119TH CONGRESS
1ST SESSION

S. _____

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

Mr. LEE introduced the following bill; which was read twice and 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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

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) in the subsection heading, by striking ''OR INTERCHANGEABLE'';

(2) in paragraph (2)—

(A) by striking subparagraph (B);

(B) by redesignating clauses (ii) and (iii) of subparagraph (A) as subparagraphs (B) and (C), respectively, and adjusting the margins accordingly;

(C) in subparagraph (A)—

(i) in clause (i), by redesignating subclauses (I) through (V) as clauses (i) through (v), respectively, and adjusting the margins accordingly;

(ii) in clause (i), as so redesignated by clause (i) of this subparagraph, by redesignating items (aa) through (cc) as subclauses (I) through (III), respectively, and adjusting the margins accordingly; and

(iii) by striking ''(A) IN GENERAL'' and all that follows through ''An application submitted under this subsection shall include information'' and inserting the following:

''(A) IN GENERAL.—An application submitted under this subsection shall include information'';

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

(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 biological product is biosimilar to the reference product; and'';

(4) by amending paragraph (4) to read as follows:

''(4) INTERCHANGEABILITY.—

''(A) IN GENERAL.—A biological product 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 licensure of the applicable biological product,

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

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

''(ii) LICENSURE PRIOR TO TRANSITION DATE.—A biological product licensed under this subsection prior to 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 on such transition date, 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 transition date,

in which case the applicable biological product shall be deemed interchangeable

with the reference product under this paragraph on the date on which the exclusivity period described in subclause (II) ends.

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

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

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

(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 criteria that the Secretary''.

(b) CONFORMING AMENDMENTS.—

(1) Section 351(i)(3) of the Public Health Service 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 requesting that the Secretary determine that the biosimilar biological product meets the standards for interchangeability described in section 351(k)(4) of the Public Health Service Act''.

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

''(l) BIOSIMILAR BIOLOGICAL PRODUCTS.—A biological product for which an application is submitted under section 351(k) of the Public Health Service Act shall not

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

''(1) a claimed indication that has been approved for the reference product in a relevant pediatric population or for which there is a deferral of the pediatric assessment under paragraph (4) for the reference product; and

''(2) the assessment would not involve the development of a biological product with a strength, dosage form, route of administration, or condition of use that could not be licensed under section 351(k) of the Public Health Service Act.''.

(c) GUIDANCE.—The Secretary shall—

(1) not later than 18 months after the date of enactment of this Act, update existing draft and final guidance to reflect the amendments made by this Act, including by revising or revoking the guidance document titled ''Considerations in Demonstrating 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.