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116TH CONGRESS
1ST SESSION

H. R. 5005

To amend the Federal Food, Drug, and Cosmetic Act to require a recall of electronic nicotine delivery systems that have not been subject to premarket review, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 8, 2019

Mr. DESAULNIER introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to require a recall of electronic nicotine delivery systems that have not been subject to premarket review, and for other purposes.

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 ''Preventing Vape Use Act''.

SEC. 2. INCLUSION OF ENDS IN DEFINITION OF TOBACCO PRODUCT.

(a) CONFIRMATION OF INCLUSION OF ENDS IN DEFINITION OF TOBACCO PRODUCT.—Section 201(rr)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(rr)(1)) is amended by adding at the end the following: ''Such term includes an electronic nicotine delivery system.''.

(b) ENDS DEFINED.—Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended by adding at the end the following:

''(ss) The term 'electronic nicotine delivery system' means a tobacco product that is an electronic device that delivers nicotine, flavor, or another substance via an aerosolized solution to the user inhaling from the device (including e-cigarettes, e-hookah, e-cigars, vape pens, advanced refillable personal vaporizers, and electronic pipes) and any component, liquid, part, or accessory of such a device, whether or not sold separately.''.

SEC. 3. MANDATORY RECALL OF ENDS PENDING PREMARKET REVIEW.

Section 908(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387h(c)) is amended by adding at the end the following:

''(4) MANDATORY RECALL OF ENDS PENDING PREMARKET REVIEW.—

''(A) ISSUANCE OF ORDER.—Notwithstanding paragraphs (1) and (2), in the case of a tobacco product that is an electronic nicotine delivery system with respect to which, as of the date of the enactment of this subparagraph, an order under section 910(c)(1)(A)(i) has not been issued, the Secretary shall, not later than 60 days after such date of enactment, issue an order requiring—

''(i) the appropriate person (including the manufacturers, importers, distributors, or retailers of the tobacco product) to immediately cease distribution of such tobacco product; and

''(ii) the recall of such tobacco product.

''(B) HEARING.—The order under subparagraph (A) shall provide the person subject to the order with an opportunity for an informal hearing, to be held not later than 10 days after the date of the issuance of the order, on the actions required by the order and the terms of the recall required by such order.

''(C) CONTENTS OF ORDER.—An order issued under subparagraph (A) shall specify a

timetable in which the tobacco product recall will occur and shall require periodic reports to the Secretary describing the progress of the recall.

''(D) NOTICE.—An order under subparagraph (A)—

''(i) shall not include recall of a tobacco product from individuals; and

''(ii) shall provide for notice to persons subject to the risks associated with the use of such tobacco product.

''(E) ASSISTANCE ALLOWED.—In providing the notice required by subparagraph (D)(ii), the Secretary may use the assistance of retailers and other persons who distributed such tobacco product. If a significant number of such persons cannot be identified, the Secretary shall notify such persons under section 705(b).

''(F) WITHDRAWAL OF ORDER.—The Secretary may only withdraw an order issued under subparagraph (A) with respect to a tobacco product described in such subparagraph upon the issuance of an order section 910(c)(1)(A)(i) with respect to that product.''.

SEC. 4. NO EXEMPTIONS ALLOWED FOR ENDS.

Section 910(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387j(a)) is amended—

(1) in paragraph (2), by adding at the end the following:

''(C) APPLICATION TO ENDS.—Notwithstanding clauses (i) and (ii) of subparagraphs (A) and (B), beginning on the date that is 60 days after the date of the enactment of this subparagraph—

''(i) electronic nicotine delivery systems are deemed to be not substantially equivalent to any predicate tobacco product; and

''(ii) the requirement for premarket review under subparagraph (A) shall apply to a tobacco product that is an electronic nicotine delivery system.''; and

(2) in paragraph (3)(C)—

(A) by striking ''equivalent to a predicate'' and inserting the following: ''equivalent—

''(A) to a predicate'';

(B) by striking ''adulterated.'' and inserting ''adulterated; or''; and

(C) by adding at the end the following:

"(B) beginning on the date that is 60 days after the date of the enactment of this subparagraph, if the tobacco product is an electronic nicotine delivery system.".

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