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 Representatives of the United States of America in Congress assembled,

2 SECTION 1. SHORT TITLE.

3 This Act may be cited as the “FDA Deeming Authority Clarification Act of 2017”.

February 10, 2017 (4:33 p.m.)
SEC. 2. DATE FOR APPLICATION OF FEDERAL FOOD, DRUG, 
AND COSMETIC ACT TO DEEMED TOBACCO 
PRODUCTS.

Section 901(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387a(b)) is amended—

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

“(1) IN GENERAL.—This chapter shall apply’’;

and

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

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

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

“(B) to ‘21 months after the date of enact-
ment of the Family Smoking Prevention and 
Tobacco Control Act’, shall be considered to be 
a reference to the later of—
“(i) ‘21 months after the date of enactment of the FDA Deeming Authority Clarification Act of 2017’; and
“(ii) ‘21 months after the effective date of such deeming regulation’.”.

SEC. 3. PRODUCT STANDARDS FOR VAPOR PRODUCT BATTERIES.

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

(b) PROMULGATION OF STANDARDS.—

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

(2) FINAL STANDARDS.—Not later than 24 months after the date of enactment of this Act, the
Secretary shall promulgate the vapor product battery standards required by this section.

(c) **Compliance With Final Standards.**—For any vapor product (including those products in test markets) that has a battery and is commercially marketed in the United States as of the date by which final standards are required to be promulgated under subsection (b)(2), the Secretary of Health and Human Services, based on any change to the battery for the purpose of conforming to such final standards, shall not—

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

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

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

**SEC. 4. Regulation of Vapor Products.**

(a) **In General.**—Chapter IX of the Federal Food, Drug, and Cosmetic Act is amended by inserting after section 920 of such Act (21 U.S.C. 387t) the following:
"SEC. 921. VAPOR PRODUCTS.

(a) Relation to Other Provisions.—The authorities vested in the Secretary by this section to regulate vapor products are in addition to, not in lieu of, the authorities vested in the Secretary by other sections of this Act to regulate vapor products as tobacco products.

(b) Advertising in Print Publications.—

(1) In General.—The manufacturer, distributor, or retailer of a vapor product shall not disseminate or cause to be disseminated advertising or labeling of the vapor product in a newspaper, magazine, periodical or other publication (whether periodic or limited distribution), other than an adult publication.

(2) Definition.—In this subsection, the term ‘adult publication’ means a newspaper, magazine, periodical, or other publication—

(A) whose readers younger than 18 years of age constitute 15 percent or less of the total readership as measured by competent and reliable survey evidence; and

(B) that is read by fewer than 2 million persons younger than 18 years of age as measured by competent and reliable survey evidence.

(c) Prohibit Self-service Displays of Vapor Products.—
“(1) In general.—A retailer may sell vapor products only in a direct face-to-face exchange.

“(2) Exception.—Paragraph (1) does not apply—

“(A) to mail order sales; or

“(B) to sales by means of a vending machine or self-service display that is located in a facility where the retailer ensures that no person under 18 years of age is present or permitted to enter at any time.

“(3) Civil penalty.—A violation of this subsection shall be subject to a civil penalty under section 303(f)(9) to the same extent and in the same manner as a violation of any requirement of this Act which relates to a tobacco product.

“(d) Labeling.—

“(1) In general.—Not later than 12 months after the date of enactment of the FDA Deeming Authority Clarification Act of 2017, the Secretary shall promulgate final regulations to require packages of vapor products to bear a label containing—

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

“(B) the phrase ‘Underage Sale Prohibited’; and
“(C) if the vapor product includes nicotine in a solution or other form at the time of sale, an accurate statement of the nicotine content.

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

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

“(1) REGISTRATION BY RETAILERS.—Every person who owns or operates an establishment in any State engaged in the retail sale of a vapor product shall register that establishment with the Secretary by the later of—

“(A) 60 days after the date of the enactment of the FDA Deeming Authority Clarification Act of 2017; and

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

“(2) EXCLUSION.—The requirements of this subsection do not apply with respect to any establishment subject to an active registration or retail license under—

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

“(B) section 905.
“(3) Public access to registration information.—The Secretary shall make available for inspection, to any person so requesting, any registration filed under this subsection.

“(f) Vapor product defined.—In this section:

“(1) In general.—The term ‘vapor product’—

“(A) means any noncombustible product that employs a heating element, power source, electronic circuit, or other electronic, chemical, or mechanical means, regardless of shape or size, to produce vapor from nicotine in a solution or other form; and

“(B) includes—

“(i) any electronic cigarette, electronic cigar, electronic cigarillo, electronic pipe, or similar product or device that is intended to produce vapor from nicotine in a solution of other form; and

“(ii) nicotine in a solution or other form, whether in a cartridge or container or otherwise dispensed, that is intended to be used with or in a product described in clause (i).
“(2) EXCLUSION.—The term ‘vapor product’ does not include any product regulated as a drug or device under chapter V.”.

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

“(eee) The disseminating or causing to be disseminated, by a manufacturer, distributor, or retailer of a vapor product, advertising or labeling of the vapor product in violation of section 921(b).

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