117TH CONGRESS
2D SESSION

S. _____

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

Mr. LEE introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

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

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 ''Biosimilar Red Tape Elimination Act''.

SEC. 2. BIOSIMILAR BIOLOGICAL PRODUCTS.

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

(1) in paragraph (2)(A)(i)(I)(bb), by striking ''; and'' and inserting ''; or''; and

(2) in paragraph (4)—

(A) at the end of subparagraph (A)(ii), by striking ''; and'' and inserting a period;

(B) by striking ''sufficient to show'' and all that follows through ''(A) the biological product—'' and inserting ''sufficient to show that the biological product—'';

(C) by striking ''Upon review of an'' and inserting the following:

''(A) IN GENERAL.—Upon review of an''; and

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

''(B) CERTAIN STUDIES NOT REQUIRED.—The Secretary may not require, for a determination of interchangeability described in subparagraph (A), that a biological product undergo studies that assess the risks of alternating or switching between use of the biological product and the reference product.''.