

111TH CONGRESS  
1ST SESSION

# S. 1315

To amend the Federal Food, Drug, and Cosmetic Act to define the term “first applicant” for purposes of filing an abbreviated application for a new drug.

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## IN THE SENATE OF THE UNITED STATES

JUNE 22, 2009

Mr. NELSON of Florida (for himself and Mr. KOHL) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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## A BILL

To amend the Federal Food, Drug, and Cosmetic Act to define the term “first applicant” for purposes of filing an abbreviated application for a new drug.

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 “Drug Price Competi-  
5 tion Act of 2009”.

6 **SEC. 2. EXCLUSIVITY PERIOD.**

7 (a) **FIRST APPLICANT.**—Section 505(j)(5) of the  
8 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
9 355(j)(5)) is amended—

1 (1) in subparagraph (B)(iv)—

2 (A) in subclause (II), by striking item (bb)  
3 and inserting the following:

4 “(bb) FIRST APPLICANT.—  
5 As used in this subsection, the  
6 term ‘first applicant’ means—

7 “(AA) an applicant  
8 that, on the first day on  
9 which a substantially com-  
10 plete application containing  
11 a certification described in  
12 paragraph (2)(A)(vii)(IV) is  
13 submitted for approval of a  
14 drug, submits a substan-  
15 tially complete application  
16 that contains and lawfully  
17 maintains a certification de-  
18 scribed in paragraph  
19 (2)(A)(vii)(IV) for the drug;  
20 or

21 “(BB) an applicant for  
22 the drug not described in  
23 item (AA) that satisfies the  
24 requirements of subclause  
25 (III).”; and

1 (B) by adding at the end the following:

2 “(III) An applicant described in  
3 subclause (II)(bb)(BB) shall—

4 “(aa) submit and lawfully  
5 maintain a certification described  
6 in paragraph (2)(A)(vii)(IV) or a  
7 statement described in paragraph  
8 (2)(A)(viii) for each unexpired  
9 patent for which a first applicant  
10 described in item (AA) had sub-  
11 mitted a certification described in  
12 paragraph (2)(A)(vii)(IV) on the  
13 first day on which a substantially  
14 complete application containing  
15 such a certification was sub-  
16 mitted;

17 “(bb) with regard to each  
18 such unexpired patent for which  
19 the applicant submitted a certifi-  
20 cation described in paragraph  
21 (2)(A)(vii)(IV), no action for pat-  
22 ent infringement was brought  
23 against the applicant within the  
24 45-day period specified in para-  
25 graph (5)(B)(iii), or if an action

1 was brought within such time pe-  
2 riod, the applicant has obtained  
3 the decision of a court (including  
4 a district court) that the patent  
5 is invalid or not infringed (in-  
6 cluding any substantive deter-  
7 mination that there is no cause  
8 of action for patent infringement  
9 or invalidity, and including a set-  
10 tlement order or consent decree  
11 signed and entered by the court  
12 stating that the patent is invalid  
13 or not infringed); and

14 “(cc) but for the effective  
15 date of approval provisions in  
16 subparagraphs (B) and (F) and  
17 sections 505A and 527, be eligi-  
18 ble to receive immediately effec-  
19 tive approval at a time before  
20 any other applicant has begun  
21 commercial marketing.”; and

22 (2) in subparagraph (D)—

23 (A) in clause (i)(IV), by striking “The first  
24 applicant” and inserting “The first applicant,

1 as defined in subparagraph  
2 (B)(iv)(II)(bb)(AA),”; and

3 (B) in clause (iii), in the matter preceding  
4 subclause (I)—

5 (i) by striking “If all first applicants  
6 forfeit the 180-day exclusivity period under  
7 clause (ii)”;

8 (ii) by inserting “If all first appli-  
9 cants, as defined in subparagraph  
10 (B)(iv)(II)(bb)(AA), forfeit the 180-day ex-  
11 clusivity period under clause (ii) at a time  
12 at which no applicant has begun commer-  
13 cial marketing”.

14 (b) EFFECTIVE DATE AND TRANSITIONAL PROVI-  
15 SION.—

16 (1) EFFECTIVE DATE.—The amendments made  
17 by subsection (a) shall be effective only with respect  
18 to an application filed under section 505(j) of the  
19 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
20 355(j)) to which the amendments made by section  
21 1102(a) of the Medicare Prescription Drug Improve-  
22 ment and Modernization Act of 2003 (Public Law  
23 108–173) apply.

24 (2) TRANSITIONAL PROVISION.—An application  
25 filed under section 505(j) of the Federal Food,

1 Drug, and Cosmetic Act (21 U.S.C. 355(j)), to  
2 which the 180-day exclusivity period described in  
3 paragraph (5)(iv) of such section does not apply,  
4 and that contains a certification under paragraph  
5 (2)(A)(vii)(IV) of such Act, shall be regarded as a  
6 previous application containing such a certification  
7 within the meaning of section 505(j)(5)(B)(iv) of  
8 such Act (as in effect before the amendments made  
9 by Medicare Prescription Drug Improvement and  
10 Modernization Act of 2003 (Public Law 108–173))  
11 if—

12 (A) no action for infringement of the pat-  
13 ent that is the subject of such certification was  
14 brought against the applicant within the 45-day  
15 period specified in section 505(j)(5)(B)(iii) of  
16 the Federal Food, Drug, and Cosmetic Act (21  
17 U.S.C. 355(j)(5)(B)(iii)), or if an action was  
18 brought within such time period, the applicant  
19 has obtained the decision of a court (including  
20 a district court) that the patent is invalid or not  
21 infringed (including any substantive determina-  
22 tion that there is no cause of action for patent  
23 infringement or invalidity, and including a set-  
24 tlement order or consent decree signed and en-

1           tered by the court stating that the patent is in-  
2           valid or not infringed);

3                   (B) the application is eligible to receive im-  
4           mediately effective approval, but for the effec-  
5           tive date of approval provisions in sections  
6           505(j)(5)(B) (as in effect before the amend-  
7           ment made by Public Law 108–173),  
8           505(j)(5)(F), 505A, and 527 of the Federal  
9           Food, Drug, and Cosmetic Act (21 U.S.C.  
10          355(j)(5)(B), 355(j)(5)(F), 355a, 360cc); and

11                   (C) no other applicant has begun commer-  
12          cial marketing.

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