

114TH CONGRESS  
2D SESSION

# H. R. 5127

To amend the Federal Food, Drug, and Cosmetic Act to extend the exclusivity period for certain drug products developed or labeled so as to reduce drug abuse, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

APRIL 29, 2016

Mr. GRIFFITH (for himself, Mr. CONNOLLY, and Mr. BILIRAKIS) 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 extend the exclusivity period for certain drug products developed or labeled so as to reduce drug abuse, 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,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Curb Opioid Misuse  
5 By Advancing Technology Act of 2016”.

1 **SEC. 2. EXTENDED EXCLUSIVITY FOR CERTAIN DRUG**  
2 **PRODUCTS TO PROTECT THE PUBLIC**  
3 **HEALTH.**

4 (a) NEW DRUG APPLICATIONS.—Section  
5 505(c)(3)(E) of the Federal Food, Drug, and Cosmetic  
6 Act (21 U.S.C. 355(c)(3)(E)) is amended by adding at  
7 the end the following:

8 “(vi) With respect to an application  
9 described in clause (iii) or a supplement to  
10 an application described in clause (iv), if  
11 such application or supplement is approved  
12 on or after the date of enactment of the  
13 Curb Opioid Misuse By Advancing Tech-  
14 nology Act of 2016, the 3-year period spec-  
15 ified in each such clause shall be extended  
16 for an additional period of 12 months if  
17 the person submitting such application or  
18 supplement provides documentation to the  
19 Secretary demonstrating that the drug  
20 that is the subject of the application or  
21 supplement—

22 “(I) is approved, in whole or in  
23 part, on the basis of one or more new  
24 clinical abuse potential studies; and

1 “(II) is approved with labeling  
2 that characterizes the abuse-deterrent  
3 properties of the drug product.”.

4 (b) ABBREVIATED NEW DRUG APPLICATIONS.—Sec-  
5 tion 505(j)(5) of the Federal Food, Drug, and Cosmetic  
6 Act (21 U.S.C. 355(j)(5)) is amended—

7 (1) in subparagraph (B), by adding at the end  
8 the following:

9 “(v) With respect to an abbreviated  
10 application described in clause (iv), if such  
11 application is approved on or after the date  
12 of enactment of the Curb Opioid Misuse  
13 By Advancing Technology Act of 2016, the  
14 180-day period specified in such clause  
15 shall be extended for an additional period  
16 of 60 days if the first applicant submitting  
17 the abbreviated application provides docu-  
18 mentation to the Secretary demonstrating  
19 that the listed drug referred to paragraph  
20 (2)(A)(i) and referenced in the abbreviated  
21 application—

22 “(I) is approved, in whole or in  
23 part, on the basis of one or more new  
24 clinical abuse potential studies; and

1 “(II) is approved with labeling  
2 that characterizes the abuse-deterrent  
3 properties of the drug product.”; and  
4 (2) in subparagraph (F), by adding at the end  
5 the following:

6 “(vi) With respect to an application  
7 described in clause (iii) or a supplement to  
8 an application described in clause (iv), if  
9 such application or supplement is approved  
10 on or after the date of enactment of the  
11 Curb Opioid Misuse By Advancing Tech-  
12 nology Act of 2016, the 3-year period spec-  
13 ified in each such clause shall be extended  
14 for an additional period of 12 months if  
15 the person submitting such application or  
16 supplement provides documentation to the  
17 Secretary demonstrating that the drug  
18 that is the subject of the application or  
19 supplement—

20 “(I) is approved, in whole or in  
21 part, on the basis of one or more new  
22 clinical abuse potential studies; and

23 “(II) is approved with labeling  
24 that characterizes the abuse-deterrent  
25 properties of that drug product.”.

1 (c) REGULATIONS.—

2 (1) IN GENERAL.—Not later than 2 years after  
3 the date of the enactment of this Act, the Secretary  
4 of Health and Human Services (referred to in this  
5 section as “the Secretary”) shall adopt final regula-  
6 tions, which shall have been promulgated in accord-  
7 ance with section 553 of title 5, United States Code,  
8 to carry out the amendments made by this section.

9 (2) RESTRICTIONS.—Notwithstanding any other  
10 provision of law, the Secretary shall promulgate reg-  
11 ulations implementing this section only as described  
12 in paragraph (1), except that the Secretary may  
13 issue interim guidance for persons claiming eligi-  
14 bility for the extension provided by clause (vi) of  
15 subsection (c)(3)(E) or (j)(5)(F) of section 505 of  
16 the Federal Food, Drug, and Cosmetic Act (as  
17 added by subsections (a) and (b)) prior to the pro-  
18 mulgation of such regulations.

19 (3) EXCLUSIVITY PRIOR TO REGULATIONS.—  
20 The Secretary shall award the extensions provided  
21 by clause (vi) of subsection (c)(3)(E) or (j)(5)(F)  
22 and by clause (v) of subsection (j)(5)(B) of section  
23 505 of the Federal Food, Drug, and Cosmetic Act  
24 (as added by subsections (a) and (b)) prior to the  
25 promulgation of regulations under this subsection, if

1 an application, supplement, or abbreviated applica-  
2 tion meets the requirements for the applicable exten-  
3 sion.

4 (d) DEFINITIONS.—

5 (1) The term “new clinical investigations” in  
6 subsections (c)(3)(E)(iii), (c)(3)(E)(iv),  
7 (j)(5)(F)(iii), and (j)(5)(F)(iv) of section 505 of the  
8 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
9 355) shall include new clinical abuse potential stud-  
10 ies intended to assess the impact of potentially  
11 abuse-deterrent properties of drug products in  
12 human subjects.

13 (2) The terms “conditions of approval” and  
14 “change approved in the supplement” in subsections  
15 (c)(3)(E)(iii) and (c)(3)(E)(iv) of section 505 of the  
16 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
17 355) shall include any abuse-deterrent properties of  
18 a drug product subject to the extension provided by  
19 subsection (c)(3)(E)(vi) of such section 505 (as  
20 added by subsection (a)), such that the Secretary  
21 may not make the approval of an application sub-  
22 mitted under subsection (b)(2) of such section 505  
23 effective before the expiration of 4 years from the  
24 date of the approval of the application or supple-  
25 ment under subsection (b) of such section 505, in-

cluding the extension under subsection (c)(3)(E)(vi) of such section 505, unless the application submitted under subsection (b)(2) of such section 505—

(A) is approved, in whole or in part, on the basis of one or more new clinical abuse potential studies; and

(B) is approved with labeling that characterizes the abuse-deterrent properties of the drug product.

(3) The terms “conditions of approval” and “change approved in the supplement” in subsections (j)(5)(F)(iii) and (j)(5)(F)(iv) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) shall include any abuse-deterrent properties of a drug product subject to the extension provided by subsection (j)(5)(F)(vi) of such section 505 (as added by subsection (b)), such that the Secretary may not make the approval of an abbreviated application for a drug product submitted under subsection (j) of such section 505 effective before the expiration of 4 years from the date of the approval of the application or supplement under subsection (b) of such section 505, including the extension under subsection (j)(5)(F)(vi) of such section 505.

1       (e) RELATION TO OTHER EXCLUSIVITY PERIODS.—  
2 Any extension under clause (vi) in subsection (c)(3)(E) or  
3 (j)(5)(F) of section 505 of the Federal Food, Drug, and  
4 Cosmetic Act (21 U.S.C. 355) (as added by subsections  
5 (a) and (b)) shall be in addition to any extensions under  
6 section 505A or 505E of the Federal Food, Drug, and  
7 Cosmetic Act (21 U.S.C. 355a; 21 U.S.C. 355f) with re-  
8 spect to the drug.

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