Committee Print

[SHOWING THE TEXT OF H.R. 1503 AS FAVORABLY FORWARDED BY THE SUBCOMMITTEE ON HEALTH ON MARCH 27, 2019]

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

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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) SUBMISSION OF PATENT INFORMATION FOR BRAND NAME DRUGS.—Paragraph (1) of section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) is amended to read as follows:

''(b)(1) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a). Such persons shall submit to the Secretary as part of the application—

''(A) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use;

''(B) a full list of the articles used as components of such drug;

''(C) a full statement of the composition of such drug;

''(D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug;

''(E) such samples of such drug and of the articles used as components thereof as the Secretary may require;

''(F) specimens of the labeling proposed to be used for such drug;

''(G) any assessments required under section 505B; and

''(H) patent information, consistent with the following requirements:

''(i) The applicant shall file with the application the patent number and the expiration date of—

''(I) any patent which claims the drug for which the applicant submitted the application and is a drug substance (including active ingredient) patent or a drug product (including formulation and composition) patent; and

''(II) any patent which claims the method of using such drug.

''(ii) The applicant shall not include in such application any patent to the extent such patent claims a device that is used for the delivery of the drug.

''(iii) If an application is filed under this subsection for a drug and a patent of the type described in clause (i) which claims such drug or a method of using such drug is issued after the filing date but before approval of the application, the applicant shall amend the application to include such patent information.

Upon approval of the application, the Secretary shall publish the information submitted under subparagraph (H). The Secretary shall, in consultation with the Director of the National Institutes of Health and with representatives of the drug manufacturing industry, review and develop guidance, as appropriate, on the inclusion of women and minorities in clinical trials required by subparagraph (A).''.

(b) CONFORMING CHANGES TO REQUIREMENTS FOR SUBSEQUENT SUBMISSION OF PATENT INFORMATION.—Section 505(c)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)) is amended—

(1) by inserting after ''the patent number and the expiration date of any patent which'' the following: ''fulfills the criteria in subsection (b) and'';

(2) by inserting after the first sentence the following: ''Patent information that is not the type of patent information required by subsection (b) shall not be submitted.''; and

(3) by inserting after ''could not file patent information under subsection (b) because no patent'' the following: ''of the type required to be submitted in subsection (b)''.

(c) LISTING OF EXCLUSIVITIES.—Subparagraph (A) of section 505(j)(7) of the Federal Food, Drug, and Cos-

metic 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 (ii), (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 (ii), (iii), or (iv) of paragraph (5)(F) of this subsection;

''(IV) section 505A;

''(V) section 505E; or

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

(d) 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 notify within 14 days the Secretary in writing if either of the following occurs:

''(I) The Patent Trial and Appeals Board issues a decision from which no appeal has been or can be taken that a patent for such drug is invalid.

''(II) A court issues a decision from which no appeal has been or can 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 paragraph (5)(B)(iv) 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.

(e) 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) solicit public comment regarding 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) transmit to the Congress an evaluation of such comments, including any recommendations about the types of patent information that should be included on or removed from such list.