

Calendar No. 521

119TH CONGRESS
2D 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, Ms. HASSAN, Mr. SCHMITT, and Mr. OSSOFF) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

JULY 27, 2026

Reported by Mr. CASSIDY, with an amendment

[Strike out all after the enacting clause and insert the part printed in *italic*]

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~~”.

1 **SEC. 2. BIOSIMILAR BIOLOGICAL PRODUCTS.**

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

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

6 (2) in paragraph (2)—

7 (A) by striking subparagraph (B);

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

12 (C) in subparagraph (A)—

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

17 (ii) in clause (i), as so redesignated by
18 clause (i) of this subparagraph, by redesi-
19 gnating items (aa) through (ee) as sub-
20 clauses (I) through (III), respectively, and
21 adjusting the margins accordingly; and

22 (iii) by striking “(A) IN GENERAL”
23 and all that follows through “An applica-
24 tion submitted under this subsection shall
25 include information” and inserting the fol-
26 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

to be interchangeable with the reference product, subject to subparagraph (B).

~~“(B) TIMING OF DEEMED INTERCHANGEABILITY.—~~

~~“(i) LICENSURE ON OR AFTER TRANSITION DATE.—A biological product licensed under this subsection on or after the transition date described in subparagraph (C) (referred to in this clause as the ‘applicable biological product’) shall be deemed to be interchangeable with the reference product upon such licensure, unless the applicable biological product relied on the same reference product as another biological product for which—~~

~~“(I) licensure under this subsection was in effect on the date of enactment of the Biosimilar Red Tape Elimination Act; and~~

~~“(II) a first interchangeable exclusivity period under paragraph (6) (as in effect on the date of enactment of the Biosimilar Red Tape Elimination 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 subelause (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)—

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

(B) by striking clause (ii); and

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

(b) CONFORMING AMENDMENTS.—

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

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

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

Product” (May 2019) and “Considerations in Demonstrating Interchangeability With a Reference Product: Update” (June 2024);

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

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

SECTION 1. SHORT TITLE.

This Act may be cited as the “Biosimilar Red Tape Elimination Act”.

SEC. 2. BIOSIMILAR BIOLOGICAL PRODUCTS.

(a) *IN GENERAL.*—Section 351(k) of the Public 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) of*
 6 *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 subclauses*
 17 *(I) through (III), respectively, and adjust-*
 18 *ing the margins accordingly;*

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

“(A) *IN GENERAL*.—An application submitted under this subsection shall include information”; and

(iv) in clause (i)(II), as so redesignated by clauses (i) and (ii) of this subparagraph, by striking “item (aa) or (cc)” and inserting “subclause (I) or (III)”;

(D) in subparagraph (B), as so redesignated by subparagraph (B) of this paragraph, by striking “clause (i)(I)” and inserting “subparagraph (A)(i)”; and

(E) in subparagraph (C), as so redesignated by subparagraph (B) of this paragraph—

(i) by redesignating subclauses (I) through (III) as clauses (i) through (iii), respectively, and adjusting the margins accordingly; and

(ii) by striking “publicly-available” each place it appears and inserting “publicly available”;

(3) by amending subparagraph (A) of paragraph (3) to read as follows:

“(A) the Secretary determines that the information submitted in the application (or the supplement) is sufficient to show that the biologi-

1 *cal product is biosimilar to the reference product;*
 2 *and”;*

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

5 “(4) *INTERCHANGEABILITY.*—

6 “(A) *IN GENERAL.*—*A biological product li-*
 7 *censed under this subsection shall be deemed to*
 8 *be interchangeable with the reference product,*
 9 *subject to subparagraph (B).*

10 “(B) *TIMING OF DEEMED INTERCHANGE-*
 11 *ABILITY.*—*A biological product licensed under*
 12 *this subsection (referred to in this subparagraph*
 13 *as the ‘applicable biological product’) shall be*
 14 *deemed to be interchangeable with the reference*
 15 *product upon such licensure (or, in the case of*
 16 *a biological product so licensed before the transi-*
 17 *tion date described in subparagraph (C), on such*
 18 *transition date), unless the applicable biological*
 19 *product relied on the same reference product as*
 20 *another biological product for which—*

21 “(i) *licensure under this subsection was*
 22 *in effect on the date of enactment of the Bio-*
 23 *similar Red Tape Elimination Act; and*

24 “(ii) *a first interchangeable exclusivity*
 25 *period under paragraph (6) (as in effect on*

1 the day before the date of enactment of the
 2 *Biosimilar Red Tape Elimination Act*) is
 3 in effect on the date of licensure of the ap-
 4 plicable biological product (or on the transi-
 5 tion date described in subparagraph (C), in
 6 the case of a biological product licensed be-
 7 fore the transition date),
 8 in which case the applicable biological product
 9 shall be deemed interchangeable with the ref-
 10 erence product under this paragraph on the date
 11 on which the exclusivity period described in
 12 clause (ii) ends.

13 “(C) *TRANSITION DATE*.—The transition
 14 date described in this subparagraph is the date
 15 that is 60 days after the date of enactment of the
 16 *Biosimilar Red Tape Elimination Act*.”;

17 (5) by amending paragraph (6) to read as fol-
 18 lows:

19 “(6) *TRANSITION WITH RESPECT TO PRESERVING*
 20 *FIRST INTERCHANGEABILITY EXCLUSIVITY WITH RE-*
 21 *SPECT TO CERTAIN BIOLOGICAL PRODUCTS*.—With re-
 22 spect to a biological product licensed under this sub-
 23 section before the date of enactment of the *Biosimilar*
 24 *Red Tape Elimination Act*, for which there was an
 25 unexpired period of first interchangeable exclusivity

1 *under this subsection (as then in effect), such unex-*
 2 *pired exclusivity period shall remain in effect for the*
 3 *duration of such period.”; and*

4 *(6) in paragraph (8)(D)—*

5 *(A) in clause (i), by striking “class; and”*
 6 *and inserting “class.”;*

7 *(B) by striking clause (ii); and*

8 *(C) by striking “description of—” and all*
 9 *that follows through “criteria that the Secretary”*
 10 *and inserting “description of the criteria that*
 11 *the Secretary”.*

12 ***(b) CONFORMING AMENDMENTS.—***

13 *(1) Section 351 of the Public Health Service Act*
 14 *(42 U.S.C. 262) is amended—*

15 *(A) in subsection (i)(3), by striking “that is*
 16 *shown to meet the standards described in sub-*
 17 *section (k)(4)” and inserting “licensed under*
 18 *subsection (k)”;* and

19 *(B) in subsection (l)(1)(F), by striking*
 20 *“publicly-available” and inserting “publicly*
 21 *available”.*

22 *(2) Section 352A of the Public Health Service*
 23 *Act (42 U.S.C. 263–1) is amended by striking “and*
 24 *interchangeable biosimilar biological products” each*
 25 *place it appears.*

1 (3) *Section 744G(14) of the Federal Food, Drug,*
 2 *and Cosmetic Act (21 U.S.C. 379j–51(14)) is amend-*
 3 *ed by striking “, including a supplement requesting*
 4 *that the Secretary determine that the biosimilar bio-*
 5 *logical product meets the standards for interchange-*
 6 *ability described in section 351(k)(4) of the Public*
 7 *Health Service Act”.*

8 (4) *Subsection (l) of section 505B of the Federal*
 9 *Food, Drug, and Cosmetic Act (21 U.S.C. 355c) is*
 10 *amended to read as follows:*

11 “(l) *BIOSIMILAR BIOLOGICAL PRODUCTS.—A biologi-*
 12 *cal product for which an application, including a supple-*
 13 *ment to an application, is submitted under section 351(k)*
 14 *of the Public Health Service Act shall not be considered to*
 15 *have a new active ingredient for purposes of this section,*
 16 *unless—*

17 “(1) *the application seeks licensure for a claimed*
 18 *indication that has been approved for the reference*
 19 *product in a relevant pediatric population or for*
 20 *which there is a deferral of the pediatric assessment*
 21 *under subsection (a)(4) for the reference product; and*

22 “(2) *the assessment or investigation described in*
 23 *subsection (a) would not involve the development of a*
 24 *biological product with a strength, dosage form, route*

1 of administration, or condition of use that could not
2 be licensed under such section 351(k).”.

3 (c) *GUIDANCE.*—*The Secretary of Health and Human*
4 *Services may issue or revise guidance, as appropriate, re-*
5 *garding the data and information that an applicant may*
6 *be required to submit to support a determination of bio-*
7 *similarity in an application submitted under section*
8 *351(k) of the Public Health Service Act (42 U.S.C. 262(k)),*
9 *as amended by this Act, including any additional informa-*
10 *tion related to the device constituent part of a biosimilar*
11 *biological product that is a combination product. The*
12 *issuance or non-issuance of such guidance shall not preclude*
13 *the review of, or action on, an application submitted under*
14 *section 351(k) of the Public Health Service Act (42 U.S.C.*
15 *262(k)), as amended by this Act.*

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119TH CONGRESS
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S. 1954

A BILL

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

JULY 27, 2026

Reported with an amendment