

119TH CONGRESS
1ST SESSION

H. R. 1051

To amend the Federal Food, Drug, and Cosmetic Act to allow for the approval of an abbreviated new drug application submitted by a subsequent applicant in the case of a failure by a first applicant to commence commercial marketing within a certain period, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 6, 2025

Ms. BUDZINSKI introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to allow for the approval of an abbreviated new drug application submitted by a subsequent applicant in the case of a failure by a first applicant to commence commercial marketing within a certain period, and for other purposes.

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. 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—

1 (1) in subclause (I)—

2 (A) by inserting “and subclause (III)”
3 after “subparagraph (D)”; and

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

17 (2) by adding at the end the following new sub-
18 clause:

19 “(III) APPLICANT APPROVAL.—The Sec-
20 retary may approve an application containing a
21 certification described in paragraph
22 (2)(A)(vii)(IV) that is for a drug for which a
23 first applicant has submitted an application
24 containing such a certification, notwithstanding
25 the eligibility of a first applicant for the 180-

1 day exclusivity period described in subclause
2 (II)(aa), if each of the following conditions is
3 met:

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

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

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

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

23 “(ee) No application for the drug sub-
24 mitted by any first applicant is effectively
25 approved on the date that the conditions

1 under items (aa), (bb), (cc), and (dd) are
2 all met and maintained.”.

3 (b) SPECIAL FORFEITURE RULE FOR CERTAIN SUB-
4 SEQUENT APPLICANTS.—Section 505(j)(5)(D) of the Fed-
5 eral Food, Drug, and Cosmetic Act (21 U.S.C. 355
6 (j)(5)(D)) is amended by adding at the end the following:

7 “(v) SPECIAL FORFEITURE RULE FOR
8 CERTAIN SUBSEQUENT APPLICANTS.—

9 “(I) IN GENERAL.—Except as
10 specified in subclause (II), an applica-
11 tion that is approved pursuant to sub-
12 clause (III) of subparagraph (B)(iv) is
13 deemed to be tentatively approved and
14 to no longer have an effective ap-
15 proval pursuant to such subclause
16 (III) beginning on the day after the
17 end of the 75-day period specified in
18 item (bb) of such subclause (III) if
19 the applicant fails to commence com-
20 mercial marketing as required under
21 such item.

22 “(II) OPPORTUNITY TO CURE.—

23 “(aa) IN GENERAL.—If the
24 applicant of an application ap-
25 proved pursuant to subclause

1 (III) of subparagraph (B)(iv)
2 submits, pursuant to item (bb) of
3 such subclause, a notification
4 that it can no longer commence
5 commercial marketing within the
6 75-day period specified in such
7 item, such application is deemed
8 to be tentatively approved and to
9 no longer be effectively approved
10 beginning on the date that such
11 a notification is received.

12 “(bb) INELIGIBILITY FOR
13 SUBSEQUENT EFFECTIVE AP-
14 PROVAL.—If an applicant de-
15 scribed in item (aa) does not
16 commence commercial marketing
17 within such 75-day period, the
18 applicant shall not be eligible for
19 a subsequent effective approval
20 for the application involved under
21 subclause (III) of subparagraph
22 (B)(iv) unless, in addition to
23 meeting each of the conditions in
24 such subclause (III), the appli-
25 cant submits a certification to its

1 abbreviated new drug application
2 that—

3 “(AA) an event that
4 could not have been reason-
5 ably foreseen by the appli-
6 cant prevented it from com-
7 mencing commercial mar-
8 keting; and

9 “(BB) it has fully re-
10 solved any issues preventing
11 such commercial marketing
12 from commencing as a result
13 of such event.

14 “(cc) TIMING FOR SUBMIS-
15 SION.—An applicant described in
16 item (aa) shall, not later than
17 one business day after com-
18 mencing marketing of the drug
19 that is the subject of the applica-
20 tion described in such item, sub-
21 mit a notification to the abbrevi-
22 ated new drug application con-
23 firming that such applicant has
24 commenced commercial mar-
25 keting of the drug.”.

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

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