Ben Ray Luján

AMENDMENT NO. 1 Calendar No._____

Purpose: 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—118th Cong., 1st Sess.

S. 2840

To improve access to and the quality of primary health care, expand the health workforce, and for other purposes.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Mr. LUJÁN

Viz:

At the appropriate place in title III, insert the following:

SEC. 3_____. 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 (C) of this paragraph, by striking "clause (i)(I)" and inserting "subparagraph (A)(i)"; and

(E) in subparagraph (C), as so redesignated by subparagraph (C) of this paragraph, by redesignating subclauses (I) through (III) as clauses (i) through (iii), respectively, and by adjusting the margins accordingly;

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

"(4) INTERCHANGEABILITY.—A biological product licensed under this subsection shall be deemed to be interchangeable with the reference product.";

(4) by striking paragraph (6); and

(5) 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 Secretary" 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 be considered to have a new active ingredient for purposes of this section, except that a pediatric assessment shall not be required for a claimed indication in a relevant pediatric population if the assessment would involve—

"(1) a condition of use that has not been previously approved for the reference product; or

"(2) a dosage form, strength, or route of administration that differs from that of the reference product.".

(c) APPLICATION.—The amendment made by subsection (a)(4) to strike paragraph (6) of section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) shall apply only with respect to applications approved under section 351(k) of such Act on or after the date of enactment of this Act. Any period of exclusivity granted under section 351(k)(6) of such Act with respect to an application approved under such section 351(k) before the date of enactment of this Act shall apply in accordance with paragraph (6) of such section 351(k), as in effect on the day before the date of enactment of this Act.