

117TH CONGRESS
2D SESSION

S. 4378

To reauthorize a provision of the Federal Food, Drug, and Cosmetic Act
pertaining to drugs containing single enantiomers.

IN THE SENATE OF THE UNITED STATES

JUNE 13, 2022

Mr. MARSHALL introduced the following bill; which was read twice and
referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To reauthorize a provision of the Federal Food, Drug, and
Cosmetic Act pertaining to drugs containing single
enantiomers.

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 “Hatch-Waxman Im-
5 provement Act of 2022”.

6 **SEC. 2. REAUTHORIZATION OF PROVISION PERTAINING TO**
7 **DRUGS CONTAINING SINGLE ENANTIOMERS.**

8 Section 505(u) of the Federal Food, Drug, and Cos-
9 metic Act (21 U.S.C. 355(u)) is amended—

1 (1) in paragraph (1)(A)(ii)(II), by adding
2 “(other than bioavailability studies)” after “any clin-
3 ical investigations”; and

4 (2) in paragraph (4), by striking “October 1,
5 2022” and inserting “October 1, 2027”.

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