the enactment of this Act.

SEC. 6. SPECIAL PROVISIONS FOR TOBACCO PRODUCTS.

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

"Subchapter F—Special Provisions for Tobacco Products

"SEC. 565. SPECIAL STANDARD FOR TOBACCO PRODUCTS.

''In the case of tobacco products, an action that provides appropriate protection of public health shall be deemed to provide a reasonable assurance of safety and effectiveness.

"SEC. 566. IMPLEMENTATION OF THE PROPOSED RESOLUTION.

''(a) ADDITIONAL RESTRICTIONS ON MARKETING, ADVERTISING, AND ACCESS.—Not later than 18 months after the date of the enactment of this subchapter, the Secretary shall revise the regulations related to tobacco products promulgated by the Secretary on August 28, 1996 (61 Fed. Reg. 44396) to include the additional restrictions on marketing, advertising, and access described in Title IA and Title IC of the Proposed Resolution entered into by the tobacco manufacturers and the State attorneys general on June 20, 1997, except that the Sec-

retary shall not include an additional restriction on marketing or advertising in such regulations if its inclusion would violate the First Amendment to the Constitution.

''(b) WARNINGS.—

''(1) CIGARETTES AND SMOKELESS TOBACCO.—Not later than 18 months after the date of the enactment of this subchapter, the Secretary shall promulgate regulations to require warnings on cigarette and smokeless tobacco labeling and advertisements. The content, format, and rotation of warnings shall conform to the specifications described in Title IB of the Proposed Resolution entered into by the tobacco manufacturers and the State attorneys general on June 20, 1997.

''(2) PROHIBITION.—It shall be unlawful to advertise tobacco products on any medium of electronic communication subject to the jurisdiction of the Federal Communications Commission.

''(c) INGREDIENTS.—

''(1) IN GENERAL.—Not later than 18 months after the date of enactment of this subchapter, the Secretary shall promulgate regulations relating to ingredients in tobacco products. Except as provided in paragraph (2), such regulations shall conform to the specifications described in Title IF of the Pro-

posed Resolution entered into by the tobacco manufacturers and the State attorneys general on June 20, 1997.

''(2) FAILURE TO ACT.—If the Secretary fails to approve or disapprove an ingredient's safety within the review period prescribed under the regulations under paragraph (1), such failure shall not be considered an approval of such ingredient.

''(d) REDUCED-RISK PRODUCTS.—No manufacturer of a tobacco product may state or imply in the labeling or advertisements of the tobacco product that the tobacco product presents a reduced risk to health unless the Secretary has determined that the tobacco product does present a significantly reduced risk to health.

''(e) OTHER AUTHORITY.—This section does not limit the authority the Secretary has under other provisions of this Act with respect to tobacco products.

''SEC. 567. STATE TOBACCO CONTROL PROGRAMS.

''(a) IN GENERAL.—Effective 2 years after the date of the enactment of this subchapter, a State may not receive funds under this Act for tobacco control activities unless the State has put into law a State tobacco control program that conforms to the model State program established by the Secretary under subsection (b).

''(b) MODEL STATE PROGRAM.—

''(1) GENERAL RULE.—Within one year of the date of the enactment of this subchapter, the Secretary shall establish a model State tobacco control program.

''(2) PROGRAM CONTENT.—The model State tobacco control program established under paragraph (1) shall—

''(A) require persons who sell tobacco products to individuals for personal consumption to obtain a license from the State;

''(B) require licensed retailers to comply with the requirements under this Act that are applicable to tobacco product retailers;

''(C) prohibit any individual from purchasing tobacco products for resale or distribution to individuals under the age of 18;

''(D) include minimum requirements for the conduct and frequency of compliance inspections of licensed retailers;

''(E) include State performance objectives, including objectives for reducing the level of violations observed during compliance inspections;

''(F) include provisions for appropriate penalties for violations of the program require-

ments, including provisions for license suspension and revocation; and

''(G) include such other provisions as the Secretary determines are appropriate to protect public health.

''(c) FAILURE TO IMPLEMENT.—If a State fails to effectively implement a State tobacco control program which conforms to the Model State program established under subsection (b) or if a State fails to achieve the performance objectives applicable to the State under the Model State program, the Secretary shall withhold up to 20 percent of the funds made available under this Act to the State for tobacco control activities.

''(d) FEDERAL LICENSING PROGRAM.—Within one year of the date of the enactment of this subchapter, the Secretary shall establish Federal licensing requirements for—

''(1) tobacco product retailers operating on Federal property;

''(2) tobacco product retailers operating in a State which does not put into law or effectively implement a State tobacco control program which conforms to the Model State Program; and

''(3) such other tobacco product retailers as the Secretary may specify.

The Federal tobacco control requirements shall conform to the licensing requirements of the Model State Program.

''(e) FEDERAL AUTHORITY.—The Secretary may order a retailer licensed by a State to suspend or cease selling tobacco products if the tobacco product retailer is in violation of a requirement under this Act related to tobacco products.

''(f) INDIAN TRIBES.—In the case of tobacco product retailers operating on Indian reservations, the governing Indian tribe or tribal organization shall be treated as a State.''.

SEC. 7. GENERAL PROVISIONS.

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

''(bb) The violation of any requirement under this Act relating to tobacco products.''.

(b) ACCESS TO INFORMATION.—Section 701 (21 U.S.C 371) is amended by adding at the end the following:

''(h) To acquire information related to tobacco products, the Secretary may administer oaths and require the testimony of witnesses and the production of documents and other materials. The Secretary may disclose to the public information acquired under this subsection if the Secretary determines that disclosure is appropriate to protect public health.''.

SEC. 8. REPEAL.

The Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1331 et seq.) and the Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4401 et seq.) are repealed on the date the regulations described in section 566(b) of the Federal Food, Drug, and Cosmetic Act take effect.

○