

116TH CONGRESS
2D SESSION

H. R. 6155

To amend the Biologics Price Competition and Innovation Act of 2009 to make improvements with respect to the transition of biological products, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 9, 2020

Mr. GROTHMAN introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Biologics Price Competition and Innovation Act of 2009 to make improvements with respect to the transition of biological products, and for other purposes.

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. STREAMLINING THE TRANSITION OF BIOLOGI-**
4 **CAL PRODUCTS.**

5 (a) CONTINUED REVIEW OF CERTAIN APPLICA-
6 TIONS.—Section 7002(e)(4)(B) of the Biologics Price
7 Competition and Innovation Act of 2009 (Public Law
8 111–148) is amended—

9 (1) by striking clauses (i), (ii), and (vi); and

1 (2) by inserting before clause (iii) the following:

2 “(i) IN GENERAL.—With respect to an
3 application for a biological product sub-
4 mitted under subsection (b) or (j) of sec-
5 tion 505 of the Federal Food, Drug, and
6 Cosmetic Act (21 U.S.C. 355) that is filed
7 not later than March 23, 2019, and that is
8 pending (or tentatively approved) as of
9 March 23, 2020—

10 “(I) the Secretary shall continue
11 to review such application under such
12 section 505, even if such review con-
13 tinues after March 23, 2020; and

14 “(II) upon approval of such ap-
15 plication, such application shall be
16 deemed to be a license for the biologi-
17 cal product under section 351 of the
18 Public Health Service Act, pursuant
19 to subparagraph (A), and any period
20 of exclusivity, as applicable, shall be
21 determined in accordance with such
22 section.

23 “(ii) TREATMENT OF LISTED
24 DRUGS.—With respect to a drug that is a
25 biological product that has been deemed li-

1 censed under section 351 of the Public
2 Health Service Act (42 U.S.C. 262) pursu-
3 ant to subparagraph (A) and that is ref-
4 erenced in an application described in
5 clause (i), such drug shall—

6 “(I) continue to be identified as a
7 listed drug on the list published pur-
8 suant to section 505(j)(7) of the Fed-
9 eral Food, Drug, and Cosmetic Act,
10 and the information for such drug on
11 such list shall not be revised (or re-
12 moved) unless and until the date on
13 which each application described in
14 clause (i) that references such drug
15 is—

16 “(aa) no longer pending re-
17 view (or the approval of such
18 drug is tentative) under section
19 505 of the Federal Food, Drug,
20 and Cosmetic Act (21 U.S.C.
21 355); or

22 “(bb) removed from such list
23 in accordance with subparagraph
24 (C) of such section 505(j)(7);

1 “(II) be subject only to require-
2 ments applicable to biological products
3 licensed under section 351 of the Pub-
4 lic Health Service Act (42 U.S.C.
5 262); and

6 “(III) be deemed to be a ref-
7 erence product under such section 351
8 on the date on which the last applica-
9 tion described in clause (i) that ref-
10 erences such drug is no longer pend-
11 ing review (or tentatively approved)
12 under section 505 of the Federal
13 Food, Drug, and Cosmetic Act (21
14 U.S.C. 355).”.

15 (b) CERTAIN INSULIN PRODUCTS DEEMED INTER-
16 CHANGEABLE BIOSIMILARS.—Section 7002(e)(4) of the
17 Biologics Price Competition and Innovation Act of 2009
18 (Public Law 111–148) is amended by adding at the end
19 the following:

20 “(C) CERTAIN INSULIN PRODUCTS
21 DEEMED INTERCHANGEABLE BIOSIMILARS.—

22 “(i) IN GENERAL.—In carrying out
23 subparagraph (A), a covered insulin prod-
24 uct shall be deemed to be an interchange-
25 able biosimilar biological product licensed

1 under section 351(k) of the Public Health
2 Service Act.

3 “(ii) DEFINITIONS.—In this subpara-
4 graph:

5 “(I) The terms ‘biosimilar’ and
6 ‘interchangeable’ have the meaning
7 given such terms in section 351(i) of
8 the Public Health Service Act.

9 “(II) The term ‘covered insulin
10 product’ means a biological product
11 (including a chemically synthesized
12 polypeptide) that is—

13 “(aa) an insulin product;

14 and

15 “(bb) approved under sec-
16 tion 505 of the Federal Food,
17 Drug, and Cosmetic Act pursu-
18 ant to an application submitted
19 under subsection (b)(2) of such
20 section.”.

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