117TH CONGRESS
2D SESSION

S. 4302

To amend the Federal Food, Drug, and Cosmetic Act to require prompt reports of marketing status by holders of approved applications for biological products, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MAY 25, 2022

Mr. KAINE (for himself, Mr. MARSHALL, Ms. HASSAN, and Mr. CASSIDY) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

---

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to require prompt reports of marketing status by holders of approved applications for biological products, 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 ''Biologics Market Transparency Act of 2022''.

SEC. 2. PROMPT REPORTS OF MARKETING STATUS BY HOLDERS OF APPROVED APPLICATIONS FOR BIOLOGICAL PRODUCTS.

(a) IN GENERAL.—Section 506I of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356i) is amended—

(1) in subsection (a)—

(A) by striking ''The holder of an application approved under subsection (c) or (j) of section 505'' and inserting ''The holder of an application approved under subsection (c) or (j) of section 505 of this Act or subsection (a) or (k) of section 351 of the Public Health Service Act'';

(B) in paragraph (2), by inserting ''(or, in the case of a biological product, the proper name)'' after ''established name''; and

(C) in paragraph (3), by striking ''or abbreviated application number'' and inserting '', abbreviated application number, or biologics license application number''; and

(2) in subsection (b)—

(A) in the matter preceding paragraph (1), by striking ''The holder of an application approved under subsection (c) or (j)'' and inserting ''The holder of an application approved under subsection (c) or (j) of section 505 of

this Act or subsection (a) or (k) of section 351 of the Public Health Service Act'';

(B) in paragraph (1), by inserting ''(or, in the case of a biological product, the proper name)'' after ''established name''; and

(C) in paragraph (2), by striking ''or abbreviated application number'' and inserting '', abbreviated application number, or biologics license application number''.

(b) ADDITIONAL ONE-TIME REPORT.—Subsection (c) of section 506I of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356i) is amended to read as follows:

''(c) ADDITIONAL ONE-TIME REPORT.—Within 180 days of the date of enactment of the Biologics Market Transparency Act of 2022, all holders of applications approved under subsection (a) or (k) of section 351 of the Public Health Service Act shall review the information in the list published under section 351(k)(9)(A) and shall submit a written notice to the Secretary—

''(1) stating that all of the application holder's biological products in the list published under section 351(k)(9)(A) that are not listed as discontinued are available for sale; or

''(2) including the information required pursuant to subsection (a) or (b), as applicable, for each

of the application holder's biological products that are in the list published under section 351(k)(9)(A) and not listed as discontinued, but have been discontinued from sale or never have been available for sale.''.

(c) PURPLE BOOK.—Section 506I of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356i) is amended—

(1) in subsection (d)—

(A) by striking ''or (c), the Secretary'' and inserting the following: ''or (c)—

''(1) the Secretary'';

(B) by striking the period at the end and inserting ''; and''; and

(C) by adding at the end the following:

''(2) the Secretary may identify the application holder's biological products as discontinued in the list published under section 351(k)(9)(A) of the Public Health Service Act, except that the Secretary shall remove from the list, in accordance with section 351(k)(9)(B) of such Act, any biological product for which the license has been revoked or suspended for reasons of safety, purity, or potency.''; and

(2) in subsection (e)—

(A) by inserting after the first sentence the following: ''The Secretary shall update the list published under section 351(k)(9)(A) of the Public Health Service Act based on information provided under subsections (a), (b), and (c) by identifying as discontinued biological products that are not available for sale, except that any biological product for which the license has been revoked or suspended for reasons of safety, purity, or potency shall be removed from the list in accordance with section 351(k)(9)(B) of the Public Health Service Act.''; and

(B) in the last sentence—

(i) by striking ''updates to the list'' and inserting ''updates to the lists published under section 505(j)(7)(A) of this Act and section 351(k)(9)(A) of the Public Health Service Act''; and

(ii) by striking ''update the list'' and inserting ''update such lists''.

○