

117TH CONGRESS
2D SESSION

S. 6

To improve the requirements for making a determination of interchangeability of a biological product and its reference product.

IN THE SENATE OF THE UNITED STATES

NOVEMBER 17, 2022

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

A BILL

To improve the requirements for making a determination of interchangeability of a biological product and its reference product.

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 “Biosimilar Red Tape
5 Elimination Act”.

6 **SEC. 2. BIOSIMILAR BIOLOGICAL PRODUCTS.**

7 Section 351(k) of the Public Health Service Act (42
8 U.S.C. 262(k)) is amended—

9 (1) in paragraph (2)(A)(i)(I)(bb), by striking “;
10 and” and inserting “; or”; and

1 (2) in paragraph (4)—

2 (A) at the end of subparagraph (A)(ii), by
3 striking “; and” and inserting a period;

4 (B) by striking “sufficient to show” and all
5 that follows through “(A) the biological prod-
6 uct—” and inserting “sufficient to show that
7 the biological product—”;

8 (C) by striking “Upon review of an” and
9 inserting the following:

10 “(A) IN GENERAL.—Upon review of an”;

11 and

12 (D) by amending subparagraph (B) to
13 read as follows:

14 “(B) CERTAIN STUDIES NOT REQUIRED.—

15 The Secretary may not require, for a deter-
16 mination of interchangeability described in sub-
17 paragraph (A), that a biological product under-
18 go studies that assess the risks of alternating or
19 switching between use of the biological product
20 and the reference product.”.

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