

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

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Abuse-Deterrent
3 Opioids Plan for Tomorrow Act of 2017”.

4 **SEC. 2. LABELING INFORMATION DESCRIBING ABUSE-DE-**
5 **TERRENT PROPERTIES.**

6 (a) IN GENERAL.—Subparagraph (E) of section
7 505(c)(3) of the Federal Food, Drug, and Cosmetic Act
8 (21 U.S.C. 355(c)(3)) is amended by adding at the end
9 the following new clause:

10 “(vi) A drug for which an application (or a sup-
11 plement to an application) described in subsection
12 (b)(2) is submitted shall not be considered ineligible
13 for approval under this subsection on the basis that
14 its labeling includes information describing the
15 abuse-deterrent properties of the drug (including
16 abuse-deterrent claims) that otherwise would be
17 blocked by exclusivity under clause (iii) or (iv) of
18 this subparagraph if—

19 “(I) the investigation or investigations re-
20 lied upon by the applicant for approval of the
21 labeling information were conducted by or for
22 the applicant or the applicant has obtained a
23 right of reference or use from the person by or
24 for whom the investigation or investigations
25 were conducted; and

1 “(II) the drug has meaningful techno-
2 logical differences compared to the drug other-
3 wise protected by exclusivity under clause (iii)
4 or (iv) of this subparagraph.”.

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

7 (1) not later than 18 months after the date of
8 enactment of this Act, issue draft guidance regard-
9 ing the award and scope of exclusivity under clauses
10 (iii) and (iv) of section 505(c)(3)(E) of the Federal
11 Food, Drug, and Cosmetic Act (21 U.S.C.
12 355(c)(3)(E)) for drugs with properties designed to
13 deter abuse and the exception to such exclusivity de-
14 scribed in clause (vi) of such section 505(c)(3)(E),
15 as added by subsection (a); and

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18 draft guidance, publish final guidance on the topics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

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

1 Cosmetic Act (21 U.S.C. 355(b)) on or after January 1,
2 2017.

