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115TH CONGRESS
1ST SESSION

H. R. 2025

To amend section 505(c)(3)(E) of the Federal Food, Drug, and Cosmetic Act to prevent certain applications from being considered ineligible for approval under section 505(c) of such Act on the basis that the proposed labeling includes information describing abuse-deterrent properties that otherwise would be blocked by exclusivity under clause (iii) or (iv) of section 503(c)(3)(E) of such Act, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

APRIL 6, 2017

Mr. GRIFFITH (for himself and Mr. COSTELLO of Pennsylvania) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend section 505(c)(3)(E) of the Federal Food, Drug, and Cosmetic Act to prevent certain applications from being considered ineligible for approval under section 505(c) of such Act on the basis that the proposed labeling includes information describing abuse-deterrent properties that otherwise would be blocked by exclusivity under clause (iii) or (iv) of section 503(c)(3)(E) of such Act, 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 ''Abuse-Deterrent Opioids Plan for Tomorrow Act of 2017''.

SEC. 2. LABELING INFORMATION DESCRIBING ABUSE-DETERRENT PROPERTIES.

(a) IN GENERAL.—Subparagraph (E) of section 505(c)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)(3)) is amended by adding at the end the following new clause:

''(vi) A drug for which an application (or a supplement to an application) described in subsection (b)(2) is submitted shall not be considered ineligible for approval under this subsection on the basis that its labeling includes information describing the abuse-deterrent properties of the drug (including abuse-deterrent claims) that otherwise would be blocked by exclusivity under clause (iii) or (iv) of this subparagraph if—

''(I) the investigation or investigations relied upon by the applicant for approval of the labeling information were conducted by or for the applicant or the applicant has obtained a right of reference or use from the person by or for whom the investigation or investigations were conducted; and

"(II) the drug has meaningful technological differences compared to the drug otherwise protected by exclusivity under clause (iii) or (iv) of this subparagraph.".

(b) GUIDANCE.—The Secretary of Health and Human Services shall—

(1) not later than 18 months after the date of enactment of this Act, issue draft guidance regarding the award and scope of exclusivity under clauses (iii) and (iv) of section 505(c)(3)(E) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)(3)(E)) for drugs with properties designed to deter abuse and the exception to such exclusivity described in clause (vi) of such section 505(c)(3)(E), as added by subsection (a); and

(2) not later than 18 months after the close of the period for receiving public comments on such draft guidance, publish final guidance on the topics described in paragraph (1).

(c) EFFECTIVE DATE.—The amendment made by subsection (a) applies with respect to applications, and supplements to applications, that are submitted or pending under section 505(b) of the Federal Food, Drug, and

Cosmetic Act (21 U.S.C. 355(b)) on or after January 1, 2017.

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