

119TH CONGRESS
1ST SESSION

S. 1954

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

JUNE 4, 2025

Mr. LEE (for himself, Mr. LUJÁN, Mr. PAUL, and Ms. HASSAN) 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 (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 (B) 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 (B) 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 subparagraph (A) of para-
 14 graph (3) to read as follows:

15 “(A) the Secretary determines that the in-
 16 formation submitted in the application (or the
 17 supplement) is sufficient to show that the bio-
 18 logical product is biosimilar to the reference
 19 product; and”;

20 (4) by amending paragraph (4) to read as fol-
 21 lows:

22 “(4) INTERCHANGEABILITY.—

23 “(A) IN GENERAL.—A biological product
 24 licensed under this subsection shall be deemed

1 to be interchangeable with the reference prod-
 2 uct, subject to subparagraph (B).

3 “(B) TIMING OF DEEMED INTERCHANGE-
 4 ABILITY.—

5 “(i) LICENSURE ON OR AFTER TRAN-
 6 SITION DATE.—A biological product li-
 7 censed under this subsection on or after
 8 the transition date described in subpara-
 9 graph (C) (referred to in this clause as the
 10 ‘applicable biological product’) shall be
 11 deemed to be interchangeable with the ref-
 12 erence product upon such licensure, unless
 13 the applicable biological product relied on
 14 the same reference product as another bio-
 15 logical product for which—

16 “(I) licensure under this sub-
 17 section was in effect on the date of
 18 enactment of the Biosimilar Red Tape
 19 Elimination Act; and

20 “(II) a first interchangeable ex-
 21 clusivity period under paragraph (6)
 22 (as in effect on the date of enactment
 23 of the Biosimilar Red Tape Elimini-
 24 nation Act) is in effect on the date of

1 licensure of the applicable biological
2 product,
3 in which case the applicable biological
4 product shall be deemed interchangeable
5 with the reference product under this para-
6 graph on the date on which the exclusivity
7 period described in subclause (II) ends.

8 “(ii) LICENSURE PRIOR TO TRANSI-
9 TION DATE.—A biological product licensed
10 under this subsection prior to the transi-
11 tion date described in subparagraph (C)
12 (referred to in this clause as the ‘applicable
13 biological product’) shall be deemed to be
14 interchangeable with the reference product
15 on such transition date, unless the applica-
16 ble biological product relied on the same
17 reference product as another biological
18 product for which—

19 “(I) licensure under this sub-
20 section was in effect on the date of
21 enactment of the Biosimilar Red Tape
22 Elimination Act; and

23 “(II) a first interchangeable ex-
24 clusivity period under paragraph (6)
25 (as in effect on the date of enactment

1 of the Biosimilar Red Tape Elimination Act) is in effect on the transition date,

2 in which case the applicable biological
3 product shall be deemed interchangeable
4 with the reference product under this paragraph on the date on which the exclusivity
5 period described in subclause (II) ends.

6 “(C) TRANSITION DATE.—The transition
7 date described in this subparagraph is the date
8 that is 60 days after the date of enactment of
9 the Biosimilar Red Tape Elimination Act.”;

10 (5) by amending paragraph (6) to read as follows:

11 “(6) TRANSITION WITH RESPECT TO PRESERVING FIRST INTERCHANGEABILITY EXCLUSIVITY
12 WITH RESPECT TO CERTAIN BIOLOGICAL PRODUCTS.—With respect to a biological product licensed
13 under this subsection before the date of enactment
14 of the Biosimilar Red Tape Elimination Act, for
15 which there was an unexpired period of first interchangeable exclusivity under this subsection (as then
16 in effect), such unexpired exclusivity period shall remain in effect for the duration of such period.”; and

17 (6) in paragraph (8)(D)—

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

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

4 (C) by striking “description of—” and all
 5 that follows through “criteria that the Sec-
 6 retary” and inserting “description of the cri-
 7 teria that the Secretary”.

8 (b) CONFORMING AMENDMENTS.—

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

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

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

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

4 “(l) BIOSIMILAR BIOLOGICAL PRODUCTS.—A biologi-
5 cal product for which an application is submitted under
6 section 351(k) of the Public Health Service Act shall not
7 be considered to have a new active ingredient for purposes
8 of this section, unless the application seeks licensure for—

9 “(1) a claimed indication that has been ap-
10 proved for the reference product in a relevant pedi-
11 atric population or for which there is a deferral of
12 the pediatric assessment under paragraph (4) for
13 the reference product; and

14 “(2) the assessment would not involve the de-
15 velopment of a biological product with a strength,
16 dosage form, route of administration, or condition of
17 use that could not be licensed under section 351(k)
18 of the Public Health Service Act.”.

19 (c) GUIDANCE.—The Secretary shall—

20 (1) not later than 18 months after the date of
21 enactment of this Act, update existing draft and
22 final guidance to reflect the amendments made by
23 this Act, including by revising or revoking the guid-
24 ance document titled “Considerations in Dem-
25 onstrating Interchangeability With a Reference

1 Product” (May 2019) and “Considerations in Dem-
2 onstrating Interchangeability With a Reference
3 Product: Update” (June 2024);

4 (2) not later than 18 months after the date of
5 enactment of this Act, issue or revise guidance on
6 review and approval of biosimilar biological products
7 under section 351(k) of the Public Health Service
8 Act (42 U.S.C. 262(k)) relating to the data and in-
9 formation that an applicant is required to submit to
10 support a determination that a biosimilar biological
11 product that is the subject of an application under
12 such section is biosimilar to the reference product
13 (as defined in section 351(i) of such Act (42 U.S.C.
14 262(i))); and

15 (3) not later than 18 months after the comment
16 period closes on the guidance under paragraphs (1)
17 and (2), issue revised draft or final versions of such
18 guidances.

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