

114TH CONGRESS
1ST SESSION

S. 131

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

JANUARY 8, 2015

Mr. VITTER (for himself and Mr. FRANKEN) 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) IN GENERAL.—Section 505(j)(5)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(B)) is amended—

(A) in clause (iv)(II)—

(i) by striking item (bb); and

(ii) by redesignating items (cc) and (dd) as items (bb) and (cc), respectively;

and

(B) by adding at the end the following:

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

“(I)(aa) that, on the first day on which a substantially complete application containing a certification described in paragraph (2)(A)(vii)(IV) is submitted for approval of a drug, submits a substantially complete application that contains and lawfully maintains a certification described in paragraph (2)(A)(vii)(IV) for the drug; and

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

“(II)(aa) for the drug that is not described in subclause (I) and that, with respect to the

1 applicant and drug, each requirement described
2 in clause (vi) is satisfied; and

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

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

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

18 “(II) With regard to each such unexpired
19 patent for which the applicant described in
20 clause (v)(II) submitted a certification de-
21 scribed in paragraph (2)(A)(vii)(IV), no action
22 for patent infringement was brought against
23 such applicant within the 45-day period speci-
24 fied in paragraph (5)(B)(iii); or if an action
25 was brought within such time period, such an

1 action was withdrawn or dismissed by a court
2 (including a district court) without a decision
3 that the patent was valid and infringed; or if an
4 action was brought within such time period and
5 was not withdrawn or so dismissed, such appli-
6 cant has obtained the decision of a court (in-
7 cluding a district court) that the patent is in-
8 valid or not infringed (including any substantive
9 determination that there is no cause of action
10 for patent infringement or invalidity, and in-
11 cluding a settlement order or consent decree
12 signed and entered by the court stating that the
13 patent is invalid or not infringed).

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

21 (2) CONFORMING AMENDMENT.—Section
22 505(j)(5)(D)(i)(IV) of such Act (21 U.S.C.
23 355(j)(5)(D)(i)(IV)) is amended by striking “The
24 first applicant” and inserting “The first applicant,
25 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 (Public Law 108–173) apply.

SEC. 3. 180-DAY EXCLUSIVITY PERIOD AMENDMENTS REGARDING AGREEMENTS TO DEFER COMMERCIAL MARKETING.

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

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

“(vii) AGREEMENT BY FIRST APPLICANT TO DEFER COMMERCIAL MARKETING; LIMITATION ON ACCELERATION OF DEFERRED COMMERCIAL MARKETING DATE.—

“(I) AGREEMENT TO DEFER APPROVAL OR COMMERCIAL MARKETING DATE.—An agreement described in this subclause is an agree-

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

18 “(II) AGREEMENT THAT DISQUALIFIES AP-
19 PLICANT FROM FIRST APPLICANT STATUS.—An
20 agreement described in this subclause is an
21 agreement between an 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

period whereby that applicant agrees, directly or indirectly, not to seek an approval of its application or not to begin the commercial marketing of its drug until a date that is after the expiration of the 180-day exclusivity period awarded to another applicant with respect to such drug (without regard to whether such 180-day exclusivity period is awarded before or after the date of the agreement).

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

“(I) the applicant may seek an approval of its application or begin such commercial marketing on the date that is the earlier of—

“(aa) the latest date set forth in the agreement on which that applicant can receive an approval that is made effective under this subparagraph, subparagraph (F) of this paragraph, section 505A, or section 527, or begin the commercial marketing of such drug, without regard to any other provision of such agreement pursu-

1 ant to which the commercial marketing
 2 could begin on an earlier date; or

3 “(bb) 180 days after another first ap-
 4 plicant begins commercial marketing of
 5 such drug; and

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

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

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

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

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

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

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

21 “(C) Any information or documentary material filed
22 with the Secretary pursuant to this paragraph shall be ex-
23 empt from disclosure under section 552 of title 5, United
24 States Code, and no such information or documentary ma-
25 terial may be made public, except as may be relevant to

1 any administrative or judicial action or proceeding. Noth-
 2 ing in this paragraph is intended to prevent disclosure to
 3 either body of the Congress or to any duly authorized com-
 4 mittee or subcommittee of the Congress.”.

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

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

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

19 (c) APPLICABILITY.—

20 (1) LIMITATIONS ON ACCELERATION OF DE-
 21 FERRED COMMERCIAL MARKETING DATE.—The
 22 amendment made by subsection (a)(1) shall apply
 23 only with respect to—

24 (A) an application filed under section
 25 505(j) of the Federal Food, Drug, and Cos-

1 metic Act (21 U.S.C. 355(j)) to which the
2 amendments made by section 1102(a) of the
3 Medicare Prescription Drug, Improvement, and
4 Modernization Act of 2003 (Public Law 108–
5 173) apply; and

6 (B) an agreement described under section
7 505(j)(5)(B)(vii)(I) of the Federal Food, Drug,
8 and Cosmetic Act (as added by subsection
9 (a)(1)) executed after the date of enactment of
10 this Act.

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

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