

106TH CONGRESS
2D SESSION

H. R. 4207

To amend the Federal Food, Drug, and Cosmetic Act with respect to tobacco products, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

APRIL 6, 2000

Mr. GANSKE (for himself, Mr. DINGELL, Mr. LEACH, Mr. WAXMAN, Mr. COX, Mr. BOSWELL, Mr. HANSEN, Mr. SNYDER, Mr. GILCHREST, Mrs. MALONEY of New York, Mrs. MORELLA, Mr. MORAN of Virginia, Mrs. ROUKEMA, Mr. MCDERMOTT, Mr. HORN, Mr. BRADY of Pennsylvania, Mr. SALMON, Mr. GILMAN, Mr. MCKEON, and Ms. DEGETTE) introduced the following bill; which was referred to the Committee on Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to tobacco products, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “FDA Tobacco Author-
5 ity Amendments Act”.

6 **SEC. 2. FINDINGS.**

7 The Congress finds as follows:

8 (1) Tobacco products are addictive.

1 (2) Such products cause over 400,000 deaths
2 each year in the United States.

3 (3) The Supreme Court has held that there is
4 no congressional intent to provide the Food and
5 Drug Administration with the authority to regulate
6 tobacco products.

7 (4) The Congress should amend the Federal
8 Food, Drug, and Cosmetic Act to provide the Food
9 and Drug Administration with the authority to regu-
10 late tobacco products.

11 **SEC. 3. DEFINITIONS.**

12 (a) DRUG.—Section 201(g)(1) of the Federal Food,
13 Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)) is amend-
14 ed by inserting after the first sentence the following:
15 “Such term includes nicotine in a tobacco product.”.

16 (b) DEVICES.—Section 201(h) of the Federal Food,
17 Drug, and Cosmetic Act (21 U.S.C. 321(h)) is amended
18 by adding at the end the following: “Such term includes
19 a tobacco product.”.

20 (c) OTHER DEFINITIONS.—Section 201 of the Fed-
21 eral Food, Drug, and Cosmetic Act (21 U.S.C. 321) is
22 amended by adding at the end the following:

23 “(kk) The term ‘tobacco product’ means any product
24 made or derived from tobacco that is intended for human
25 consumption.”.

1 **SEC. 4. AMENDMENTS TO CHAPTER V.**

2 (a) MISBRANDING.—Section 502 of the Federal
3 Food, Drug, and Cosmetic Act (21 U.S.C. 360) is amend-
4 ed by adding at the end the following:

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

7 (b) CLARIFICATION OF AUTHORITY REGARDING AD-
8 VERTISING AND PROMOTION; EQUAL TREATMENT OF RE-
9 TAIL OUTLETS.—Section 520(e) of the Federal Food,
10 Drug, and Cosmetic Act (21 U.S.C. 360j(e)) is amended
11 by adding at the end the following:

12 “(3) In the case of tobacco products:

13 “(A) The restrictions on sale and distribution
14 authorized by paragraph (1) shall include restric-
15 tions on advertising and promotion of tobacco prod-
16 ucts.

17 “(B) The Secretary shall ensure that such re-
18 strictions are applied uniformly to all entities that
19 make retail sales of tobacco products. For purposes
20 of the preceding sentence, such restrictions may not
21 exempt or apply differently to retail establishments
22 that predominantly or exclusively sell tobacco prod-
23 ucts.”.

24 (c) PREEMPTION.—Section 521(a) of the Federal
25 Food, Drug, and Cosmetic Act (21 U.S.C. 360k(a)) is
26 amended—

1 (1) by striking “Except as provided in sub-
2 section (b)” and inserting “Except in the case of to-
3 bacco products and as provided in subsection (b)”;
4 and

5 (2) by adding at the end the following:

6 “TOBACCO PRODUCTS

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

14 **SEC. 5. SPECIAL PROVISIONS FOR TOBACCO PRODUCTS.**

15 Chapter V of the Federal Food, Drug, and Cosmetic
16 Act (21 U.S.C. 351 et seq.) is amended by adding at the
17 end the following:

18 **“Subchapter F—Special Provisions for**
19 **Tobacco Products**

20 **“SEC. 565. SPECIAL STANDARD FOR TOBACCO PRODUCTS.**

21 “In the case of tobacco products, an action that is
22 appropriate for the protection of public health shall be
23 deemed to provide a reasonable assurance of safety and
24 effectiveness.

1 **“SEC. 566. WARNINGS REGARDING CIGARETTES AND**
2 **SMOKELESS TOBACCO; REGULATIONS.**

3 “(a) IN GENERAL.—Not later than 18 months after
4 the date of the enactment of this subchapter, the Sec-
5 retary shall promulgate regulations to require warnings on
6 cigarette and smokeless tobacco labeling and advertise-
7 ments. The content, format, and rotation of warnings shall
8 conform to the specifications described in Title IB of the
9 Proposed Resolution entered into by the tobacco manufac-
10 turers and the State attorneys general on June 20, 1997.

11 “(b) REDUCED-RISK PRODUCTS.—No manufacturer
12 of a tobacco product may state or imply in the labeling
13 or advertisements of the tobacco product that the tobacco
14 product presents a reduced risk to health unless the Sec-
15 retary has determined that the tobacco product does
16 present a significantly reduced risk to public health.

17 “(c) SAVINGS PROVISION.—Subsection (a) or (b) may
18 not be construed as limiting the authority provided under
19 other provisions of this Act with respect to tobacco prod-
20 ucts.

21 **“SEC. 567. RULE OF CONSTRUCTION REGARDING FARMERS**
22 **AND RELATED ENTITIES.**

23 “The provisions of this Act relating to tobacco prod-
24 ucts shall not apply to tobacco leaf that is not in the pos-
25 session of the manufacturer, or to the producers of tobacco
26 leaf, including tobacco growers, tobacco warehouses, and

1 tobacco grower cooperatives, nor shall any employee of the
2 Food and Drug Administration have any authority what-
3 soever to enter onto a farm owned by a producer of to-
4 bacco leaf without the written consent of such producer.
5 Notwithstanding any other provision of this subparagraph,
6 if a producer of tobacco leaf is also a tobacco product man-
7 ufacturer or controlled by a tobacco product manufac-
8 turer, the producer shall be subject to this chapter in the
9 producer's capacity as a manufacturer. Nothing in this
10 chapter shall be construed to grant the Secretary author-
11 ity to promulgate regulations on any matter that involves
12 the production of tobacco leaf or a producer thereof, other
13 than activities by a manufacturer affecting production.
14 For purposes of the preceding sentence, the term 'con-
15 trolled by' means a member of the same controlled group
16 of corporations as that term is used in section 52(a) of
17 the Internal Revenue Code of 1986, or under common con-
18 trol within the meaning of the regulations promulgated
19 under section 52(b) of such Code.".

20 **SEC. 6. VALIDATION OF FDA RULE.**

21 All provisions of the regulations related to tobacco
22 products promulgated by the Secretary of Health and
23 Human Services on August 28, 1996 (61 Fed. Reg.
24 44615–44618), and codified in title 21, Code of Federal
25 Regulations, shall, upon the date of the enactment of this

1 Act, take effect under authority of the Federal Food,
2 Drug, and Cosmetic Act as amended by this Act. The Sec-
3 retary shall amend the designations of authorities in such
4 regulations accordingly.

5 **SEC. 7. GENERAL PROVISIONS.**

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

8 “(aa) The violation of any requirement under this Act
9 relating to tobacco products.”.

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

12 “(i) To acquire information related to tobacco prod-
13 ucts, the Secretary may administer oaths and require the
14 testimony of witnesses and the production of documents
15 and other materials. The Secretary may disclose to the
16 public information acquired under this subsection if the
17 Secretary determines that disclosure is appropriate to pro-
18 tect public health.”.

19 **SEC. 8. REPEALS.**

20 Effective on the date the regulations described in sec-
21 tion 566(a) of the Federal Food, Drug, and Cosmetic Act
22 take effect—

23 (1) the Federal Cigarette Labeling and Adver-
24 tising Act (15 U.S.C. 1331 et seq.), other than sec-
25 tions 6, 8, 10, and 11, is repealed; and

1 (2) the Comprehensive Smokeless Tobacco
2 Health Education Act of 1986 (15 U.S.C. 4401 et
3 seq.), other than sections 3(f), 5, and 6, is repealed.

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