

.....
(Original Signature of Member)

119TH CONGRESS
1ST SESSION

H. R. _____

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

IN THE HOUSE OF REPRESENTATIVES

Mr. PFLUGER introduced the following bill; which was 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 redesi-
16 gnating items (aa) through (cc) as sub-
17 clauses (I) through (III), respectively, and
18 adjusting the margins accordingly;

19 (iii) in subclause (II) of clause (i), as
20 so redesignated by clause (ii) of this sub-
21 paragraph, by striking “item (aa) or (cc)”
22 and inserting “subclause (I) or (III)”;

23 (iv) by striking “(A) IN GENERAL” and
24 all that follows through “An application
25 submitted under this subsection shall in-

1 clude information” and inserting the fol-
2 lowing:

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

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

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

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

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

22 (4) by amending paragraph (4) to read as fol-
23 lows:

24 “(4) INTERCHANGEABILITY.—

1 “(A) IN GENERAL.—A biological product
2 licensed under this subsection shall be deemed
3 to be interchangeable with the reference prod-
4 uct, subject to subparagraph (B).

5 “(B) TIMING OF DEEMED INTERCHANGE-
6 ABILITY.—

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

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

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

1 date of enactment of the Biosimilar
2 Red Tape Elimination Act) is in effect
3 on the date of licensure of the applica-
4 ble biological product,
5 in which case the applicable biological
6 product shall be deemed interchangeable
7 with the reference product under this para-
8 graph on the date on which the exclusivity
9 period described in subclause (II) ends.

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

21 “(I) licensure under this sub-
22 section was in effect on the day before
23 the date of enactment of the Bio-
24 similar Red Tape Elimination Act;
25 and

1 “(II) a first interchangeable ex-
2 clusivity period under paragraph (6)
3 (as in effect on the day before the
4 date of enactment of the Biosimilar
5 Red Tape Elimination Act) is in effect
6 on the transition date,
7 in which case the applicable biological
8 product shall be deemed interchangeable
9 with the reference product under this para-
10 graph on the date on which the exclusivity
11 period described in subclause (II) ends.

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

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

18 “(6) TRANSITION WITH RESPECT TO PRE-
19 SERVING FIRST INTERCHANGEABLE EXCLUSIVITY
20 WITH RESPECT TO CERTAIN BIOLOGICAL PROD-
21 UCTS.—With respect to a biological product licensed
22 under this subsection before the date of enactment
23 of the Biosimilar Red Tape Elimination Act, for
24 which there was an unexpired period of first inter-
25 changeable exclusivity under this subsection (as then

1 in effect), such unexpired exclusivity period shall re-
2 main in effect for the duration of such period.”; and

3 (6) in paragraph (8)(D)—

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

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

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

11 (b) CONFORMING AMENDMENTS.—

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

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

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

1 interchangeability described in section 351(k)(4) of
2 the Public Health Service Act”.

3 (4) Section 505B(l) of the Federal Food, Drug,
4 and Cosmetic Act (21 U.S.C. 355c(l)) to read as fol-
5 lows:

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

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

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

21 (c) GUIDANCE.—The Secretary shall—

22 (1) not later than 18 months after the date of
23 enactment of this Act, update existing draft and
24 final guidance to reflect the amendments made by
25 this Act, including by revising or revoking the guid-

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

6 (2) not later than 18 months after the date of
7 enactment of this Act, issue or revise guidance on
8 review and approval of biosimilar biological products
9 under section 351(k) of the Public Health Service
10 Act (42 U.S.C. 262(k)) relating to the data and in-
11 formation that an applicant is required to submit to
12 support a determination that a biosimilar biological
13 product that is the subject of an application under
14 such section is biosimilar to the reference product
15 (as defined in section 351(i) of such Act (42 U.S.C.
16 262(i))); and

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

21 (d) **RULES OF CONSTRUCTION.**—The amendments
22 made by this section shall not be construed—

23 (1) to alter the standard or the information re-
24 quired for licensure of a biological product as bio-
25 similar to a reference product pursuant to section

1 351(k) of the Public Health Service Act (42 U.S.C.
2 262(k)); or
3 (2) to limit the information that may be re-
4 quired by the Secretary of Health and Human Serv-
5 ices to support the licensure of a biological product
6 as biosimilar to a reference product pursuant to
7 such section.