

Union Calendar No.

116TH CONGRESS
1ST SESSION

H. R. 1503

[Report No. 116-]

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

APRIL --, 2019

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

[Strike out all after the enacting clause and insert the part printed in italics]

[For text of introduced bill, see copy of bill as introduced on March 5, 2019]

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.

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

3 **SECTION 1. SHORT TITLE.**

4 *This Act may be cited as the “Orange Book Trans-*
5 *parency Act of 2019”.*

6 **SEC. 2. ORANGE BOOK.**

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

11 *“(b)(1) Any person may file with the Secretary an ap-*
12 *plication with respect to any drug subject to the provisions*
13 *of subsection (a). Such persons shall submit to the Secretary*
14 *as part of the application—*

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

18 *“(B) a full list of the articles used as components*
19 *of such drug;*

20 *“(C) a full statement of the composition of such*
21 *drug;*

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

1 “(E) such samples of such drug and of the arti-
2 cles used as components thereof as the Secretary may
3 require;

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

6 “(G) any assessments required under section
7 505B; and

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

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

16 “(I) any patent which claims the drug
17 for which the applicant submitted the appli-
18 cation and is a drug substance (including
19 active ingredient) patent or a drug product
20 (including formulation and composition)
21 patent; and

22 “(II) any patent which claims the
23 method of using such drug.

24 “(ii) If an application is filed under this
25 subsection for a drug and a patent of the type

1 *described in clause (i) which claims such drug or*
2 *a method of using such drug is issued after the*
3 *filing date but before approval of the applica-*
4 *tion, the applicant shall amend the application*
5 *to include such patent information.*

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

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

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

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

1 (3) *by inserting after “could not file patent in-*
2 *formation under subsection (b) because no patent” the*
3 *following: “of the type required to be submitted in*
4 *subsection (b)”.*

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

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

12 “(I) *clause (ii), (iii), or (iv) of subsection*
13 *(c)(3)(E) of this section;*

14 “(II) *clause (iv) or (v) of paragraph (5)(B) of*
15 *this subsection;*

16 “(III) *clause (ii), (iii), or (iv) of paragraph*
17 *(5)(F) of this subsection;*

18 “(IV) *section 505A;*

19 “(V) *section 505E; or*

20 “(VI) *section 527(a).”.*

21 (d) *REMOVAL OF INVALID PATENTS.—*

22 (1) *IN GENERAL.—Section 505(j)(7) of the Fed-*
23 *eral Food, Drug, and Cosmetic Act (21 U.S.C.*
24 *355(j)(7)) is amended by adding at the end the fol-*
25 *lowing:*

1 “(D)(i) *The holder of an application approved under*
2 *subsection (c) for a drug on the list shall notify within 14*
3 *days the Secretary in writing if either of the following oc-*
4 *curs:*

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

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

11 “(ii) *The holder of an approved application shall in-*
12 *clude in any notification under clause (i) a copy of the deci-*
13 *sion described in subclause (I) or (II) of clause (i).*

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

17 “(I) *promptly; but*

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

22 (2) *APPLICABILITY.—Subparagraph (D) of sec-*
23 *tion 505(j)(7) of the Federal Food, Drug, and Cos-*
24 *metic Act (21 U.S.C. 355(j)(7)), as added by para-*
25 *graph (1), applies only with respect to a decision de-*

1 scribed in such subparagraph that is issued on or
2 after the date of enactment of this Act.

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

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

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

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

16 (a) *IN GENERAL.*—Not later than one year after the
17 date of enactment of this Act, the Comptroller General of
18 the United States (referred to in this section as the “Comp-
19 troller General”) shall submit to the Committee on Energy
20 and Commerce of the House of Representatives a report on
21 the patents included in the list published under section
22 505(j)(7) of the Federal Food, Drug and Cosmetic Act (21
23 U.S.C. 355(j)(7)), including an analysis and evaluation of
24 the types of patents included in such list and the claims
25 such patents make about the products they 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 Fed-*
6 *eral Food, Drug and Cosmetic Act (21 U.S.C.*
7 *355(j)), that claim the active ingredient or for-*
8 *mulation of a drug in combination with a device*
9 *that is used for delivery of the drug, together*
10 *comprising the finished dosage form of the drug;*
11 *and*

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

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

21 (3) *an analysis regarding the impact of includ-*
22 *ing on the list under paragraph (7) of such section*
23 *505(j) certain types of patent information for drug*
24 *product applicants and approved application holders,*
25 *including an analysis of whether—*

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

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

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