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Thia Smith

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.