

115TH CONGRESS
2D SESSION

S. _____

To amend the Federal Food, Drug, and Cosmetic Act to ensure that valid generic drugs may enter the market.

IN THE SENATE OF THE UNITED STATES

Ms. SMITH introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to ensure that valid generic drugs may enter the market.

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 “Expanding Access to
5 Low Cost Generic Drugs Act”.

6 SEC. 2. 180-DAY EXCLUSIVITY PERIOD AMENDMENTS RE-

7 GARDING FIRST APPLICANT STATUS.

8 (a) AMENDMENTS TO FEDERAL FOOD, DRUG, AND
9 COSMETIC ACT.—

1 (1) IN GENERAL.—Section 505(j)(5)(B) of the
2 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
3 355(j)(5)(B)) is amended—

4 (A) in clause (iv)(II)—
5 (i) by striking item (bb); and
6 (ii) by redesignating items (cc) and
7 (dd) as items (bb) and (cc), respectively;
8 (B) by redesignating clause (v) as clause
9 (ix); and

10 (C) by inserting after clause (iv) the fol-
11 lowing:

12 “(v) FIRST APPLICANT DEFINED.—As used in
13 this subsection, the term ‘first applicant’ means an
14 applicant—

15 “(I)(aa) that, on the first day on which a
16 substantially complete application containing a
17 certification described in paragraph
18 (2)(A)(vii)(IV) is submitted for approval of a
19 drug, submits a substantially complete applica-
20 tion that contains and lawfully maintains a cer-
21 tification described in paragraph (2)(A)(vii)(IV)
22 for the drug; and

23 “(bb) that has not entered into a disquali-
24 fying agreement described under clause
25 (vii)(II); or

1 “(II)(aa) for the drug that is not described
2 in subclause (I) and that, with respect to the
3 applicant and drug, each requirement described
4 in clause (vi) is satisfied; and

5 “(bb) that has not entered into a disquali-
6 fying agreement described under clause
7 (vii)(II).

8 “(vi) REQUIREMENT.—The requirements de-
9 scribed in this clause are the following:

10 “(I) The applicant described in clause
11 (v)(II) submitted and lawfully maintains a cer-
12 tification described in paragraph (2)(A)(vii)(IV)
13 or a statement described in paragraph
14 (2)(A)(viii) for each unexpired patent for which
15 a first applicant described in clause (v)(I) had
16 submitted a certification described in paragraph
17 (2)(A)(vii)(IV) on the first day on which a sub-
18 stantially complete application containing such
19 a certification was submitted.

20 “(II) With regard to each such unexpired
21 patent for which the applicant described in
22 clause (v)(II) submitted a certification de-
23 scribed in paragraph (2)(A)(vii)(IV), no action
24 for patent infringement was brought against
25 such applicant within the 45-day period speci-

1 fied in clause (iii); or if an action was brought
2 within such time period, such an action was
3 withdrawn or dismissed by a court (including a
4 district court) without a decision that the pat-
5 ent was valid and infringed; or if an action was
6 brought within such time period and was not
7 withdrawn or so dismissed, such applicant has
8 obtained the decision of a court (including a
9 district court) that the patent is invalid or not
10 infringed (including any substantive determina-
11 tion that there is no cause of action for patent
12 infringement or invalidity, and including a set-
13 tlement order or consent decree signed and en-
14 tered by the court stating that the patent is in-
15 valid or not infringed).

16 “(III) If an applicant described in clause
17 (v)(I) has begun commercial marketing of such
18 drug, the applicant described in clause (v)(II)
19 does not begin commercial marketing of such
20 drug until the date that is 30 days after the
21 date on which the applicant described in clause
22 (v)(I) began such commercial marketing.”.

23 (2) CONFORMING AMENDMENT.—Section
24 505(j)(5)(D)(i)(IV) of such Act (21 U.S.C.
25 355(j)(5)(D)(i)(IV)) is amended by striking “The

1 first applicant” and inserting “The first applicant,
2 as defined in subparagraph (B)(v)(I),”.

(b) APPLICABILITY.—The amendments made by subsection (a) shall apply only with respect to an application filed under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) to which the amendments made by section 1102(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub-lic Law 108–173) apply.

10 SEC. 3. 180-DAY EXCLUSIVITY PERIOD AMENDMENTS RE-
11 GARDING AGREEMENTS TO DEFER COMMER-
12 CIAL MARKETING.

13 (a) AMENDMENTS TO FEDERAL FOOD, DRUG, AND
14 COSMETIC ACT.—

21 “(vii) AGREEMENT BY FIRST APPLICANT TO
22 DEFER COMMERCIAL MARKETING; LIMITATION ON
23 ACCELERATION OF DEFERRED COMMERCIAL MAR-
24 KETING DATE.—

1 “(I) AGREEMENT TO DEFER APPROVAL OR
2 COMMERCIAL MARKETING DATE.—An agree-
3 ment described in this subclause is an agree-
4 ment between a first applicant and the holder
5 of the application for the listed drug or an
6 owner of one or more of the patents as to which
7 any applicant submitted a certification quali-
8 fying such applicant for the 180-day exclusivity
9 period whereby that applicant agrees, directly
10 or indirectly, (aa) not to seek an approval of its
11 application that is made effective on the earliest
12 possible date under this subparagraph, subpara-
13 graph (F) of this paragraph, section 505A, or
14 section 527, (bb) not to begin the commercial
15 marketing of its drug on the earliest possible
16 date after receiving an approval of its applica-
17 tion that is made effective under this subpara-
18 graph, subparagraph (F) of this paragraph, sec-
19 tion 505A, or section 527, or (cc) to both items
20 (aa) and (bb).

21 “(II) AGREEMENT THAT DISQUALIFIES AP-
22 PLICANT FROM FIRST APPLICANT STATUS.—An
23 agreement described in this subclause is an
24 agreement between an applicant and the holder
25 of the application for the listed drug or an

1 owner of one or more of the patents as to which
2 any applicant submitted a certification qualifi-
3 fying such applicant for the 180-day exclusivity
4 period whereby that applicant agrees, directly
5 or indirectly, not to seek an approval of its ap-
6 plication or not to begin the commercial mar-
7 keting of its drug until a date that is after the
8 expiration of the 180-day exclusivity period
9 awarded to another applicant with respect to
10 such drug (without regard to whether such 180-
11 day exclusivity period is awarded before or after
12 the date of the agreement).

13 “(viii) LIMITATION ON ACCELERATION.—If an
14 agreement described in clause (vii)(I) includes more
15 than 1 possible date when an applicant may seek an
16 approval of its application or begin the commercial
17 marketing of its drug—

18 “(I) the applicant may seek an approval of
19 its application or begin such commercial mar-
20 keting on the date that is the earlier of—

21 “(aa) the latest date set forth in the
22 agreement on which that applicant can re-
23 ceive an approval that is made effective
24 under this subparagraph, subparagraph
25 (F) of this paragraph, section 505A, or

1 section 527, or begin the commercial mar-
2 keting of such drug, without regard to any
3 other provision of such agreement pursu-
4 ant to which the commercial marketing
5 could begin on an earlier date; or

6 “(bb) 180 days after another first ap-
7 licant begins commercial marketing of
8 such drug; and

9 “(II) the latest date set forth in the agree-
10 ment on which that applicant can receive an ap-
11 proval that is made effective under this sub-
12 paragraph, subparagraph (F) of this paragraph,
13 section 505A, or section 527, or begin the com-
14 mercial marketing of such drug, without regard
15 to any other provision of such agreement pursu-
16 ant to which commercial marketing could begin
17 on an earlier date, shall be the date used to de-
18 termine whether an applicant is disqualified
19 from first applicant status pursuant to clause
20 (vii)(II).”.

21 (2) NOTIFICATION OF FDA.—Section 505(j) of
22 such Act (21 U.S.C. 355(j)) is amended by adding
23 at the end the following:

1 “(14)(A) The holder of an abbreviated application
2 under this subsection shall submit to the Secretary a noti-
3 fication that includes—

4 “(i)(I) the text of any agreement entered into
5 by such holder described under paragraph
6 (5)(B)(vii)(I); or

7 “(II) if such an agreement has not been re-
8 duced to text, a written detailed description of such
9 agreement that is sufficient to disclose all the terms
10 and conditions of the agreement; and

11 “(ii) the text, or a written detailed description
12 in the event of an agreement that has not been re-
13 duced to text, of any other agreements that are con-
14 tingent upon, provide a contingent condition for, or
15 are otherwise related to an agreement described in
16 clause (i).

17 “(B) The notification described under subparagraph
18 (A) shall be submitted not later than 10 business days
19 after execution of the agreement described in subpara-
20 graph (A)(i). Such notification is in addition to any notifi-
21 cation required under section 1112 of the Medicare Pre-
22 scription Drug, Improvement, and Modernization Act of
23 2003.

24 “(C) Any information or documentary material filed
25 with the Secretary pursuant to this paragraph shall be ex-

1 empt from disclosure under section 552 of title 5, United
2 States Code, and no such information or documentary ma-
3 terial may be made public, except as may be relevant to
4 any administrative or judicial action or proceeding. Noth-
5 ing in this paragraph is intended to prevent disclosure to
6 either body of the Congress or to any duly authorized com-
7 mittee or subcommittee of the Congress.”.

8 (3) PROHIBITED ACTS.—Section 301(e) of such
9 Act (21 U.S.C. 331(e)) is amended by striking “505
10 (i) or (k)” and inserting “505 (i), (j)(14), or (k)”.

11 (b) INFRINGEMENT OF PATENT.—Section 271(e) of
12 title 35, United States Code, is amended by adding at the
13 end the following:

14 “(7) The exclusive remedy under this section for an
15 infringement of a patent for which the Secretary of Health
16 and Human Services has published information pursuant
17 to subsection (b)(1) or (c)(2) of section 505 of the Federal
18 Food, Drug, and Cosmetic Act shall be an action brought
19 under this subsection within the 45-day period described
20 in subsection (j)(5)(B)(iii) or (e)(3)(C) of section 505 of
21 the Federal Food, Drug, and Cosmetic Act.”.

22 (c) APPLICABILITY.—

23 (1) LIMITATIONS ON ACCELERATION OF DE-
24 FERRED COMMERCIAL MARKETING DATE.—The

1 amendment made by subsection (a)(1) shall apply
2 only with respect to—

3 (A) an application filed under section
4 505(j) of the Federal Food, Drug, and Cos-
5 metic Act (21 U.S.C. 355(j)) to which the
6 amendments made by section 1102(a) of the
7 Medicare Prescription Drug, Improvement, and
8 Modernization Act of 2003 (Public Law 108–
9 173) apply; and

10 (B) an agreement described under section
11 505(j)(5)(B)(vii)(I) of the Federal Food, Drug,
12 and Cosmetic Act (as added by subsection
13 (a)(1)) executed after the date of enactment of
14 this Act.

15 (2) NOTIFICATION OF FDA.—The amendments
16 made by paragraphs (2) and (3) of subsection (a)
17 shall apply only with respect to an agreement de-
18 scribed under section 505(j)(5)(B)(vii)(I) of the
19 Federal Food, Drug, and Cosmetic Act (as added by
20 subsection (a)(1)) executed after the date of enact-
21 ment of this Act.