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(Original Signature of Member)

115TH CONGRESS
1ST SESSION

H. R.

To amend the Federal Food, Drug, and Cosmetic Act to provide for a certain effective date with respect to deemed tobacco products, to provide for the establishment of product standards for vapor product batteries, to provide for regulation of vapor products, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. COLE introduced the following bill; which was referred to the Committee
on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide for a certain effective date with respect to deemed tobacco products, to provide for the establishment of product standards for vapor product batteries, to provide for regulation of vapor 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 Deeming Author-
5 ity Clarification Act of 2017”.

1 **SEC. 2. DATE FOR APPLICATION OF FEDERAL FOOD, DRUG,**
2 **AND COSMETIC ACT TO DEEMED TOBACCO**
3 **PRODUCTS.**

4 Section 901(b) of the Federal Food, Drug, and Cos-
5 metic Act (21 U.S.C. 387a(b)) is amended—

6 (1) by striking “This chapter shall apply” and
7 inserting the following:

8 “(1) IN GENERAL.—This chapter shall apply”;
9 and

10 (2) by adding at the end the following new
11 paragraph:

12 “(2) DEEMED TOBACCO PRODUCTS.—For each
13 tobacco product deemed subject to the requirements
14 of this chapter pursuant to paragraph (1), each ref-
15 erence in sections 905(j) and 910(a)—

16 “(A) to ‘February 15, 2007’, shall be con-
17 sidered to be a reference to ‘the effective date
18 of the regulation under which a tobacco product
19 is deemed subject to the requirements of this
20 chapter pursuant to section 901(b)’; and

21 “(B) to ‘21 months after the date of enact-
22 ment of the Family Smoking Prevention and
23 Tobacco Control Act’, shall be considered to be
24 a reference to the later of—

1 “(i) ‘21 months after the date of en-
2 actment of the FDA Deeming Authority
3 Clarification Act of 2017’; and

4 “(ii) ‘21 months after the effective
5 date of such deeming regulation’.”.

6 **SEC. 3. PRODUCT STANDARDS FOR VAPOR PRODUCT BAT-**
7 **TERIES.**

8 (a) **APPLICABILITY OF STANDARDS.**—Section 907 of
9 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
10 387g) and any related provisions of such Act shall apply
11 with respect to a vapor product battery to the same extent
12 and in the same manner as such section 907 and related
13 provisions apply with respect to a component of a tobacco
14 product.

15 (b) **PROMULGATION OF STANDARDS.**—

16 (1) **PROPOSED STANDARDS.**—Not later than 12
17 months after the date of enactment of this Act, the
18 Secretary of Health and Human Services shall issue
19 a notice of proposed rulemaking to establish product
20 standards for vapor product batteries pursuant to
21 section 907 of the Federal Food, Drug, and Cos-
22 metic Act (21 U.S.C. 387g).

23 (2) **FINAL STANDARDS.**—Not later than 24
24 months after the date of enactment of this Act, the

1 Secretary shall promulgate the vapor product bat-
2 tery standards required by this section.

3 (c) COMPLIANCE WITH FINAL STANDARDS.—For
4 any vapor product (including those products in test mar-
5 kets) that has a battery and is commercially marketed in
6 the United States as of the date by which final standards
7 are required to be promulgated under subsection (b)(2),
8 the Secretary of Health and Human Services, based on
9 any change to the battery for the purpose of conforming
10 to such final standards, shall not—

11 (1) require the submission of a report under
12 section 905(j) of such Federal Food, Drug, and Cos-
13 metic Act (21 U.S.C. 387e(j)); or

14 (2) treat such vapor product as a new tobacco
15 product for which an order is required under section
16 910(c)(1)(A)(i) of such Act (21 U.S.C.
17 387j(c)(1)(A)(i)).

18 (d) DEFINITION.—In this section, the term “vapor
19 product” has the meaning given to such term in section
20 921(f) of the Federal Food, Drug, and Cosmetic Act, as
21 added by section 4 of this Act.

22 **SEC. 4. REGULATION OF VAPOR PRODUCTS.**

23 (a) IN GENERAL.—Chapter IX of the Federal Food,
24 Drug, and Cosmetic Act is amended by inserting after sec-
25 tion 920 of such Act (21 U.S.C. 387t) the following:

1 **“SEC. 921. VAPOR PRODUCTS.**

2 “(a) RELATION TO OTHER PROVISIONS.—The au-
3 thorities vested in the Secretary by this section to regulate
4 vapor products are in addition to, not in lieu of, the au-
5 thorities vested in the Secretary by other sections of this
6 Act to regulate vapor products as tobacco products.

7 “(b) ADVERTISING IN PRINT PUBLICATIONS.—

8 “(1) IN GENERAL.—The manufacturer, dis-
9 tributor, or retailer of a vapor product shall not dis-
10 seminate or cause to be disseminated advertising or
11 labeling of the vapor product in a newspaper, maga-
12 zine, periodical or other publication (whether peri-
13 odic or limited distribution), other than an adult
14 publication.

15 “(2) DEFINITION.—In this subsection, the term
16 ‘adult publication’ means a newspaper, magazine,
17 periodical, or other publication—

18 “(A) whose readers younger than 18 years
19 of age constitute 15 percent or less of the total
20 readership as measured by competent and reli-
21 able survey evidence; and

22 “(B) that is read by fewer than 2 million
23 persons younger than 18 years of age as meas-
24 ured by competent and reliable survey evidence.

25 “(c) PROHIBIT SELF-SERVICE DISPLAYS OF VAPOR
26 PRODUCTS.—

1 “(1) IN GENERAL.—A retailer may sell vapor
2 products only in a direct face-to-face exchange.

3 “(2) EXCEPTION.—Paragraph (1) does not
4 apply—

5 “(A) to mail order sales; or

6 “(B) to sales by means of a vending ma-
7 chine or self-service display that is located in a
8 facility where the retailer ensures that no per-
9 son under 18 years of age is present or per-
10 mitted to enter at any time.

11 “(3) CIVIL PENALTY.—A violation of this sub-
12 section shall be subject to a civil penalty under sec-
13 tion 303(f)(9) to the same extent and in the same
14 manner as a violation of any requirement of this Act
15 which relates to a tobacco product.

16 “(d) LABELING.—

17 “(1) IN GENERAL.—Not later than 12 months
18 after the date of enactment of the FDA Deeming
19 Authority Clarification Act of 2017, the Secretary
20 shall promulgate final regulations to require pack-
21 ages of vapor products to bear a label containing—

22 “(A) the phrase ‘Keep Out of Reach of
23 Children’;

24 “(B) the phrase ‘Underage Sale Prohib-
25 ited’; and

1 “(C) if the vapor product includes nicotine
2 in a solution or other form at the time of sale,
3 an accurate statement of the nicotine content.

4 “(2) MISBRANDING.—A vapor product whose
5 label is in violation of paragraph (1) is deemed to
6 be a misbranded tobacco product under section 903.

7 “(e) ANNUAL REGISTRATION REQUIREMENTS FOR
8 VAPOR PRODUCT RETAILERS.—

9 “(1) REGISTRATION BY RETAILERS.—Every
10 person who owns or operates an establishment in
11 any State engaged in the retail sale of a vapor prod-
12 uct shall register that establishment with the Sec-
13 retary by the later of—

14 “(A) 60 days after the date of the enact-
15 ment of the FDA Deeming Authority Clarifica-
16 tion Act of 2017; and

17 “(B) 30 days after first engaging in such
18 retail sale.

19 “(2) EXCLUSION.—The requirements of this
20 subsection do not apply with respect to any estab-
21 lishment subject to an active registration or retail li-
22 cense under—

23 “(A) any State law relating to tobacco
24 products; or

25 “(B) section 905.

1 “(3) PUBLIC ACCESS TO REGISTRATION INFOR-
2 MATION.—The Secretary shall make available for in-
3 spection, to any person so requesting, any registra-
4 tion filed under this subsection.

5 “(f) VAPOR PRODUCT DEFINED.—In this section:

6 “(1) IN GENERAL.—The term ‘vapor product’—

7 “(A) means any noncombustible product
8 that employs a heating element, power source,
9 electronic circuit, or other electronic, chemical,
10 or mechanical means, regardless of shape or
11 size, to produce vapor from nicotine in a solu-
12 tion or other form; and

13 “(B) includes—

14 “(i) any electronic cigarette, electronic
15 cigar, electronic cigarillo, electronic pipe,
16 or similar product or device that is in-
17 tended to produce vapor from nicotine in a
18 solution of other form; and

19 “(ii) nicotine in a solution or other
20 form, whether in a cartridge or container
21 or otherwise dispensed, that is intended to
22 be used with or in a product described in
23 clause (i).

1 “(2) EXCLUSION.—The term ‘vapor product’
2 does not include any product regulated as a drug or
3 device under chapter V.”.

4 (b) PROHIBITED ACTS.—Section 301 of the Federal
5 Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amend-
6 ed by adding at the end the following:

7 “(eee) The disseminating or causing to be dissemi-
8 nated, by a manufacturer, distributor, or retailer of a
9 vapor product, advertising or labeling of the vapor product
10 in violation of section 921(b).

11 “(fff) The failure of a person who owns or operates
12 an establishment in any State engaged in the retail sale
13 of a vapor product to register as required by section
14 921(e).”.