

117TH CONGRESS  
1ST SESSION

# S. 1463

To amend the Federal Food, Drug, and Cosmetic Act to modernize therapeutic equivalence rating determinations.

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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 modernize therapeutic equivalence rating determinations.

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 “Modernizing Thera-  
5 peutic Equivalence Rating Determination Act”.

6 **SEC. 2. THERAPEUTIC EQUIVALENCE DETERMINATIONS.**

7 Section 505(j)(7)(A) of the Federal Food, Drug, and  
8 Cosmetic Act (21 U.S.C. 355(j)(7)(A)) is amended by  
9 adding at the end the following:

1 “(v)(I) The Secretary shall make a determination  
2 under clause (i)(III)—

3 “(aa) with respect to an application submitted  
4 under this subsection, at the time of approval of  
5 such application or not later than 30 days after the  
6 date of such approval; or

7 “(bb) with respect to an application submitted  
8 under subsection (b)(2), at the time of approval of  
9 such application or not later than 30 days after the  
10 date of such approval, provided that the sponsor re-  
11 quests such a determination in the original applica-  
12 tion, in a form prescribed by the Secretary.

13 “(II) When the Secretary makes a determination  
14 under clause (i)(III), the Secretary shall, in revisions made  
15 to the list pursuant to clause (ii), include such information  
16 for such drug.

17 “(III) When the Secretary makes a determination  
18 under clause (i)(III) with respect to a drug, the Secretary  
19 shall, at the same time, make such a determination with  
20 respect to any other drug—

21 “(aa) whose application under subsection (b)(2)  
22 was approved;

23 “(bb) which references the same listed drug as  
24 the application for the first drug for which such de-  
25 termination is made; and

1           “(cc) for which there is a citizen petition pend-  
2           ing requesting that the Secretary make a determina-  
3           tion under clause (i)(III).”.

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