

113TH CONGRESS
1ST SESSION

S. 504

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

MARCH 7, 2013

Mr. FRANKEN (for himself, Mr. VITTER, Mr. DURBIN, Mrs. SHAHEEN, and Mr. SANDERS) 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 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 “Fair And Immediate
5 Release of Generic Drugs Act” or the “FAIR Generics
6 Act”.

7 **SEC. 2. 180-DAY EXCLUSIVITY PERIOD AMENDMENTS RE-**
8 **GARDING FIRST APPLICANT STATUS.**

9 (a) AMENDMENTS TO FEDERAL FOOD, DRUG, AND
10 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 and

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

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

12 “(I)(aa) that, on the first day on which a sub-
13 stantially complete application containing a certifi-
14 cation described in paragraph (2)(A)(vii)(IV) is sub-
15 mitted for approval of a drug, submits a substan-
16 tially complete application that contains and lawfully
17 maintains a certification described in paragraph
18 (2)(A)(vii)(IV) for the drug; and

19 “(bb) that has not entered into a disqualifying
20 agreement described under clause (vii)(II); or

21 “(II)(aa) for the drug that is not described in
22 subclause (I) and that, with respect to the applicant
23 and drug, each requirement described in clause (vi)
24 is satisfied; and

1 “(bb) that has not entered into a disqualifying
2 agreement described under clause (vii)(II).

3 “(vi) REQUIREMENT.—The requirements described in
4 this clause are the following:

5 “(I) The applicant described in clause (v)(II)
6 submitted and lawfully maintains a certification de-
7 scribed in paragraph (2)(A)(vii)(IV) or a statement
8 described in paragraph (2)(A)(viii) for each unex-
9 pired patent for which a first applicant described in
10 clause (v)(I) had submitted a certification described
11 in paragraph (2)(A)(vii)(IV) on the first day on
12 which a substantially complete application contain-
13 ing such a certification was submitted.

14 “(II) With regard to each such unexpired pat-
15 ent for which the applicant described in clause
16 (v)(II) submitted a certification described in para-
17 graph (2)(A)(vii)(IV), no action for patent infringe-
18 ment was brought against such applicant within the
19 45-day period specified in paragraph (5)(B)(iii); or
20 if an action was brought within such time period,
21 such an action was withdrawn or dismissed by a
22 court (including a district court) without a decision
23 that the patent was valid and infringed; or if an ac-
24 tion was brought within such time period and was
25 not withdrawn or so dismissed, such applicant has

1 obtained the decision of a court (including a district
2 court) that the patent is invalid or not infringed (in-
3 cluding any substantive determination that there is
4 no cause of action for patent infringement or inva-
5 lidity, and including a settlement order or consent
6 decree signed and entered by the court stating that
7 the patent is invalid or not infringed).

8 “(III) If an applicant described in clause (v)(I)
9 has begun commercial marketing of such drug, the
10 applicant described in clause (v)(II) does not begin
11 commercial marketing of such drug until the date
12 that is 30 days after the date on which the applicant
13 described in clause (v)(I) began such commercial
14 marketing.”.

15 (2) CONFORMING AMENDMENT.—Section
16 505(j)(5)(D)(i)(IV) of such Act (21 U.S.C.
17 355(j)(5)(D)(i)(IV)) is amended by striking “The
18 first applicant” and inserting “The first applicant,
19 as defined in subparagraph (B)(v)(I),”.

20 (b) APPLICABILITY.—The amendments made by sub-
21 section (a) shall apply only with respect to an application
22 filed under section 505(j) of the Federal Food, Drug, and
23 Cosmetic Act (21 U.S.C. 355(j)) to which the amendments
24 made by section 1102(a) of the Medicare Prescription

1 Drug, Improvement, and Modernization Act of 2003 (Pub-
2 lic Law 108–173) apply.

3 **SEC. 3. 180-DAY EXCLUSIVITY PERIOD AMENDMENTS RE-**
4 **GARDING AGREEMENTS TO DEFER COMMER-**
5 **CIAL MARKETING.**

6 (a) AMENDMENTS TO FEDERAL FOOD, DRUG, AND
7 COSMETIC ACT.—

8 (1) LIMITATIONS ON AGREEMENTS TO DEFER
9 COMMERCIAL MARKETING DATE.—Section
10 505(j)(5)(B) of the Federal Food, Drug, and Cos-
11 metic Act (21 U.S.C. 355(j)(5)(B)), as amended by
12 section 2, is further amended by adding at the end
13 the following:

14 “(vii) AGREEMENT BY FIRST APPLICANT TO
15 DEFER COMMERCIAL MARKETING; LIMITATION ON
16 ACCELERATION OF DEFERRED COMMERCIAL MAR-
17 KETING DATE.—

18 “(I) AGREEMENT TO DEFER APPROVAL OR
19 COMMERCIAL MARKETING DATE.—An agree-
20 ment described in this subclause is an agree-
21 ment between a first applicant and the holder
22 of the application for the listed drug or an
23 owner of one or more of the patents as to which
24 any applicant submitted a certification quali-
25 fying such applicant for the 180-day exclusivity

1 period whereby that applicant agrees, directly
2 or indirectly, (aa) not to seek an approval of its
3 application that is made effective on the earliest
4 possible date under this subparagraph, subpara-
5 graph (F) of this paragraph, section 505A, or
6 section 527, (bb) not to begin the commercial
7 marketing of its drug on the earliest possible
8 date after receiving an approval of its applica-
9 tion that is made effective under this subpara-
10 graph, subparagraph (F) of this paragraph, sec-
11 tion 505A, or section 527, or (cc) to both items
12 (aa) and (bb).

13 “(II) AGREEMENT THAT DISQUALIFIES AP-
14 PPLICANT FROM FIRST APPLICANT STATUS.—An
15 agreement described in this subclause is an
16 agreement between an applicant and the holder
17 of the application for the listed drug or an
18 owner of one or more of the patents as to which
19 any applicant submitted a certification quali-
20 fying such applicant for the 180-day exclusivity
21 period whereby that applicant agrees, directly
22 or indirectly, not to seek an approval of its ap-
23 plication or not to begin the commercial mar-
24 keting of its drug until a date that is after the
25 expiration of the 180-day exclusivity period

1 awarded to another applicant with respect to
2 such drug (without regard to whether such 180-
3 day exclusivity period is awarded before or after
4 the date of the agreement).

5 “(viii) LIMITATION ON ACCELERATION.—If an
6 agreement described in clause (vii)(I) includes more
7 than 1 possible date when an applicant may seek an
8 approval of its application or begin the commercial
9 marketing of its drug—

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

13 “(aa) the latest date set forth in the
14 agreement on which that applicant can re-
15 ceive an approval that is made effective
16 under this subparagraph, subparagraph
17 (F) of this paragraph, section 505A, or
18 section 527, or begin the commercial mar-
19 keting of such drug, without regard to any
20 other provision of such agreement pursu-
21 ant to which the commercial marketing
22 could begin on an earlier date; or

23 “(bb) 180 days after another first ap-
24 plicant begins commercial marketing of
25 such drug; and

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

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

16 “(11)(A) The holder of an abbreviated application
17 under this subsection shall submit to the Secretary a noti-
18 fication that includes—

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

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

1 “(ii) the text, or a written detailed description
2 in the event of an agreement that has not been re-
3 duced to text, of any other agreements that are con-
4 tingent upon, provide a contingent condition for, or
5 are otherwise related to an agreement described in
6 clause (i).

7 “(B) The notification described under subparagraph
8 (A) shall be submitted not later than 10 business days
9 after execution of the agreement described in subpara-
10 graph (A)(i). Such notification is in addition to any notifi-
11 cation required under section 1112 of the Medicare Pre-
12 scription Drug, Improvement, and Modernization Act of
13 2003.

14 “(C) Any information or documentary material filed
15 with the Secretary pursuant to this paragraph shall be ex-
16 empt from disclosure under section 552 of title 5, United
17 States Code, and no such information or documentary ma-
18 terial may be made public, except as may be relevant to
19 any administrative or judicial action or proceeding. Noth-
20 ing in this paragraph is intended to prevent disclosure to
21 either body of the Congress or to any duly authorized com-
22 mittee or subcommittee of the Congress.”.

23 (3) PROHIBITED ACTS.—Section 301(e) of such
24 Act (21 U.S.C. 331(e)) is amended by striking “505
25 (i) or (k)” and inserting “505 (i), (j)(11), or (k)”.

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

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

12 (c) APPLICABILITY.—

13 (1) LIMITATIONS ON ACCELERATION OF DE-
14 FERRED COMMERCIAL MARKETING DATE.—The
15 amendment made by subsection (a)(1) shall apply
16 only with respect to—

17 (A) an application filed under section
18 505(j) of the Federal Food, Drug, and Cos-
19 metic Act (21 U.S.C. 355(j)) to which the
20 amendments made by section 1102(a) of the
21 Medicare Prescription Drug, Improvement, and
22 Modernization Act of 2003 (Public Law 108–
23 173) apply; and

24 (B) an agreement described under section
25 505(j)(5)(B)(vii)(I) of the Federal Food, Drug,

1 and Cosmetic Act (as added by subsection
2 (a)(1)) executed after the date of enactment of
3 this Act.

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

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