

BINGAMAN/  
AMND. # 1

TAM12160

S.L.C.

AMENDMENT NO. #1

Calendar No. \_\_\_\_\_

Purpose: 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—112th Cong., 2d Sess.

(no.) \_\_\_\_\_

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes.

Referred to the Committee on \_\_\_\_\_ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by SENATOR BINGAMAN

Viz:

- 1 In title IX, add at the end the following:
- 2 **SEC. 907. ENSURING THAT VALID GENERIC DRUGS MAY**
- 3 **ENTER THE MARKET.**
- 4 (a) 180-DAY EXCLUSIVITY PERIOD AMENDMENTS
- 5 REGARDING FIRST APPLICANT STATUS.—
- 6 (1) AMENDMENTS TO THE FEDERAL FOOD,
- 7 DRUG, AND COSMETIC ACT.—
- 8 (A) IN GENERAL.—Section 505(j)(5)(B)
- 9 (21 U.S.C. 355(j)(5)(B)) is amended—
- 10 (i) in clause (iv)(II)—

1 (I) by striking item (bb); and  
2 (II) by redesignating items (cc)  
3 and (dd) as items (bb) and (cc), re-  
4 spectively; and  
5 (ii) by adding at the end the fol-  
6 lowing:

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

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

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

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

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

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

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

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

1 lidity, and including a settlement order or consent  
2 decree signed and entered by the court stating that  
3 the patent is invalid or not infringed).

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

11 (B) CONFORMING AMENDMENT.—Section  
12 505(j)(5)(D)(i)(IV) (21 U.S.C.  
13 355(j)(5)(D)(i)(IV)) is amended by striking  
14 “The first applicant” and inserting “The first  
15 applicant, as defined in subparagraph  
16 (B)(v)(I),”.

17 (2) APPLICABILITY.—The amendments made  
18 by paragraph (1) shall apply only with respect to an  
19 application filed under section 505(j) of the Federal  
20 Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) to  
21 which the amendments made by section 1102(a) of  
22 the Medicare Prescription Drug, Improvement, and  
23 Modernization Act of 2003 (Public Law 108–173)  
24 apply.

1 (b) 180-DAY EXCLUSIVITY PERIOD AMENDMENTS  
2 REGARDING AGREEMENTS TO DEFER COMMERCIAL MAR-  
3 KETING.—

4 (1) AMENDMENTS TO FEDERAL FOOD, DRUG,  
5 AND COSMETIC ACT.—

6 (A) LIMITATIONS ON AGREEMENTS TO  
7 DEFER COMMERCIAL MARKETING DATE.—Sec-  
8 tion 505(j)(5)(B) (21 U.S.C. 355(j)(5)(B)), as  
9 amended by subsection (a), is further amended  
10 by adding at the end the following:

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

15 “(I) AGREEMENT TO DEFER APPROVAL OR  
16 COMMERCIAL MARKETING DATE.—An agree-  
17 ment described in this subclause is an agree-  
18 ment between a first applicant and the holder  
19 of the application for the listed drug or an  
20 owner of one or more of the patents as to which  
21 any applicant submitted a certification quali-  
22 fying such applicant for the 180-day exclusivity  
23 period whereby that applicant agrees, directly  
24 or indirectly, (aa) not to seek an approval of its  
25 application that is made effective on the earliest

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

10 “(II) AGREEMENT THAT DISQUALIFIES AP-  
11 PPLICANT FROM FIRST APPLICANT STATUS.—An  
12 agreement described in this subclause is an  
13 agreement between an applicant and the holder  
14 of the application for the listed drug or an  
15 owner of one or more of the patents as to which  
16 any applicant submitted a certification quali-  
17 fying such applicant for the 180-day exclusivity  
18 period whereby that applicant agrees, directly  
19 or indirectly, not to seek an approval of its ap-  
20 plication or not to begin the commercial mar-  
21 keting of its drug until a date that is after the  
22 expiration of the 180-day exclusivity period  
23 awarded to another applicant with respect to  
24 such drug (without regard to whether such 180-

1           day exclusivity period is awarded before or after  
2           the date of the agreement).

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

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

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

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

24                           “(II) the latest date set forth in the agree-  
25                           ment on which that applicant can receive an ap-

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

11                   (B) NOTIFICATION OF FDA.—Section  
12           505(j) (21 U.S.C. 355(j)) is amended by adding  
13           at the end the following:

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

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

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

24                   “(ii) the text, or a written detailed description  
25           in the event of an agreement that has not been re-

1       duced to text, of any other agreements that are con-  
2       tingent upon, provide a contingent condition for, or  
3       are otherwise related to an agreement described in  
4       clause (i).

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

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

21                   (C) PROHIBITED ACTS.—Section 301(e)  
22                   (21 U.S.C. 331(e)) is amended by striking “505  
23                   (i) or (k)” and inserting “505 (i), (j)(11), or  
24                   (k)”.

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

13           (A) LIMITATIONS ON ACCELERATION OF  
14      DEFERRED COMMERCIAL MARKETING DATE.—

15      The amendment made by paragraph (1)(A)  
16      shall apply only with respect to—

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

24           (ii) an agreement described under sec-  
25           tion 505(j)(5)(B)(vii)(I) of the Federal

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

4 (B) NOTIFICATION OF FDA.—The amend-  
5 ments made by subparagraphs (B) and (C) of  
6 paragraph (1) shall apply only with respect to  
7 an agreement described under section  
8 505(j)(5)(B)(vii)(I) of the Federal Food, Drug,  
9 and Cosmetic Act (as added by paragraph  
10 (1)(A)) executed after the date of enactment of  
11 this Act.

12 On page 73, line 5, strike “505(j)(5)(B)(iv)(II)(cc)”  
13 and insert “505(j)(5)(B)(iv)(II)(bb)”.