

117TH CONGRESS
1ST SESSION

S. _____

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

IN THE SENATE OF THE UNITED STATES

Mr. CASSIDY (for himself and Ms. SMITH) introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

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

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. SHORT TITLE.**

4 This Act may be cited as the “Simplifying the Ge-
5 neric Drug Application Process Act”.

6 **SEC. 2. SUBMISSION FOR SUITABILITY.**

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

1 “(C) SUBMISSION FOR SUITABILITY DETERMINA-
2 TIONS.—

3 “(i) IN GENERAL.—A person may submit an
4 abbreviated application for a new drug that has a
5 different dosage form or strength from that of a list-
6 ed drug.

7 “(ii) SECRETARY’S DETERMINATION ON SUB-
8 MISSION.—The Secretary shall approve or dis-
9 approve the submission of such an abbreviated appli-
10 cation during the course of its determination wheth-
11 er to receive the application pursuant to section
12 314.101 of title 21, Code of Federal Regulations (or
13 any successor regulations).

14 “(iii) APPROVAL OF SUBMISSION.—The Sec-
15 retary shall approve the submission of such an ab-
16 breviated application, provided the application is oth-
17 erwise determined to be eligible to be received, un-
18 less the Secretary finds that—

19 “(I) clinical investigations are required to
20 be conducted to show the safety and effective-
21 ness of the drug or of any of its dosage forms
22 or strengths which differ from the listed drug;
23 or

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

1 tive use of the product so as to necessitate sig-
2 nificant labeling changes to address the newly
3 introduced safety or effectiveness problem.

4 “(iv) DISAPPROVAL OF SUBMISSION.—If the
5 Secretary disapproves the submission of an abbre-
6 viated application under this subparagraph, the ap-
7 plication shall be considered not to have been re-
8 ceived within the meaning of paragraph (5)(A).”.