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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

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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.

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 ''Lower Insulin Costs Now Act''.

SEC. 2. STREAMLINING THE TRANSITION OF BIOLOGICAL PRODUCTS.

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

(1) by striking ''An approved application'' and inserting the following:

''(A) IN GENERAL.—An approved application''; and

(2) by adding at the end the following:

''(B) TREATMENT OF CERTAIN APPLICATIONS.—

''(i) IN GENERAL.—With respect to an application for a biological product submitted under subsection (b) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) that is filed not later than March 23, 2019, and is not approved as of March 23, 2020, the Secretary shall continue to review such application under such section 505, after March 23, 2020.

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

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

"(I) Any drug that is a biological product that has been deemed licensed under section 351 of the Public Health Service Act (42 U.S.C. 262) pursuant to subparagraph (A) and that is referenced in an application described in clause (i), shall continue to be identified as a listed drug on the list published pursuant to section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act, and the information for such drug on such list shall not be revised after March 20, 2020, until—

"(aa) such drug is removed from such list in accordance with subclause (III) or subparagraph (C) of such section 505(j)(7); or

"(bb) this subparagraph no longer has force or effect.

"(II) Any drug that is a biological product that has been deemed licensed under section 351 of the Pub-

lic Health Service Act (42 U.S.C. 262) pursuant to subparagraph (A) and that is referenced in an application described in clause (i) shall be subject only to requirements applicable to biological products licensed under such section.

''(III) Upon approval under subsection (c) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act of an application described in clause (i), the Secretary shall remove from the list published pursuant to section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act any listed drug that is a biological product that has been deemed licensed under section 351 of the Public Health Service Act pursuant to subparagraph (A) and that is referenced in such approved application, unless such listed drug is referenced in one or more additional applications described in clause (i).

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

"(iv) RULE OF CONSTRUCTION.—

"(I) APPLICATION OF CERTAIN PROVISIONS.—

"(aa) PATENT CERTIFICATION OR STATEMENT.—An application described in clause (i) shall contain a patent certification or statement described in, as applicable, section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act or clauses (vii) and (viii) of section 505(j)(2)(A) of such Act and, with respect to any listed drug referenced in such application, comply with related requirements concerning any timely filed patent information listed pursuant to section 505(j)(7).

"(bb) DATE OF APPROVAL.—The earliest possible date on which any pending application described in clause (i) may be approved shall be determined based on—

"(AA) the last expiration date of any applicable period of exclusivity that would prevent such approval and that is described in section 505(c)(3)(E), 505(j)(5)(B)(iv), 505(j)(5)(F), 505A, 505E, or 527 of the Federal Food, Drug, and Cosmetic Act; and

"(BB) if the application was submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act and references any listed drug, the last applicable date determined under subparagraph (A),

(B), or (C) of section 505(c)(3) of such Act, or, if the application was submitted under section 505(j) of such Act, the last applicable date determined under clause (i), (ii), or (iii) of section 505(j)(5)(B).

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

''(v) LISTING.—The Secretary may continue to review an application after March 23, 2020, pursuant to clause (i), and continue to identify any applicable listed drug pursuant to clause (ii) on the list published pursuant to section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act, even if such review or listing may reveal the existence of such application and the identity of any listed drug for which the investigations described in section 505(b)(1)(A) of the Federal Food, Drug, and Cosmetic Act are relied upon by the

applicant for approval of the pending application. Nothing in this subparagraph shall be construed as authorizing the Secretary to disclose any other information that is a trade secret or confidential information described in section 552(b)(4) of title 5, United States Code.

''(vi) SUNSET.—Beginning on October 1, 2022, this subparagraph shall have no force or effect and any applications described in clause (i) that have not been approved shall be deemed withdrawn.''.

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