

***In the Senate of the United States,***

*December 7, 2020.*

*Resolved*, That the bill from the House of Representatives (H.R. 1503) entitled “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.”, do pass with the following

**AMENDMENT:**

Strike all after the enacting clause and insert the following:

1 ***SECTION 1. SHORT TITLE.***

2       *This Act may be cited as the “Orange Book Trans-*  
3 *parency Act of 2020”.*

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

5       *(a) SUBMISSION OF PATENT INFORMATION FOR BRAND*  
6 *NAME DRUGS.—*

7           *(1) IN GENERAL.—Paragraph (1) of section*  
8 *505(b) of the Federal Food, Drug, and Cosmetic Act*  
9 *(21 U.S.C. 355(b)) is amended to read as follows:*

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

5           “(i) full reports of investigations which have  
6 been made to show whether such drug is safe for use  
7 and whether such drug is effective in use;

8           “(ii) a full list of the articles used as components  
9 of such drug;

10          “(iii) a full statement of the composition of such  
11 drug;

12          “(iv) a full description of the methods used in,  
13 and the facilities and controls used for, the manufac-  
14 ture, processing, and packing of such drug;

15          “(v) such samples of such drug and of the arti-  
16 cles used as components thereof as the Secretary may  
17 require;

18          “(vi) specimens of the labeling proposed to be  
19 used for such drug;

20          “(vii) any assessments required under section  
21 505B; and

22          “(viii) the patent number and expiration date of  
23 each patent for which a claim of patent infringement  
24 could reasonably be asserted if a person not licensed

1       *by the owner of the patent engaged in the manufac-*  
 2       *ture, use, or sale of the drug, and that—*

3               *“(I) claims the drug for which the applicant*  
 4               *submitted the application and is a drug sub-*  
 5               *stance (active ingredient) patent or a drug prod-*  
 6               *uct (formulation or composition) patent; or*

7               *“(II) claims a method of using such drug*  
 8               *for which approval is sought or has been granted*  
 9               *in the application.*

10       *“(B) If an application is filed under this subsection*  
 11       *for a drug, and a patent of the type described in subpara-*  
 12       *graph (A)(viii) is issued after the filing date but before ap-*  
 13       *proval of the application, the applicant shall amend the ap-*  
 14       *plication to include the patent number and expiration*  
 15       *date.”.*

16       *(b) SUBSEQUENT SUBMISSION OF PATENT INFORMA-*  
 17       *TION.—*

18               *(1) IN GENERAL.—Section 505(c)(2) of the Fed-*  
 19       *eral Food, Drug, and Cosmetic Act (21 U.S.C.*  
 20       *355(c)(2)) is amended—*

21               *(A) by inserting before the first sentence the*  
 22               *following: “Not later than 30 days after the date*  
 23               *of approval of an application submitted under*  
 24               *subsection (b), the holder of the approved appli-*  
 25               *cation shall file with the Secretary the patent*

1        *number and the expiration date of any patent*  
2        *described in subsection (b)(1)(A)(viii), except*  
3        *that a patent that is identified as claiming a*  
4        *method of using such drug shall be filed only if*  
5        *the patent claims a method of use approved in*  
6        *the application. If a patent described in sub-*  
7        *section (b)(1)(A)(viii) is issued after the date of*  
8        *approval of an application submitted under sub-*  
9        *section (b), the holder of the approved applica-*  
10       *tion shall, not later than 30 days after the date*  
11       *of issuance of the patent, file the patent number*  
12       *and the expiration date of the patent, except that*  
13       *a patent that claims a method of using such*  
14       *drug shall be filed only if approval for such use*  
15       *has been granted in the application.”;*

16        *(B) in the first sentence following the sen-*  
17        *tences added by subparagraph (A), by striking*  
18        *“which claims the drug for which” and all that*  
19        *follows through “of the drug.” and inserting “de-*  
20        *scribed in subsection (b)(1)(A)(viii).”;*

21        *(C) in the second sentence following the sen-*  
22        *tences added by subparagraph (A), by inserting*  
23        *after “could not file patent information under*  
24        *subsection (b) because no patent” the following:*

1           *“of the type for which information is required to*  
 2           *be submitted in subsection (b)(1)(A)(viii)”;* and  
 3           *(D) by adding at the end the following:*  
 4           *“Patent information that is not the type of pat-*  
 5           *ent information required by subsection*  
 6           *(b)(1)(A)(viii) shall not be submitted under this*  
 7           *paragraph.”.*

8           (2) *UPDATING LIST.*—*Clause (iii) of section*  
 9           *505(j)(7)(A) of the Federal Food, Drug, and Cosmetic*  
 10          *Act (21 U.S.C. 355(j)(7)) is amended by striking “(b)*  
 11          *or”.*

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

16          *“(iv) For each drug included on the list, the Secretary*  
 17          *shall specify any exclusivity period that is applicable, for*  
 18          *which the Secretary has determined the expiration date,*  
 19          *and for which such period has not yet expired, under—*

20                 *“(I) clause (ii), (iii), or (iv) of subsection*  
 21                 *(c)(3)(E);*

22                 *“(II) clause (iv) or (v) of paragraph (5)(B);*

23                 *“(III) clause (ii), (iii), or (iv) of paragraph*  
 24                 *(5)(F);*

25                 *“(IV) section 505A;*

1           “(V) section 505E;  
 2           “(VI) section 527(a); or  
 3           “(VII) subsection (u).”.

4           (d) *ORANGE BOOK UPDATES WITH RESPECT TO IN-*  
 5 *VALIDATED PATENTS.*—

6           (1) *AMENDMENT.*—Section 505(j)(7) of the *Fed-*  
 7 *eral Food, Drug, and Cosmetic Act* (21 U.S.C.  
 8 355(j)(7)) is amended by adding at the end the fol-  
 9 *lowing:*

10          “(D) *In the case of a listed drug for which the list*  
 11 *under subparagraph (A)(i) includes a patent for such drug,*  
 12 *and any claim of the patent has been cancelled or invali-*  
 13 *dated pursuant to a final decision issued by the Patent*  
 14 *Trial and Appeal Board of the United States Patent and*  
 15 *Trademark Office or by a court, from which no appeal has*  
 16 *been, or can be, taken, if the holder of the applicable appli-*  
 17 *cation approved under subsection (c) determines that a pat-*  
 18 *ent for such drug, or any patent information for such drug,*  
 19 *no longer meets the listing requirements under this sec-*  
 20 *tion—*

21           “(i) *the holder of such approved application*  
 22 *shall notify the Secretary, in writing, within 14 days*  
 23 *of such decision of such cancellation or invalidation*  
 24 *and request that such patent or patent information,*  
 25 *as applicable, be amended or withdrawn in accord-*

1      *ance with the decision issued by the Patent Trial and*  
 2      *Appeal Board or a court;*

3            *“(ii) the holder of such approved application*  
 4      *shall include in any notification under clause (i) in-*  
 5      *formation related to such patent cancellation or in-*  
 6      *validation decision and submit such information, in-*  
 7      *cluding a copy of such decision, to the Secretary; and*

8            *“(iii) the Secretary shall, in response to a notifi-*  
 9      *cation under clause (i), amend or remove patent or*  
 10     *patent information in accordance with the relevant*  
 11     *decision from the Patent Trial and Appeals Board or*  
 12     *court, as applicable, except that the Secretary shall*  
 13     *not remove from the list any patent or patent infor-*  
 14     *mation before the expiration of any 180-day exclu-*  
 15     *sivity period under paragraph (5)(B)(iv) that relies*  
 16     *on a certification described in paragraph*  
 17     *(2)(A)(vii)(IV).”.*

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

24            *(e) REVIEW AND REPORT.—Not later than 1 year after*  
 25     *the date of enactment of this Act, the Secretary of Health*

1 *and Human Services, acting through the Commissioner of*  
 2 *Food and Drugs, shall—*

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

8       *(2) transmit to Congress a summary of such*  
 9       *comments and actions the Food and Drug Adminis-*  
 10       *tration is considering taking, if any, in response to*  
 11       *public comment pursuant to paragraph (1) about the*  
 12       *types of patent information that should be included or*  
 13       *removed from such list.*

14       *(f) GAO REPORT TO CONGRESS.—*

15       *(1) IN GENERAL.—Not later than 2 years after*  
 16       *the date of enactment of this Act, the Comptroller*  
 17       *General of the United States (referred to in this sec-*  
 18       *tion as the “Comptroller General”) shall submit to the*  
 19       *Committee on Health, Education, Labor, and Pen-*  
 20       *sions of the Senate and the Committee on Energy and*  
 21       *Commerce of the House of Representatives a report on*  
 22       *the patents included in the list published under sec-*  
 23       *tion 505(j)(7) of the Federal Food, Drug and Cos-*  
 24       *metic Act (21 U.S.C. 355(j)(7)) that claim an active*  
 25       *ingredient or formulation of a drug in combination*



1     *with a device that is used for delivery of such drug,*  
2     *including an analysis of such patents and their*  
3     *claims.*

4             (2) *CONTENT.—The Comptroller General shall*  
5     *include in the report under paragraph (1)—*

6             (A) *data on—*

7                 (i) *the number of patents included in*  
8                 *the list published under section 505(j)(7) of*  
9                 *the Federal Food, Drug and Cosmetic Act*  
10                *(21 U.S.C. 355(j)(7)) that claim the active*  
11                *ingredient or formulation of a drug in com-*  
12                *bination with a device that is used for de-*  
13                *livery of the drug, and that together claim*  
14                *the finished dosage form of the drug; and*

15               (ii) *the number of claims with respect*  
16                *to each patent included in the list published*  
17                *under such section 505(j)(7) that claim a*  
18                *device that is used for the delivery of the*  
19                *drug, but do not claim such device in com-*  
20                *bination with an active ingredient or for-*  
21                *mulation of a drug;*

22             (B) *an analysis of the listing of patents de-*  
23             *scribed in subparagraph (A)(ii), including the*  
24             *timing of listing such patents in relation to pat-*  
25             *ents described in subparagraph (A)(i), and the*

1        *effect listing the patents described in subpara-*  
 2        *graph (A)(ii) has on market entry of one or more*  
 3        *drugs approved under section 505(j) of the Fed-*  
 4        *eral Food, Drug, and Cosmetic Act as compared*  
 5        *to the effect of not listing the patents described*  
 6        *in subparagraph (A)(ii); and*

7                *(C) recommendations about which kinds of*  
 8        *patents relating to devices described in subpara-*  
 9        *graph (A)(i) should be submitted to the Secretary*  
 10        *of Health and Human Services for inclusion on*  
 11        *the list under section 505(j)(7) of the Federal*  
 12        *Food, Drug, and Cosmetic Act and which patents*  
 13        *should not be required to be so submitted in*  
 14        *order to reduce barriers to approval and market*  
 15        *entry.*

16        *(g) CONFORMING AMENDMENTS.—Section 505 of the*  
 17        *Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is*  
 18        *amended—*

19                *(1) in subsection (c)(3)(E), by striking “clause*  
 20        *(A) of subsection (b)(1)” each place it appears and*  
 21        *inserting “subsection (b)(1)(A)(i)”;* *and*

22                *(2) in subsection (j)(2)(A)(vi), by striking*  
 23        *“clauses (B) through (F) of subsection (b)(1)” and in-*

1       serting “clauses (ii) through (vi) of subsection  
2       (b)(1)(A)”.

Attest:

*Secretary.*

116<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

**H.R. 1503**

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**AMENDMENT**