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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

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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.

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 ''Curb Opioid Misuse By Advancing Technology Act of 2016''.

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

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

''(vi) With respect to an application described in clause (iii) or a supplement to an application described in clause (iv), if such application or supplement is approved on or after the date of enactment of the Curb Opioid Misuse By Advancing Technology Act of 2016, the 3-year period specified in each such clause shall be extended for an additional period of 12 months if the person submitting such application or supplement provides documentation to the Secretary demonstrating that the drug that is the subject of the application or supplement—

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

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

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

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

"(v) With respect to an abbreviated application described in clause (iv), if such application is approved on or after the date of enactment of the Curb Opioid Misuse By Advancing Technology Act of 2016, the 180-day period specified in such clause shall be extended for an additional period of 60 days if the first applicant submitting the abbreviated application provides documentation to the Secretary demonstrating that the listed drug referred to paragraph (2)(A)(i) and referenced in the abbreviated application—

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

''(II) is approved with labeling that characterizes the abuse-deterrent properties of the drug product.''; and

(2) in subparagraph (F), by adding at the end the following:

''(vi) With respect to an application described in clause (iii) or a supplement to an application described in clause (iv), if such application or supplement is approved on or after the date of enactment of the Curb Opioid Misuse By Advancing Technology Act of 2016, the 3-year period specified in each such clause shall be extended for an additional period of 12 months if the person submitting such application or supplement provides documentation to the Secretary demonstrating that the drug that is the subject of the application or supplement—

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

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

(c) REGULATIONS.—

(1) IN GENERAL.—Not later than 2 years after the date of the enactment of this Act, the Secretary of Health and Human Services (referred to in this section as ''the Secretary'') shall adopt final regulations, which shall have been promulgated in accordance with section 553 of title 5, United States Code, to carry out the amendments made by this section.

(2) RESTRICTIONS.—Notwithstanding any other provision of law, the Secretary shall promulgate regulations implementing this section only as described in paragraph (1), except that the Secretary may issue interim guidance for persons claiming eligibility for the extension provided by clause (vi) of subsection (c)(3)(E) or (j)(5)(F) of section 505 of the Federal Food, Drug, and Cosmetic Act (as added by subsections (a) and (b)) prior to the promulgation of such regulations.

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

an application, supplement, or abbreviated application meets the requirements for the applicable extension.

(d) DEFINITIONS.—

(1) The term ''new clinical investigations'' in subsections (c)(3)(E)(iii), (c)(3)(E)(iv), (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 new clinical abuse potential studies intended to assess the impact of potentially abuse-deterrent properties of drug products in human subjects.

(2) The terms ''conditions of approval'' and ''change approved in the supplement'' in subsections (c)(3)(E)(iii) and (c)(3)(E)(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 (c)(3)(E)(vi) of such section 505 (as added by subsection (a)), such that the Secretary may not make the approval of an application submitted under subsection (b)(2) 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, 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.

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

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