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116TH CONGRESS
1ST SESSION

H. R. 3812

To amend the Federal Food, Drug, and Cosmetic Act with respect to approval of abbreviated new drug applications.

IN THE HOUSE OF REPRESENTATIVES

JULY 17, 2019

Mr. MCKINLEY (for himself and Mr. WELCH) 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 with respect to approval of abbreviated new drug applications.

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 ''Reforming Evergreening and Manipulation that Extends Drug Years Act'' or the ''REMEDY Act''.

SEC. 2. AMENDMENTS TO ANDA APPROVAL PROVISION.

(a) IN GENERAL.—Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended—

(1) in subsection (c)(3)(C), by inserting ''in the case of a certification with respect to a patent that claims a drug substance (and not in the case of a certification with respect to a patent that claims a drug product or method of use for a drug, except that, in the case of a patent that claims a drug substance and a drug product or method of use, this subparagraph shall apply, but only to the extent the patent claims a drug substance),'' after ''immediately unless,''; and

(2) in subsection (j)(5)(B)(iii), by inserting ''in the case of a certification with respect to a patent that claims a drug substance (and not in the case of a certification with respect to a patent that claims a drug product or method of use for a drug, except that, in the case of a patent that claims a drug substance and a drug product or method of use, this clause shall apply, but only to the extent the patent claims a drug substance),'' after ''immediately unless,''.

(b) ORANGE BOOK UPDATES WITH RESPECT TO INVALIDATED PATENTS.—

(1) IN GENERAL.—Section 505(j)(7)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.

355(j)(7)(A)) is amended by adding at the end the following:

''(iv) In the case of a listed drug for which the list under clause (i) includes a patent that claims the drug or a use for such drug, and where the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office has cancelled any claim of the patent relating to such drug or such use pursuant to a determination by the Patent Trial and Appeal Board in an inter partes review conducted under chapter 31 of title 35, United States Code, or a post-grant review conducted under chapter 32 of that title, and any such cancellation, if appealed, has been upheld upon appeal, the holder of the applicable approved application shall notify the Secretary of such cancellation, and the revisions required under clause (iii) shall include striking the patent from the list with respect to such drug.''.

(2) NO EFFECT ON FIRST APPLICANT EXCLUSIVITY PERIOD.—Section 505(j)(5)(B)(iv)(I) is amended by adding at the end the following: ''This subclause shall apply even if a patent is stricken from the list under paragraph (7)(A), pursuant to the second sentence of clause (iii) of such paragraph,

provided that, at the time that the first applicant submitted an application under this subsection containing a certification described in paragraph (2)(A)(vii)(IV), the patent that was the subject of such certification was included in such list with respect to the listed drug.''.

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