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112TH CONGRESS
2D SESSION

H. R. 6160

To amend the Federal Food, Drug, and Cosmetic Act to incentivize the development of tamper-resistant drugs.

IN THE HOUSE OF REPRESENTATIVES

JULY 19, 2012

Mr. KEATING (for himself, Mrs. BONO MACK, Mr. ROGERS of Kentucky, Mr. LYNCH, Mr. RAHALL, Mr. TOWNS, and Mr. TIERNEY) 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 incentivize the development of tamper-resistant drugs.

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 ''Stop Tampering of Prescription Pills Act of 2012''.

SEC. 2. TAMPER-RESISTANT TECHNOLOGY.

(a) DEFINITION.—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 'tamper-resistant drug' means a drug that—

''(1) contains as an active moiety a controlled substance that has been classified as opium, an opiate, or a derivative thereof, as such terms are defined or used in section 102 of the Controlled Substances Act;

''(2) has been formulated for oral administration; and

''(3)(A) exhibits physicochemical properties (demonstrated by in vitro, in vivo, or other testing, or some combination thereof, as determined appropriate by the Secretary) that make product manipulation significantly more difficult or ineffective in altering the characteristics of the drug for purposes of misuse or abuse when compared to drugs without such properties; or

''(B) contains one or more additional active or inactive ingredients that are intended to deter abuse through potential pharmacological effects, the effectiveness of which has been demonstrated by at least one adequate and well-controlled investigation.''.

(b) REQUIRED INFORMATION IN APPLICATION FOR APPROVAL OF BRAND NAME DRUGS.—Section 505(b) of

the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) is amended by adding at the end the following:

''(7) TAMPER-RESISTANT DRUGS.—If an application submitted under this subsection is potentially subject to refusal under subsection (d)(7), the application shall include such information as the Secretary determines necessary to demonstrate that the application is not subject to such refusal.''.

(c) APPROVAL OF NEW BRAND NAME DRUGS.—Section 505(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(d)) is amended—

(1) by inserting ''(7)(A) such drug has been formulated for oral administration; (B) such drug contains as an active moiety a controlled substance that has been classified as opium, an opiate, or a derivative thereof, as such terms are defined or used in section 102 of the Controlled Substances Act; (C) such drug is not a tamper-resistant drug; and (D) the Secretary has previously approved pursuant to an application submitted under subsection (b) or (j) a drug that (i) contains the same active moiety; (ii) is a tamper-resistant drug, and (iii) has not been discontinued from marketing; or'' after ''(6) the application failed to contain the patent information prescribed by subsection (b); or'';

(2) by striking ''(7) based on fair'' and inserting ''(8) based on fair'';

(3) by striking ''clauses (1) through (6)'' and inserting ''paragraphs (1) through (7)''; and

(4) by inserting ''The Secretary may issue an order approving an application, even if paragraph (7) applies, upon a finding that paragraphs (1) through (6) and paragraph (8) do not apply and that such approval is necessary either to prevent or alleviate a drug shortage or to otherwise address a significant unmet public health need.'' before ''As used in this subsection and subsection (e)''.

(d) GENERIC DRUGS.—Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) is amended—

(1) in paragraph (2)—

(A) subparagraph (A)—

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

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

(iii) by inserting after clause (viii) the following:

''(ix) if the listed drug is a tamper-resistant drug due to its physicochemical properties, informa-

tion from comparative in vitro, in vivo, or other testing, or some combination thereof, as appropriate based on the type of data submitted for the listed drug, that demonstrates the new drug resists manipulation or the effect of manipulation to a degree at least comparable to the listed drug.''; and

(iv) in the continuation text at the end of the subparagraph, by striking ''clauses (i) through (viii)'' and inserting ''clauses (i) through (ix)'';

(B) in subparagraph (C)—

(i) in clause (i), by striking ''or'' at the end;

(ii) in clause (ii), by striking the period at the end and inserting ''; or''; and

(iii) by adding at the end the following:

''(iii) that the listed drug is a tamper-resistant drug and one or more of the new drug's active moieties differ in any material respect (in amount or otherwise) from those of the listed drug.'';

(2) in paragraph (5), by adding at the end the following:

''(G) If a drug has been approved pursuant to an application submitted under paragraph (2), and thereafter

the listed drug referred to in the application becomes a tamper-resistant drug, the drug so approved shall not be considered to be bioequivalent to, or to have the same therapeutic effect as, the listed drug (as described in paragraph (2)(A)(iv)) unless and until the drug so approved has been found by the Secretary to meet the requirements of paragraph (2)(A)(ix).''; and

(3) in paragraph (6)—

(A) by striking ''(6) If a drug'' and inserting ''(6)(A) If a drug'';

(B) by striking ''(A) for the'' and inserting ''(i) for the'';

(C) by striking ''(B) if the'' and inserting ''(ii) if the''; and

(D) by adding at the end the following:

''(B) For purposes of this paragraph and paragraph (7)(C), a withdrawal or suspension of a drug formulated for oral administration shall be considered to have been for safety or effectiveness reasons if—

''(i) the approval of a listed drug, which is not a tamper-resistant drug, is withdrawn or suspended, or a listed drug, which is not a tamper-resistant drug, is withdrawn from sale; and

''(ii) the Secretary has previously approved pursuant to an application under subsection (b) a drug that—

''(I) is in the same dosage form;

''(II) contains the same controlled substance as an active moiety;

''(III) is a tamper-resistant drug; and

''(IV) has not been discontinued from marketing.''.

(e) WITHDRAWAL OF PREVIOUSLY APPROVED BRAND NAME AND GENERIC DRUGS.—Section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) is amended—

(1) by inserting ''or (6)(A) the drug contains as an active moiety a controlled substance that has been classified as opium, an opiate, or a derivative thereof, as such terms are defined or used in section 102 of the Controlled Substances Act; (B) the drug is formulated for oral administration; (C) the drug is not a tamper-resistant drug; and (D) the Secretary has previously approved pursuant to an application submitted under subsection (b) or (j) a drug that contains the same active moiety, is a tamper-resistant drug, and has not been discontinued from marketing'' before '': *Provided,*''; and

(2) by adding at the end the following: ''The Secretary may waive the application of paragraph (6) of the first sentence of this subsection in the case of a drug intended for use in a special needs population. In withdrawing (under paragraph (6) of the first sentence of this subsection) the approval of an application with respect to any drug, the Secretary shall, on a case-by-case basis, delay the effective date of such withdrawal for a period deemed sufficient by the Secretary to give the sponsor an opportunity to obtain approval under this section for a formulation of the drug meeting the criteria described in paragraph (2) of the definition of a 'tamper-resistant drug' in section 201(ss).''.

(f) LISTED DRUGS.—Section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)) is amended by adding at the end the following:

''(D) Beginning 60 days after the date of the enactment of the Stop Tampering of Prescription Pills Act of 2012, the Secretary shall—

''(i) include in the list under subparagraph (A) a list of each drug or category of drugs which the Secretary has found to be tamper-resistant drugs; and

''(ii) update the list under subparagraph (A)—

"(I) to remove from the list of tamper-resistant drugs any drug the Secretary later determines is not a tamper-resistant drug; and

"(II) as required by subparagraph (C) to reflect the application of paragraph (6)(B) to drugs that are withdrawn or suspended.".

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