

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.

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

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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