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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

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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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. 180-DAY EXCLUSIVITY PERIOD.

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

(1) in subclause (I)—

(A) by inserting ''and subclause (III)'' after ''subparagraph (D)''; and

(B) by inserting before the period at the end the following: ''or an applicant whose application was approved pursuant to subclause (III). If an applicant described in subclause (III) is eligible for effective approval on the same day a tentatively approved first applicant who has requested final approval is determined by the Secretary to be eligible for effective approval by meeting all the approval requirements of this subsection, such applicant may not receive effective approval until 180 days after the first applicant begins commercial marketing of the drug''; and

(2) by adding at the end the following new subclause:

''(III) APPLICANT APPROVAL.—The Secretary may approve an application containing a certification described in paragraph (2)(A)(vii)(IV) that is for a drug for which a first applicant has submitted an application containing such a certification, notwithstanding the eligibility of a first applicant for the 180-

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

"(aa) The approval of such application could be made effective, but for the eligibility of a first applicant for 180-day exclusivity under this clause.

"(bb) The applicant of such application has submitted a certification to the abbreviated new drug application that there are no conditions that would prevent the applicant from commercial marketing within 75 days after the date of approval and that the applicant intends to so market the drug.

"(cc) At least 33 months have passed since the date of submission of an application for the drug by at least one first applicant.

"(dd) Approval of an application for the drug submitted by at least one first applicant is not precluded under clause (iii).

"(ee) No application for the drug submitted by any first applicant is effectively approved on the date that the conditions

under items (aa), (bb), (cc), and (dd) are all met and maintained.''.

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

''(v) SPECIAL FORFEITURE RULE FOR CERTAIN SUBSEQUENT APPLICANTS.—

''(I) IN GENERAL.—Except as specified in subclause (II), an application that is approved pursuant to subclause (III) of subparagraph (B)(iv) is deemed to be tentatively approved and to no longer have an effective approval pursuant to such subclause (III) beginning on the day after the end of the 75-day period specified in item (bb) of such subclause (III) if the applicant fails to commence commercial marketing as required under such item.

''(II) OPPORTUNITY TO CURE.—

''(aa) IN GENERAL.—If the applicant of an application approved pursuant to subclause

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

''(bb) INELIGIBILITY FOR SUBSEQUENT EFFECTIVE APPROVAL.—If an applicant described in item (aa) does not commence commercial marketing within such 75-day period, the applicant shall not be eligible for a subsequent effective approval for the application involved under subclause (III) of subparagraph (B)(iv) unless, in addition to meeting each of the conditions in such subclause (III), the applicant submits a certification to its

abbreviated new drug application that—

"(AA) an event that could not have been reasonably foreseen by the applicant prevented it from commencing commercial marketing; and

"(BB) it has fully resolved any issues preventing such commercial marketing from commencing as a result of such event.

"(cc) TIMING FOR SUBMISSION.—An applicant described in item (aa) shall, not later than one business day after commencing marketing of the drug that is the subject of the application described in such item, submit a notification to the abbreviated new drug application confirming that such applicant has commenced commercial marketing of the drug.".

(c) APPLICABILITY.—The amendments made by subsections (a) and (b) 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)) after the date of enactment of this Act that identifies a listed drug for which no certification under paragraph (2)(A)(vii)(IV) of such section was made before such date of enactment.

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