

118TH CONGRESS
1ST 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 (for himself, Mr. LUJÁN, Mr. BRAUN, and Mr. VANCE) 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.

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

1 (1) in the subsection heading, by striking “OR
2 INTERCHANGEABLE”;

3 (2) in paragraph (2)—

4 (A) by striking subparagraph (B);

5 (B) by redesignating clauses (ii) and (iii)
6 of subparagraph (A) as subparagraphs (B) and
7 (C), respectively, and adjusting the margins ac-
8 cordingly;

9 (C) in subparagraph (A)—

10 (i) in clause (i), by redesignating sub-
11 clauses (I) through (V) as clauses (i)
12 through (v), respectively, and adjusting the
13 margins accordingly;

14 (ii) in clause (i), as so redesignated by
15 clause (i) of this subparagraph, by redesign-
16 ating items (aa) through (cc) as sub-
17 clauses (I) through (III), respectively, and
18 adjusting the margins accordingly; and

19 (iii) by striking “(A) IN GENERAL”
20 and all that follows through “An applica-
21 tion submitted under this subsection shall
22 include information” and inserting the fol-
23 lowing:

1 “(A) IN GENERAL.—An application sub-
2 mitted under this subsection shall include infor-
3 mation”;

4 (D) in subparagraph (B), as so redesign-
5 ated by subparagraph (C) of this paragraph,
6 by striking “clause (i)(I)” and inserting “sub-
7 paragraph (A)(i)”;

8 (E) in subparagraph (C), as so redesign-
9 ated by subparagraph (C) of this paragraph,
10 by redesignating subclauses (I) through (III) as
11 clauses (i) through (iii), respectively, and by ad-
12 justing the margins accordingly;

13 (3) by amending paragraph (4) to read as fol-
14 lows:

15 “(4) INTERCHANGEABILITY.—

16 “(A) IN GENERAL.—A biological product
17 licensed under this subsection shall be deemed
18 to be interchangeable with the reference prod-
19 uct.

20 “(B) CONGRESSIONAL BRIEFING PRIOR TO
21 CERTAIN STUDY REQUIREMENTS.—The Sec-
22 retary may require the sponsor of an applica-
23 tion submitted under this section to conduct a
24 study to evaluate the risk, in terms of safety,
25 purity, or potency, of alternating or switching

1 between the use of the biological product that
2 is the subject of the application and the ref-
3 erence product, if, before requiring such a
4 study, the Secretary first holds a private brief-
5 ing with the chair and ranking member of the
6 Committee on Health, Education, Labor, and
7 Pensions of the Senate and the chair and the
8 ranking member of the Committee on Energy
9 and Commerce of the House of Representatives,
10 to explain why such a study is necessary for the
11 biological product, what information the Sec-
12 retary expects such a study to reveal, what al-
13 ternatives to such study have been considered,
14 and why those alternatives are not sufficient.”;

15 (4) by striking paragraph (6); and

16 (5) in paragraph (8)(D)—

17 (A) in clause (i), by striking “class; and”
18 and inserting “class.”;

19 (B) by striking clause (ii); and

20 (C) by striking “description of—” and all
21 that follows through “criteria that the Sec-
22 retary” and inserting “description of the cri-
23 teria that the Secretary”.

24 (b) CONFORMING AMENDMENTS.—

1 (1) Section 351(i)(3) of the Public Health Serv-
2 ice Act (42 U.S.C. 262(i)(3)) is amended by striking
3 “that is shown to meet the standards described in
4 subsection (k)(4)” and inserting “licensed under
5 subsection (k)”.

6 (2) Section 352A of the Public Health Service
7 Act (42 U.S.C. 263–1) is amended by striking “and
8 interchangeable biosimilar biological products” each
9 place it appears.

10 (3) Section 744G(14) of the Federal Food,
11 Drug, and Cosmetic Act (21 U.S.C. 379j–51(14)) is
12 amended by striking “, including a supplement re-
13 questing that the Secretary determine that the bio-
14 similar biological product meets the standards for
15 interchangeability described in section 351(k)(4) of
16 the Public Health Service Act”.

17 (4) By amending subsection (l) of section 505B
18 of the Federal Food, Drug, and Cosmetic Act (21
19 U.S.C. 355c) to read as follows:

20 “(l) BIOSIMILAR BIOLOGICAL PRODUCTS.—A biologi-
21 cal product for which an application is submitted under
22 section 351(k) of the Public Health Service Act shall be
23 considered to have a new active ingredient for purposes
24 of this section, except that a pediatric assessment shall

1 not be required for a claimed indication in a relevant pedi-
2 atric population if the assessment would involve—

3 “(1) a condition of use that has not been pre-
4 viously approved for the reference product; or

5 “(2) a dosage form, strength, or route of ad-
6 ministration that differs from that of the reference
7 product.”.

8 (c) APPLICATION.—The amendments made by sub-
9 section (a)(4) to section 351(k)(6) of the Public Health
10 Service Act (42 U.S.C. 262(k)(6)) shall apply only with
11 respect to applications approved under section 351(k) of
12 such Act on or after the date of enactment of this Act.
13 Any period of exclusivity granted under section 351(k)(6)
14 of such Act with respect to an application approved under
15 such section 351(k) before the date of enactment of this
16 Act shall apply in accordance with such section 351(k)(6),
17 as in effect on the day before the date of enactment of
18 this Act.