

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.

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

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-

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

4 (A) is approved, in whole or in part, on the
5 basis of one or more new clinical abuse poten-
6 tial studies; and

7 (B) is approved with labeling that charac-
8 terizes the abuse-deterrent properties of the
9 drug product.

10 (3) The terms “conditions of approval” and
11 “change approved in the supplement” in subsections
12 (j)(5)(F)(iii) and (j)(5)(F)(iv) of section 505 of the
13 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
14 355) shall include any abuse-deterrent properties of
15 a drug product subject to the extension provided by
16 subsection (j)(5)(F)(vi) of such section 505 (as
17 added by subsection (b)), such that the Secretary
18 may not make the approval of an abbreviated appli-
19 cation for a drug product submitted under sub-
20 section (j) of such section 505 effective before the
21 expiration of 4 years from the date of the approval
22 of the application or supplement under subsection
23 (b) of such section 505, including the extension
24 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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