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(Original Signature of Member)

115TH CONGRESS
2D SESSION

H. R. _____

To amend the Federal Food, Drug, and Cosmetic Act to require improved packaging and disposal methods with respect to certain drugs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

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

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to require improved packaging and disposal methods with respect to certain drugs, 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. IMPROVED TECHNOLOGIES, CONTROLS, OR MEASURES WITH RESPECT TO THE PACKAGING OR DISPOSAL OF CERTAIN DRUGS.

(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act is amended by inserting after section 505–1 (21 U.S.C. 355–1) the following new section:

"SEC. 505–2. SAFETY-ENHANCING PACKAGING AND DISPOSAL FEATURES.

"(a) IN GENERAL.—The Secretary may issue an order requiring the holder of a covered application to implement or modify technologies, controls, or measures with respect to the packaging or disposal of one or more drugs identified in the covered application, if the Secretary determines such technologies, controls, or measures to be appropriate to help mitigate the risk of abuse or misuse of such drug or drugs.

"(b) COMPLIANCE.—The holder of a covered application shall—

"(1) submit a supplement proposing changes to the covered application to comply with an order issued under subsection (a) not later than 180 days after the date on which the order is issued, or such longer time period as determined to be appropriate by the Secretary; and

"(2) implement the changes approved in a supplement described in paragraph (1) not later than 90 days after the date on which the supplement is approved, or such longer time period as determined to be appropriate by the Secretary.

"(c) ORDER CONTENTS.—The requirements in an order under subsection (a) may include a requirement—

''(1) to make one or more drugs approved in the covered application available in unit dose packaging or another packaging configuration that meets standards determined to be appropriate by the Secretary;

''(2) to make available, for one or more drugs approved in the covered application, a disposal system for such a drug that meets standards determined to be appropriate by Secretary; or

''(3) to implement other technologies, controls, or measures that meet standards determined to be appropriate by the Secretary with respect to packaging or disposal for one or more drugs approved in the covered application.

''(d) OFFICIAL COMPENDIUM STANDARDS.—An order issued under subsection (a) may incorporate by reference the standards set forth in an official compendium or described on the public Internet website of the Food and Drug Administration.

''(e) COVERED APPLICATION.—In this section, the term 'covered application' means an application submitted under subsection (b) or (j) of section 505 for approval under such section or an application approved under section 351 of Public Health Service Act, with respect to a drug that is or contains a controlled substance for which

a listing in any schedule is in effect (on a temporary or permanent basis) under section 201 of the Controlled Substances Act.''.

(b) PROHIBITED ACTS.—Section 501 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351) is amended by inserting after paragraph (j) the following:

''(k) If it is a drug approved under a covered application (as defined in section 505–2(e)), the holder of which does not meet the requirements of paragraphs (1) and (2) of subsection (b) of such section.''.

(c) REQUIRED CONTENT OF AN ABBREVIATED NEW DRUG APPLICATION.—Section 505(j)(2)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(2)(A)) is amended—

(1) in clause (vii)(IV), by striking ''and'' at the end;

(2) in clause (viii, by striking the period at the end and inserting ''; and''; and

(3) by adding at the end the following:

''(ix) if the drug is or contains a controlled substance for which a listing in any schedule is in effect (on a temporary or permanent basis) under section 201 of the Controlled Substances Act, information to show that the applicant has proposed tech-

nologies, controls, or measures related to the packaging or disposal of the drug that the Secretary determines are expected to be at least as effective as those required for the applicable listed drug under 505–2, if applicable.''.

(d) GROUNDS FOR REFUSING TO APPROVE AN ABBREVIATED NEW DRUG APPLICATION.—Section 505(j)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(4), is amended—

(1) in subparagraph (J), by striking ''or'' at the end;

(2) in subparagraph (K), by striking the period at the end and inserting ''; or''; and

(3) by adding at the end the following:

''(L) if the drug is a drug described in paragraph (2)(A)(ix) and the applicant has not proposed technologies, controls, or measures related to the packaging or disposal of the drug described in such paragraph.''.

(e) RULE OF CONSTRUCTION.—Any change in labeling of a drug that is subject to an abbreviated new drug application that describes product modifications resulting from the application of section 505–2 of the Federal Food,

Drug, and Cosmetic Act, as added by subsection (a), shall not be construed—

(1) as changes to labeling not permissible under clause (v) of section 505(j)(2)(A) of such Act (21 U.S.C. 355(j)(2)(A)), or a change in the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug under clause (i) of such section; or

(2) to prohibit approval of an abbreviated new drug application under subparagraph (B) or (G) of section 505(j)(4) of such Act (21 U.S.C. 355(j)(4)).

(f) GAO REPORT.—Not later than 12 months after the date of enactment of this Act, the Comptroller General of the United States shall prepare and submit to the Congress a report containing—

(1) a description of available evidence, if any, on the effectiveness of controlled substance disposal products;

(2) identification of ways in which such disposal products are made available to the public and barriers to the use of such disposal products;

(3) a description of Federal oversight, if any, of controlled substance disposal products, including—

(A) identification of the Federal agencies that oversee such products;

(B) identification of the methods of disposal of controlled substances recommended by these agencies, including site-of-use, in-home disposal; and

(C) a description of the effectiveness of such recommendations at preventing the diversion of legally prescribed controlled substances; and

(4) recommendations on—

(A) whether controlled substance disposal products require Federal oversight and, if so, which agencies should be responsible for such oversight and, as applicable, approval of such products; and

(B) the potential role of the Federal Government in evaluating such products to ensure product efficacy.