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II

116TH CONGRESS
1ST SESSION

S. 2103

To improve access to affordable insulin.

IN THE SENATE OF THE UNITED STATES

JULY 11, 2019

Mr. DURBIN (for himself, Mr. CRAMER, and Ms. SMITH) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To improve access to affordable insulin.

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 ''Affordable Insulin Approvals Now Act''.

SEC. 2. DEEMED APPROVAL UNDER SECTION 351.

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

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

''(A) IN GENERAL.—An amended''; and

(2) by adding at the end the following:

''(B) TREATMENT OF CERTAIN PENDING APPLICATIONS.—With respect to an application for an insulin biological product submitted under subsection (b)(2) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) with a filing date that is not later than December 31, 2019, until the Secretary makes a determination on final approval with respect to such application, the Secretary shall continue to review and approve (as appropriate) such application under such section 505, even if such review and approval process continues after March 23, 2020. For purposes of completing the review and approval process for such an application, any listed drug referenced in the application shall be treated as a listed drug under section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act, even if such listed drug is deemed licensed under section 351 of the Public Health Service Act during such review and approval process. Effective on the later of March 23, 2020, or the date of approval under subsection (c) or (j) of section 505

of the Federal Food, Drug, and Cosmetic Act of any such application, such approved application shall be deemed to be a license for the biological product under section 351 of the Public Health Service Act.''.

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