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(Original Signature of Member)

111TH CONGRESS
1ST SESSION

H. R. _____

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 HOUSE OF REPRESENTATIVES

Mr. HASTINGS of Florida introduced the following bill; which was referred to the Committee on _____

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”.

1 **SEC. 2. EXCLUSIVITY PERIOD.**

2 (a) **FIRST APPLICANT.**—Section 505(j)(5) of the
3 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
4 355(j)(5)) is amended—

5 (1) in subparagraph (B)(iv)—

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

8 “(bb) **FIRST APPLICANT.**—
9 As used in this subsection, the
10 term ‘first applicant’ means—

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

25 “(BB) an applicant for
26 the drug not described in

1 item (AA) that satisfies the
2 requirements of subclause
3 (III).”; and

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

5 “(III) An applicant described in
6 subclause (II)(bb)(BB) shall—

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

20 “(bb) with regard to each
21 such unexpired patent for which
22 the applicant submitted a certifi-
23 cation described in paragraph
24 (2)(A)(vii)(IV), no action for pat-
25 ent infringement was brought

1 against the applicant within the
2 45-day period specified in para-
3 graph (5)(B)(iii), or if an action
4 was brought within such time pe-
5 riod, the applicant has obtained
6 the decision of a court (including
7 a district court) that the patent
8 is invalid or not infringed (in-
9 cluding any substantive deter-
10 mination that there is no cause
11 of action for patent infringement
12 or invalidity, and including a set-
13 tlement order or consent decree
14 signed and entered by the court
15 stating that the patent is invalid
16 or not infringed); and

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

25 (2) in subparagraph (D)—

1 (A) in clause (i)(IV), by striking “The first
2 applicant” and inserting “The first applicant,
3 as defined in subparagraph
4 (B)(iv)(II)(bb)(AA),”; and

5 (B) in clause (iii), in the matter preceding
6 subclause (I)—

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

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

16 (b) EFFECTIVE DATE AND TRANSITIONAL PROVI-
17 SION.—

18 (1) EFFECTIVE DATE.—The amendments made
19 by subsection (a) shall be effective only with respect
20 to an application filed under section 505(j) of the
21 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
22 355(j)) to which the amendments made by section
23 1102(a) of the Medicare Prescription Drug Improve-
24 ment and Modernization Act of 2003 (Public Law
25 108–173) apply.

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

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

1 tlement order or consent decree signed and en-
2 tered by the court stating that the patent is in-
3 valid or not infringed);

4 (B) the application is eligible to receive im-
5 mediately effective approval, but for the effec-
6 tive date of approval provisions in sections
7 505(j)(5)(B) (as in effect before the amend-
8 ment made by Public Law 108–173),
9 505(j)(5)(F), 505A, and 527 of the Federal
10 Food, Drug, and Cosmetic Act (21 U.S.C.
11 355(j)(5)(B), 355(j)(5)(F), 355a, 360cc); and

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