II

117TH CONGRESS
1ST SESSION

S. 1462

To amend the Federal Food, Drug, and Cosmetic Act to simplify the generic drug application process.

IN THE SENATE OF THE UNITED STATES

APRIL 29, 2021

Mr. CASSIDY (for himself and Ms. SMITH) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to simplify the generic drug application process.

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

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Simplifying the Generic Drug Application Process Act''.

SEC. 2. SUBMISSION FOR SUITABILITY.

Subparagraph (C) of section 505(j)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(2)) is amended to read as follows:

''(C) SUBMISSION FOR SUITABILITY DETERMINATIONS.—

''(i) IN GENERAL.—A person may submit an abbreviated application for a new drug that has a different dosage form or strength from that of a listed drug.

''(ii) SECRETARY'S DETERMINATION ON SUBMISSION.—The Secretary shall approve or disapprove the submission of such an abbreviated application during the course of its determination whether to receive the application pursuant to section 314.101 of title 21, Code of Federal Regulations (or any successor regulations).

''(iii) APPROVAL OF SUBMISSION.—The Secretary shall approve the submission of such an abbreviated application, provided the application is otherwise determined to be eligible to be received, unless the Secretary finds that—

''(I) clinical investigations are required to be conducted to show the safety and effectiveness of the drug or of any of its dosage forms or strengths which differ from the listed drug; or

''(II) any of the proposed changes from the listed drug would jeopardize the safe or effec-

tive use of the product so as to necessitate significant labeling changes to address the newly introduced safety or effectiveness problem.

''(iv) DISAPPROVAL OF SUBMISSION.—If the Secretary disapproves the submission of an abbreviated application under this subparagraph, the application shall be considered not to have been received within the meaning of paragraph (5)(A).''.

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