

AMENDMENT NO. _____ Calendar No. _____

Purpose: To amend the Federal Food, Drug, and Cosmetic Act with respect to the 180-day exclusivity period.

IN THE SENATE OF THE UNITED STATES—117th Cong., 2d Sess.

S. 4348

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs, medical devices, generic drugs, and biosimilar biological products, 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 Ms. SMITH (for herself and Mr. BRAUN)

Viz:

1 At the appropriate place in title V, insert the fol-
2 lowing:

3 **SEC. 5 ____ . 180-DAY EXCLUSIVITY PERIOD.**

4 (a) IN GENERAL.—Section 505(j)(5)(B)(iv) of the
5 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
6 355(j)(5)(B)(iv)) is amended—

7 (1) in subclause (I)—

8 (A) by inserting “and subclause (III)”

9 after “subparagraph (D)”; and

1 (B) by inserting before the period at the
2 end the following: “or an applicant whose appli-
3 cation was approved pursuant to subclause
4 (III). If an applicant described in subclause
5 (III) is eligible for effective approval on the
6 same day a tentatively approved first applicant
7 who has requested final approval is determined
8 by the Secretary to be eligible for effective ap-
9 proval by meeting all the approval requirements
10 of this subsection, such applicant may not re-
11 ceive effective approval until 180 days after the
12 first applicant begins commercial marketing of
13 the drug.”; and

14 (2) by adding at the end the following new sub-
15 clause:

16 “(III) APPLICANT APPROVAL.—The Sec-
17 retary may approve an application containing a
18 certification described in paragraph
19 (2)(A)(vii)(IV) that is for a drug for which a
20 first applicant has submitted an application
21 containing such a certification, notwithstanding
22 the eligibility of a first applicant for the 180-
23 day exclusivity period described in subclause
24 (II)(aa), if each of the following conditions is
25 met:

1 “(aa) The approval of such applica-
2 tion could be made effective, but for the
3 eligibility of a first applicant for 180-day
4 exclusivity under this clause.

5 “(bb) The applicant of such applica-
6 tion has submitted a certification to the
7 abbreviated new drug application that
8 there are no conditions that would prevent
9 the applicant from commercial marketing
10 within 75 days after the date of approval
11 and that the applicant intends to so mar-
12 ket the drug.

13 “(cc) At least 33 months have passed
14 since the date of submission of an applica-
15 tion for the drug by at least one first ap-
16 plicant.

17 “(dd) Approval of an application for
18 the drug submitted by at least one first ap-
19 plicant is not precluded under clause (iii).

20 “(ee) No application for the drug sub-
21 mitted by any first applicant is effectively
22 approved on the date that the conditions
23 under items (aa), (bb), (cc), and (dd) are
24 all met and maintained.”.

1 (b) SPECIAL APPROVAL STATUS RULE FOR CERTAIN
2 SUBSEQUENT APPLICANTS.—Section 505(j)(5)(D) of the
3 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355
4 (j)(5)(D)) is amended at the end by adding the following:

5 “(v) SPECIAL APPROVAL STATUS RULE
6 FOR CERTAIN SUBSEQUENT APPLICANTS.—An
7 application that is approved pursuant to sub-
8 clause (III) of subparagraph (B)(iv) is deemed
9 to be tentatively approved and to no longer
10 have an effective approval pursuant to such
11 subclause (III) on the date that is 76 days after
12 the date on which the approval has been made
13 effective pursuant to such subclause (III) if the
14 applicant fails to commercially market such
15 drug within the 75-day period after the date on
16 which the approval is made effective. If the ap-
17 plicant of an application approved pursuant to
18 such subclause (III) submits a notification that
19 it can no longer commence commercial mar-
20 keting within 75 days after the date of ap-
21 proval, as required under subparagraph
22 (B)(iv)(III)(bb), its application is deemed to be
23 tentatively approved and to no longer be effec-
24 tively approved on the date that such a notifica-
25 tion is received. If an applicant does not com-

1 mence commercial marketing within the 75-day
2 period, it shall not be eligible for a subsequent
3 effective approval for the application under sub-
4 clause (III) of subparagraph (B)(iv) unless, in
5 addition to meeting each of the conditions in
6 such subclause (III), it submits a certification
7 to its abbreviated new drug application that an
8 event that could not have been reasonably fore-
9 seen by the applicant prevented it from com-
10 mencing commercial marketing and that it has
11 fully resolved this issue. The applicant shall
12 submit notification to the abbreviated new drug
13 application confirming that such applicant has
14 commenced commercial marketing of the drug
15 not later than one business day after com-
16 mencing such marketing.”.

17 (c) APPLICABILITY.—The amendments made by sub-
18 sections (a) and (b) shall apply only with respect to an
19 application filed under section 505(j) of the Federal Food,
20 Drug, and Cosmetic Act (21 U.S.C. 355(j)) after the date
21 of enactment of this Act that identifies a listed drug for
22 which no certification under paragraph (2)(A)(vii)(IV) of
23 such section was made before such date of enactment.