

119TH CONGRESS  
1ST SESSION

**S.** \_\_\_\_\_

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

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IN THE SENATE OF THE UNITED STATES

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

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## 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—

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

1 (2) in paragraph (2)—

2 (A) by striking subparagraph (B);

3 (B) by redesignating clauses (ii) and (iii)

4 of subparagraph (A) as subparagraphs (B) and

5 (C), respectively, and adjusting the margins ac-

6 cordingly;

7 (C) in subparagraph (A)—

8 (i) in clause (i), by redesignating sub-

9 clauses (I) through (V) as clauses (i)

10 through (v), respectively, and adjusting the

11 margins accordingly;

12 (ii) in clause (i), as so redesignated by

13 clause (i) of this subparagraph, by redesign-

14 ating items (aa) through (cc) as sub-

15 clauses (I) through (III), respectively, and

16 adjusting the margins accordingly; and

17 (iii) by striking “(A) IN GENERAL”

18 and all that follows through “An applica-

19 tion submitted under this subsection shall

20 include information” and inserting the fol-

21 lowing:

22 “(A) IN GENERAL.—An application sub-

23 mitted under this subsection shall include infor-

24 mation”;

1 (D) in subparagraph (B), as so redesign-  
2 nated by subparagraph (B) of this paragraph,  
3 by striking “clause (i)(I)” and inserting “sub-  
4 paragraph (A)(i)”;

5 (E) in subparagraph (C), as so redesign-  
6 nated by subparagraph (B) of this paragraph,  
7 by redesignating subclauses (I) through (III) as  
8 clauses (i) through (iii), respectively, and by ad-  
9 justing the margins accordingly;

10 (3) by amending subparagraph (A) of para-  
11 graph (3) to read as follows:

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

17 (4) by amending paragraph (4) to read as fol-  
18 lows:

19 “(4) INTERCHANGEABILITY.—

20 “(A) IN GENERAL.—A biological product  
21 licensed under this subsection shall be deemed  
22 to be interchangeable with the reference prod-  
23 uct, subject to subparagraph (B).

24 “(B) TIMING OF DEEMED INTERCHANGE-  
25 ABILITY.—

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

12                   “(I) licensure under this sub-  
13                   section was in effect on the date of  
14                   enactment of the Biosimilar Red Tape  
15                   Elimination Act; and

16                   “(II) a first interchangeable ex-  
17                   clusivity period under paragraph (6)  
18                   (as in effect on the date of enactment  
19                   of the Biosimilar Red Tape Elimini-  
20                   nation Act) is in effect on the date of  
21                   licensure of the applicable biological  
22                   product,

23                  in which case the applicable biological  
24                  product shall be deemed interchangeable  
25                  with the reference product under this para-

1 graph on the date on which the exclusivity  
2 period described in subclause (II) ends.

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

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

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

24 in which case the applicable biological  
25 product shall be deemed interchangeable

1 with the reference product under this para-  
2 graph on the date on which the exclusivity  
3 period described in subclause (II) ends.

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

8 (5) by amending paragraph (6) to read as fol-  
9 lows:

10 “(6) TRANSITION WITH RESPECT TO PRE-  
11 SERVING FIRST INTERCHANGEABILITY EXCLUSIVITY  
12 WITH RESPECT TO CERTAIN BIOLOGICAL PROD-  
13 UCTS.—With respect to a biological product licensed  
14 under this subsection before the date of enactment  
15 of the Biosimilar Red Tape Elimination Act, for  
16 which there was an unexpired period of first inter-  
17 changeable exclusivity under this subsection (as then  
18 in effect), such unexpired exclusivity period shall re-  
19 main in effect for the duration of such period.”; and

20 (6) in paragraph (8)(D)—

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

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

24 (C) by striking “description of—” and all  
25 that follows through “criteria that the Sec-

1           retary” and inserting “description of the cri-  
2           teria that the Secretary”.

3           (b) CONFORMING AMENDMENTS.—

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

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

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

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

23          “(l) BIOSIMILAR BIOLOGICAL PRODUCTS.—A biologi-  
24          cal product for which an application is submitted under  
25          section 351(k) of the Public Health Service Act shall not

1 be considered to have a new active ingredient for purposes  
2 of this section, unless the application seeks licensure for—

3 “(1) a claimed indication that has been ap-  
4 proved for the reference product in a relevant pedi-  
5 atric population or for which there is a deferral of  
6 the pediatric assessment under paragraph (4) for  
7 the reference product; and

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

13 (c) GUIDANCE.—The Secretary shall—

14 (1) not later than 18 months after the date of  
15 enactment of this Act, update existing draft and  
16 final guidance to reflect the amendments made by  
17 this Act, including by revising or revoking the guid-  
18 ance document titled “Considerations in Dem-  
19 onstrating Interchangeability With a Reference  
20 Product” (May 2019) and “Considerations in Dem-  
21 onstrating Interchangeability With a Reference  
22 Product: Update” (June 2024);

23 (2) not later than 18 months after the date of  
24 enactment of this Act, issue or revise guidance on  
25 review and approval of biosimilar biological products

1 under section 351(k) of the Public Health Service  
2 Act (42 U.S.C. 262(k)) relating to the data and in-  
3 formation that an applicant is required to submit to  
4 support a determination that a biosimilar biological  
5 product that is the subject of an application under  
6 such section is biosimilar to the reference product  
7 (as defined in section 351(i) of such Act (42 U.S.C.  
8 262(i))); and

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