

116TH CONGRESS
1ST SESSION

H. R. 1503

IN THE SENATE OF THE UNITED STATES

MAY 9, 2019

Received; read twice and referred to the Committee on Health, Education,
Labor, and Pensions

AN ACT

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Orange Book Trans-
3 parency Act of 2019”.

4 **SEC. 2. ORANGE BOOK.**

5 (a) SUBMISSION OF PATENT INFORMATION FOR
6 BRAND NAME DRUGS.—Paragraph (1) of section 505(b)
7 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
8 355(b)) is amended to read as follows:

9 “(b)(1) Any person may file with the Secretary an
10 application with respect to any drug subject to the provi-
11 sions of subsection (a). Such persons shall submit to the
12 Secretary as part of the application—

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

16 “(B) a full list of the articles used as compo-
17 nents of such drug;

18 “(C) a full statement of the composition of such
19 drug;

20 “(D) a full description of the methods used in,
21 and the facilities and controls used for, the manufac-
22 ture, processing, and packing of such drug;

23 “(E) such samples of such drug and of the arti-
24 cles used as components thereof as the Secretary
25 may require;

1 “(F) specimens of the labeling proposed to be
2 used for such drug;

3 “(G) any assessments required under section
4 505B; and

5 “(H) patent information, with respect to each
6 patent for which a claim of patent infringement
7 could reasonably be asserted if a person not licensed
8 by the owner engaged in the manufacture, use, or
9 sale of the drug, and consistent with the following
10 requirements:

11 “(i) The applicant shall file with the appli-
12 cation the patent number and the expiration
13 date of—

14 “(I) any patent which claims the drug
15 for which the applicant submitted the ap-
16 plication and is a drug substance (includ-
17 ing active ingredient) patent or a drug
18 product (including formulation and com-
19 position) patent; and

20 “(II) any patent which claims the
21 method of using such drug.

22 “(ii) If an application is filed under this
23 subsection for a drug and a patent of the type
24 described in clause (i) which claims such drug
25 or a method of using such drug is issued after

1 the filing date but before approval of the appli-
2 cation, the applicant shall amend the applica-
3 tion to include such patent information.

4 Upon approval of the application, the Secretary shall pub-
5 lish the information submitted under subparagraph (H).
6 The Secretary shall, in consultation with the Director of
7 the National Institutes of Health and with representatives
8 of the drug manufacturing industry, review and develop
9 guidance, as appropriate, on the inclusion of women and
10 minorities in clinical trials required by subparagraph
11 (A).”.

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

16 (1) by inserting after “the patent number and
17 the expiration date of any patent which” the fol-
18 lowing: “fulfills the criteria in subsection (b) and”;

19 (2) by inserting after the first sentence the fol-
20 lowing: “Patent information that is not the type of
21 patent information required by subsection (b) shall
22 not be submitted.”; and

23 (3) by inserting after “could not file patent in-
24 formation under subsection (b) because no patent”

1 the following: “of the type required to be submitted
2 in subsection (b)”.

3 (c) LISTING OF EXCLUSIVITIES.—Subparagraph (A)
4 of section 505(j)(7) of the Federal Food, Drug, and Cos-
5 metic Act (21 U.S.C. 355(j)(7)) is amended by adding at
6 the end the following:

7 “(iv) For each drug included on the list, the Sec-
8 retary shall specify each exclusivity period that is applica-
9 ble and has not concluded under—

10 “(I) clause (ii), (iii), or (iv) of subsection
11 (c)(3)(E) of this section;

12 “(II) clause (iv) or (v) of paragraph (5)(B) of
13 this subsection;

14 “(III) clause (ii), (iii), or (iv) of paragraph
15 (5)(F) of this subsection;

16 “(IV) section 505A;

17 “(V) section 505E; or

18 “(VI) section 527(a).”.

19 (d) REMOVAL OF INVALID PATENTS.—

20 (1) IN GENERAL.—Section 505(j)(7) of the
21 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
22 355(j)(7)) is amended by adding at the end the fol-
23 lowing:

24 “(D)(i) The holder of an application approved under
25 subsection (c) for a drug on the list shall notify within

1 14 days the Secretary in writing if either of the following
2 occurs:

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

6 “(II) A court issues a decision from which no
7 appeal has been or can be taken that a patent for
8 such drug is invalid.

9 “(ii) The holder of an approved application shall in-
10 clude in any notification under clause (i) a copy of the
11 decision described in subclause (I) or (II) of clause (i).

12 “(iii) The Secretary shall remove from the list any
13 patent that is determined to be invalid in a decision de-
14 scribed in subclause (I) or (II) of clause (i)—

15 “(I) promptly; but

16 “(II) not before the expiration of any 180-day
17 exclusivity period under paragraph (5)(B)(iv) that
18 relies on a certification described in paragraph
19 (2)(A)(vii)(IV) that such patent was invalid.”.

20 (2) APPLICABILITY.—Subparagraph (D) of sec-
21 tion 505(j)(7) of the Federal Food, Drug, and Cos-
22 metic Act (21 U.S.C. 355(j)(7)), as added by para-
23 graph (1), applies only with respect to a decision de-
24 scribed in such subparagraph that is issued on or
25 after the date of enactment of this Act.

1 (e) REVIEW AND REPORT.—Not later than 1 year
2 after the date of enactment of this Act, the Secretary of
3 Health and Human Services, acting through the Commis-
4 sioner of Food and Drugs, shall—

5 (1) solicit public comment regarding the types
6 of patent information that should be included on the
7 list under section 507(j)(7) of the Federal Food,
8 Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)); and

9 (2) transmit to the Congress an evaluation of
10 such comments, including any recommendations
11 about the types of patent information that should be
12 included on or removed from such list.

13 **SEC. 3. GAO REPORT TO CONGRESS.**

14 (a) IN GENERAL.—Not later than 1 year after the
15 date of enactment of this Act, the Comptroller General
16 of the United States (referred to in this section as the
17 “Comptroller General”) shall submit to the Committee on
18 Energy and Commerce of the House of Representatives
19 a report on the patents included in the list published under
20 section 505(j)(7) of the Federal Food, Drug and Cosmetic
21 Act (21 U.S.C. 355(j)(7)), including an analysis and eval-
22 uation of the types of patents included in such list and
23 the claims such patents make about the products they
24 claim.

1 (b) CONTENTS.—The Comptroller General shall in-
2 clude in the report under subsection (a)—

3 (1) data on the number of—

4 (A) patents included in the list published
5 under paragraph (7) of section 505(j) of the
6 Federal Food, Drug and Cosmetic Act (21
7 U.S.C. 355(j)), that claim the active ingredient
8 or formulation of a drug in combination with a
9 device that is used for delivery of the drug, to-
10 gether comprising the finished dosage form of
11 the drug; and

12 (B) claims in each patent that claim a de-
13 vice that is used for the delivery of the drug,
14 but do not claim such device in combination
15 with an active ingredient or formulation of a
16 drug;

17 (2) data on the date of inclusion in the list
18 under paragraph (7) of such section 505(j) for all
19 patents under such list, as compared to patents that
20 claim a method of using the drug in combination
21 with a device;

22 (3) an analysis regarding the impact of includ-
23 ing on the list under paragraph (7) of such section
24 505(j) certain types of patent information for drug

1 product applicants and approved application holders,
2 including an analysis of whether—

3 (A) the listing of the patents described in
4 paragraph (1)(A) delayed the market entry of
5 one or more drugs approved under such section
6 505(j); and

7 (B) not listing the patents described in
8 paragraph (1)(A) would delay the market entry
9 of one or more such drugs; and

10 (4) recommendations about which kinds of pat-
11 ents relating to devices described in paragraph
12 (1)(A) should be submitted to the Secretary of
13 Health and Human Services for inclusion on the list
14 under paragraph (7) of such section 505(j) and
15 which patents should not be required to be so sub-
16 mitted.

Passed the House of Representatives May 8, 2019.

Attest: CHERYL L. JOHNSON,
Clerk.