

AMENDMENT NO. _____ Calendar No. _____

Purpose: In the nature of a substitute.

IN THE SENATE OF THE UNITED STATES—118th Cong., 2d Sess.

S. 2305

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

Referred to the Committee on _____ and
ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT IN THE NATURE OF A SUBSTITUTE intended
to be proposed by _____

Viz:

1 Strike all after the enacting clause and insert the fol-
2 lowing:

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”;

11 (2) in paragraph (2)—

1 (A) by striking subparagraph (B);

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

6 (C) in subparagraph (A)—

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

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

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

21 “(A) IN GENERAL.—An application sub-
22 mitted under this subsection shall include infor-
23 mation”;

24 (D) in subparagraph (B), as so redesign-
25 ated by subparagraph (B) of this paragraph,

1 by striking “clause (i)(I)” and inserting “sub-
2 paragraph (A)(i)”;

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

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

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

15 (4) by amending paragraph (4) to read as fol-
16 lows:

17 “(4) INTERCHANGEABILITY.—

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

22 “(B) TIMING OF DEEMED INTERCHANGE-
23 ABILITY.—

24 “(i) LICENSURE ON OR AFTER TRAN-
25 SITION DATE.—A biological product li-

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

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

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

21 in which case the applicable biological
22 product shall be deemed interchangeable
23 with the reference product under this para-
24 graph on the date on which the exclusivity
25 period described in subclause (II) ends.

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

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

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

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

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

9 “(6) TRANSITION WITH RESPECT TO PRE-
10 SERVING FIRST INTERCHANGEABILITY EXCLUSIVITY
11 WITH RESPECT TO CERTAIN BIOLOGICAL PROD-
12 UCTS.—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 inter-
16 changeable exclusivity under this subsection (as then
17 in effect), such unexpired exclusivity period shall re-
18 main in effect for the duration of such period.”; and

19 (6) in paragraph (8)(D)—

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

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

23 (C) by striking “description of—” and all
24 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.