I

116TH CONGRESS
1ST SESSION

H. R. 1503

To amend the Federal Food, Drug, and Cosmetic Act regarding the list under section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 5, 2019

Ms. KELLY of Illinois 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 regarding the list under section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act, 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 ''Orange Book Transparency Act of 2019''.

SEC. 2. ORANGE BOOK.

(a) PATENTS.—Clause (iii) of section 505(j)(7)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)) is amended to read as follows:

''(iii)(I) When patent information submitted under subsection (b) or (c) respecting a drug included on the list is to be published by the Secretary, the Secretary shall, in revisions made under clause (ii), include such information for such drug.

''(II) The Secretary—

''(aa) shall include on the list, from such patent information respecting a drug, drug substance (including active ingredient) patents, drug product (including formulation and composition) patents, and method of use patents; and

''(bb) may choose to include on the list additional patent information respecting the drug.

''(III) The Secretary shall not include on the list any patent to the extent such patent claims a device that is used for the delivery of the drug. Notwithstanding the preceding sentence, the Secretary may require (under other applicable provisions of law) the holder of the approved application for a drug to submit, for purposes other than the list under this paragraph, patent information respecting a device that is used for the delivery of the drug.''.

(b) LISTING OF EXCLUSIVITIES.—Subparagraph (A) of section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)) is amended by adding at the end the following:

''(iv) For each drug included on the list, the Secretary shall specify each exclusivity period that is applicable and has not concluded under—

''(I) clause (iii) or (iv) of subsection (c)(3)(E) of this section;

''(II) clause (iv) or (v) of paragraph (5)(B) of this subsection;

''(III) clause (iii) or (iv) of paragraph (5)(F) of this subsection;

''(IV) section 505A;

''(V) section 505E; or

''(VI) section 527(a).''.

(c) REMOVAL OF INVALID PATENTS.—

(1) IN GENERAL.—Section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)) is amended by adding at the end the following:

''(D)(i) The holder of an application approved under subsection (c) for a drug on the list shall promptly notify the Secretary in writing if either of the following occurs:

''(I) The Patent Trial and Appeals Board issues a decision that a patent for such drug is invalid.

''(II) A court issues a decision from which no appeal may be taken that a patent for such drug is invalid.

''(ii) The holder of an approved application shall include in any notification under clause (i) a copy of the decision described in subclause (I) or (II) of clause (i).

''(iii) The Secretary shall remove from the list any patent that is determined to be invalid in a decision described in subclause (I) or (II) of clause (i)—

''(I) promptly; but

''(II) not before the expiration of any 180-day exclusivity period under clause (iv) or (v) of paragraph (5)(B) that relies on a certification described in paragraph (2)(A)(vii)(IV) that such patent was invalid.''.

(2) APPLICABILITY.—Subparagraph (D) of section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), as added by paragraph (1), applies only with respect to a decision described in such subparagraph that is issued on or after the date of enactment of this Act.

(d) REVIEW AND REPORT.—Not later than one year after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall—

(1) review the types of patent information that should be included on the list under section

507(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)); and

(2) report to the Congress on the results of such review, including any recommendations about the types of patent information that should be included on or removed from such list.

○