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(Original Signature of Member)

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

M\_\_\_\_. \_\_\_\_\_ introduced the following bill; which was referred to the Committee on \_\_\_\_\_

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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”.

1 **SEC. 2. ORANGE BOOK.**

2 (a) PATENTS.—Clause (iii) of section 505(j)(7)(A) of  
3 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
4 355(j)(7)) is amended to read as follows:

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

10 “(II) The Secretary—

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

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

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

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

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

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

10 “(II) clause (iv) or (v) of paragraph (5)(B) of  
11 this subsection;

12 “(III) clause (iii) or (iv) of paragraph (5)(F) of  
13 this subsection;

14 “(IV) section 505A;

15 “(V) section 505E; or

16 “(VI) section 527(a).”.

17 (c) REMOVAL OF INVALID PATENTS.—

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

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

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

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

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

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

12           “(I) promptly; but

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

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           (d) REVIEW AND REPORT.—Not later than one year  
25 after the date of enactment of this Act, the Secretary of

1 Health and Human Services, acting through the Commis-  
2 sioner of Food and Drugs, shall—

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

7 (2) report to the Congress on the results of  
8 such review, including any recommendations about  
9 the types of patent information that should be in-  
10 cluded on or removed from such list.