

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.

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## 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.

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) PATENTS.—Clause (iii) of section 505(j)(7)(A) of  
8 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
9 355(j)(7)) is amended to read as follows:

1       “(iii)(I) When patent information submitted under  
2 subsection (b) or (c) respecting a drug included on the  
3 list is to be published by the Secretary, the Secretary shall,  
4 in revisions made under clause (ii), include such informa-  
5 tion for such drug.

6       “(II) The Secretary—

7           “(aa) shall include on the list, from such patent  
8 information respecting a drug, drug substance (in-  
9 cluding active ingredient) patents, drug product (in-  
10 cluding formulation and composition) patents, and  
11 method of use patents; and

12           “(bb) may choose to include on the list addi-  
13 tional patent information respecting the drug.

14       “(III) The Secretary shall not include on the list any  
15 patent to the extent such patent claims a device that is  
16 used for the delivery of the drug. Notwithstanding the pre-  
17 ceding sentence, the Secretary may require (under other  
18 applicable provisions of law) the holder of the approved  
19 application for a drug to submit, for purposes other than  
20 the list under this paragraph, patent information respect-  
21 ing a device that is used for the delivery of the drug.”.

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

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

4               “(I) clause (iii) or (iv) of subsection (c)(3)(E)  
5       of this section;

6               “(II) clause (iv) or (v) of paragraph (5)(B) of  
7       this subsection;

8               “(III) clause (iii) or (iv) of paragraph (5)(F) of  
9       this subsection;

10              “(IV) section 505A;

11              “(V) section 505E; or

12              “(VI) section 527(a).”.

13       (c) REMOVAL OF INVALID PATENTS.—

14              (1) IN GENERAL.—Section 505(j)(7) of the  
15       Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
16       355(j)(7)) is amended by adding at the end the fol-  
17       lowing:

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

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

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

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

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

7               “(I) promptly; but

8               “(II) not before the expiration of any 180-day  
9 exclusivity period under clause (iv) or (v) of para-  
10 graph (5)(B) that relies on a certification described  
11 in paragraph (2)(A)(vii)(IV) that such patent was  
12 invalid.”.

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

19               (d) REVIEW AND REPORT.—Not later than one year  
20 after the date of enactment of this Act, the Secretary of  
21 Health and Human Services, acting through the Commis-  
22 sioner of Food and Drugs, shall—

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

1       507(j)(7) of the Federal Food, Drug, and Cosmetic  
2       Act (21 U.S.C. 355(j)(7)); and

3           (2) report to the Congress on the results of  
4       such review, including any recommendations about  
5       the types of patent information that should be in-  
6       cluded on or removed from such list.

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