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:

In title IX, add at the end the following:

SEC. 907. ENSURING THAT VALID GENERIC DRUGS MAY ENTER THE MARKET.

(a) 180-DAY EXCLUSIVITY PERIOD AMENDMENTS REGARDING FIRST APPLICANT STATUS.—

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

(A) IN GENERAL.—Section 505(j)(5)(B) (21 U.S.C. 355(j)(5)(B)) is amended—

(i) in clause (iv)(II)—

(I) by striking item (bb); and

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

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

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

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

"(I) The applicant described in clause (v)(II) submitted and lawfully maintains a certification described in paragraph (2)(A)(vii)(IV) or a statement described in paragraph (2)(A)(viii) for each unexpired patent for which a first applicant described in clause (v)(I) had submitted a certification described in paragraph (2)(A)(vii)(IV) on the first day on which a substantially complete application containing such a certification was submitted.

"(II) With regard to each such unexpired patent for which the applicant described in clause (v)(II) submitted a certification described in paragraph (2)(A)(vii)(IV), no action for patent infringement was brought against such applicant within the 45 day period specified in paragraph (5)(B)(iii); or if an action was brought within such time period, such an action was withdrawn or dismissed by a court (including a district court) without a decision that the patent was valid and infringed; or if an action was brought within such time period and was not withdrawn or so dismissed, such applicant has obtained the decision of a court (including a district court) that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or inva-

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

"(III) If an applicant described in clause (v)(I) has begun commercial marketing of such drug, the applicant described in clause (v)(II) does not begin commercial marketing of such drug until the date that is 30 days after the date on which the applicant described in clause (v)(I) began such commercial marketing.".

(B) CONFORMING AMENDMENT.—Section 505(j)(5)(D)(i)(IV) (21 U.S.C. 355(j)(5)(D)(i)(IV)) is amended by striking "The first applicant" and inserting "The first applicant, as defined in subparagraph (B)(v)(I),".

(2) APPLICABILITY.—The amendments made by paragraph (1) 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.

(b) 180-DAY EXCLUSIVITY PERIOD AMENDMENTS REGARDING AGREEMENTS TO DEFER COMMERCIAL MARKETING.—

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

(A) LIMITATIONS ON AGREEMENTS TO DEFER COMMERCIAL MARKETING DATE.—Section 505(j)(5)(B) (21 U.S.C. 355(j)(5)(B)), as amended by subsection (a), 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 agreement between a first applicant and the holder of the application for the listed drug or an owner of one or more of the patents as to which any applicant submitted a certification qualifying such applicant for the 180-day exclusivity period whereby that applicant agrees, directly or indirectly, (aa) not to seek an approval of its application that is made effective on the earliest

possible date under this subparagraph, subparagraph (F) of this paragraph, section 505A, or section 527, (bb) not to begin the commercial marketing of its drug on the earliest possible date after receiving an approval of its application that is made effective under this subparagraph, subparagraph (F) of this paragraph, section 505A, or section 527, or (cc) to both items (aa) and (bb).

"(II) AGREEMENT THAT DISQUALIFIES APPLICANT FROM FIRST APPLICANT STATUS.—An agreement described in this subclause is an agreement between an applicant and the holder of the application for the listed drug or an owner of one or more of the patents as to which any applicant submitted a certification qualifying 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 pursuant to which the commercial marketing could begin on an earlier date; or

"(bb) 180 days after another first applicant begins commercial marketing of such drug; and

"(II) the latest date set forth in the agreement on which that applicant can receive an ap-

proval 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 pursuant to which commercial marketing could begin on an earlier date, shall be the date used to determine whether an applicant is disqualified from first applicant status pursuant to clause (vii)(II).".

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

"(11)(A) The holder of an abbreviated application under this subsection shall submit to the Secretary a notification that includes—

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

"(II) if such an agreement has not been reduced to text, a written detailed description of such agreement that is sufficient to disclose all the terms and conditions of the agreement; and

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

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

"(B) The notification described under subparagraph (A) shall be submitted not later than 10 business days after execution of the agreement described in subparagraph (A)(i). Such notification is in addition to any notification required under section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

"(C) Any information or documentary material filed with the Secretary pursuant to this paragraph shall be exempt from disclosure under section 552 of title 5, United States Code, and no such information or documentary material may be made public, except as may be relevant to any administrative or judicial action or proceeding. Nothing in this paragraph is intended to prevent disclosure to either body of the Congress or to any duly authorized committee or subcommittee of the Congress.".

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

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

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

(3) APPLICABILITY.—

(A) LIMITATIONS ON ACCELERATION OF DEFERRED COMMERCIAL MARKETING DATE.—The amendment made by paragraph (1)(A) shall apply only with respect to—

(i) 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; and

(ii) an agreement described under section 505(j)(5)(B)(vii)(I) of the Federal

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

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

On page 73, line 5, strike "505(j)(5)(B)(iv)(II)(cc)" and insert "505(j)(5)(B)(iv)(II)(bb)".