

116TH CONGRESS
1ST SESSION

H. R. 5444

To amend the Biologics Price Competition and Innovation Act of 2009 to streamline the transition of certain products from approval as a drug to licensure as a biological product, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

DECEMBER 17, 2019

Ms. UNDERWOOD (for herself, Ms. SCHAKOWSKY, Mr. GUTHRIE, Mr. KELLY of Pennsylvania, and Mr. LEVIN of Michigan) 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 streamline the transition of certain products from approval as a drug to licensure as a biological product, 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. SHORT TITLE.**

4 This Act may be cited as the “Lower Insulin Costs
5 Now Act”.

1 **SEC. 2. STREAMLINING THE TRANSITION OF BIOLOGICAL**
2 **PRODUCTS.**

3 Section 7002(e)(4) of the Biologics Price Competition
4 and Innovation Act of 2009 (Public Law 111–148) is
5 amended—

6 (1) by striking “An approved application” and
7 inserting the following:

8 “(A) IN GENERAL.—An approved applica-
9 tion”; and

10 (2) by adding at the end the following:

11 “(B) TREATMENT OF CERTAIN APPLICA-
12 TIONS.—

13 “(i) IN GENERAL.—With respect to an
14 application for a biological product sub-
15 mitted under subsection (b) or (j) of sec-
16 tion 505 of the Federal Food, Drug, and
17 Cosmetic Act (21 U.S.C. 355) that is filed
18 not later than March 23, 2019, and is not
19 approved as of March 23, 2020, the Sec-
20 retary shall continue to review such appli-
21 cation under such section 505, after March
22 23, 2020.

23 “(ii) EFFECT ON LISTED DRUGS.—
24 Only for purposes of carrying out clause
25 (i), with respect to any applicable listed

1 drug with respect to such application, the
2 following shall apply:

3 “(I) Any drug that is a biological
4 product that has been deemed licensed
5 under section 351 of the Public
6 Health Service Act (42 U.S.C. 262)
7 pursuant to subparagraph (A) and
8 that is referenced in an application
9 described in clause (i), shall continue
10 to be identified as a listed drug on the
11 list published pursuant to section
12 505(j)(7) of the Federal Food, Drug,
13 and Cosmetic Act, and the informa-
14 tion for such drug on such list shall
15 not be revised after March 20, 2020,
16 until—

17 “(aa) such drug is removed
18 from such list in accordance with
19 subclause (III) or subparagraph
20 (C) of such section 505(j)(7); or

21 “(bb) this subparagraph no
22 longer has force or effect.

23 “(II) Any drug that is a biologi-
24 cal product that has been deemed li-
25 censed under section 351 of the Pub-

1 lic Health Service Act (42 U.S.C.
2 262) pursuant to subparagraph (A)
3 and that is referenced in an applica-
4 tion described in clause (i) shall be
5 subject only to requirements applica-
6 ble to biological products licensed
7 under such section.

8 “(III) Upon approval under sub-
9 section (c) or (j) of section 505 of the
10 Federal Food, Drug, and Cosmetic
11 Act of an application described in
12 clause (i), the Secretary shall remove
13 from the list published pursuant to
14 section 505(j)(7) of the Federal Food,
15 Drug, and Cosmetic Act any listed
16 drug that is a biological product that
17 has been deemed licensed under sec-
18 tion 351 of the Public Health Service
19 Act pursuant to subparagraph (A)
20 and that is referenced in such ap-
21 proved application, unless such listed
22 drug is referenced in one or more ad-
23 ditional applications described in
24 clause (i).

1 “(iii) DEEMED LICENSURE.—Upon
2 approval of an application described in
3 clause (i), such approved application shall
4 be deemed to be a license for the biological
5 product under section 351 of the Public
6 Health Service Act.

7 “(iv) RULE OF CONSTRUCTION.—

8 “(I) APPLICATION OF CERTAIN
9 PROVISIONS.—

10 “(aa) PATENT CERTIFI-
11 CATION OR STATEMENT.—An ap-
12 plication described in clause (i)
13 shall contain a patent certifi-
14 cation or statement described in,
15 as applicable, section 505(b)(2)
16 of the Federal Food, Drug, and
17 Cosmetic Act or clauses (vii) and
18 (viii) of section 505(j)(2)(A) of
19 such Act and, with respect to any
20 listed drug referenced in such ap-
21 plication, comply with related re-
22 quirements concerning any timely
23 filed patent information listed
24 pursuant to section 505(j)(7).

1 “(bb) DATE OF AP-
2 PROVAL.—The earliest possible
3 date on which any pending appli-
4 cation described in clause (i) may
5 be approved shall be determined
6 based on—

7 “(AA) the last expira-
8 tion date of any applicable
9 period of exclusivity that
10 would prevent such approval
11 and that is described in sec-
12 tion 505(c)(3)(E),
13 505(j)(5)(B)(iv),
14 505(j)(5)(F), 505A, 505E,
15 or 527 of the Federal Food,
16 Drug, and Cosmetic Act;
17 and

18 “(BB) if the application
19 was submitted pursuant to
20 section 505(b)(2) of the
21 Federal Food, Drug, and
22 Cosmetic Act and references
23 any listed drug, the last ap-
24 plicable date determined
25 under subparagraph (A),

1 (B), or (C) of section
2 505(c)(3) of such Act, or, if
3 the application was sub-
4 mitted under section 505(j)
5 of such Act, the last applica-
6 ble date determined under
7 clause (i), (ii), or (iii) of sec-
8 tion 505(j)(5)(B).

9 “(II) EXCLUSIVITY.—Nothing in
10 this subparagraph shall be construed
11 to affect section 351(k)(7)(D) of the
12 Public Health Service Act.

13 “(v) LISTING.—The Secretary may
14 continue to review an application after
15 March 23, 2020, pursuant to clause (i),
16 and continue to identify any applicable list-
17 ed drug pursuant to clause (ii) on the list
18 published pursuant to section 505(j)(7) of
19 the Federal Food, Drug, and Cosmetic
20 Act, even if such review or listing may re-
21 veal the existence of such application and
22 the identity of any listed drug for which
23 the investigations described in section
24 505(b)(1)(A) of the Federal Food, Drug,
25 and Cosmetic Act are relied upon by the

1 applicant for approval of the pending ap-
2 plication. Nothing in this subparagraph
3 shall be construed as authorizing the Sec-
4 retary to disclose any other information
5 that is a trade secret or confidential infor-
6 mation described in section 552(b)(4) of
7 title 5, United States Code.

8 “(vi) SUNSET.—Beginning on October
9 1, 2022, this subparagraph shall have no
10 force or effect and any applications de-
11 scribed in clause (i) that have not been ap-
12 proved shall be deemed withdrawn.”.

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