

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.

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 “Biologics Market
5 Transparency Act of 2022”.

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

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

6 (1) in subsection (a)—

7 (A) by striking “The holder of an applica-
 8 tion approved under subsection (c) or (j) of sec-
 9 tion 505” and inserting “The holder of an ap-
 10 plication approved under subsection (c) or (j) of
 11 section 505 of this Act or subsection (a) or (k)
 12 of section 351 of the Public Health Service
 13 Act”;

14 (B) in paragraph (2), by inserting “(or, in
 15 the case of a biological product, the proper
 16 name)” after “established name”; and

17 (C) in paragraph (3), by striking “or ab-
 18 breviated application number” and inserting “,
 19 abbreviated application number, or biologics li-
 20 cense application number”; and

21 (2) in subsection (b)—

22 (A) in the matter preceding paragraph (1),
 23 by striking “The holder of an application ap-
 24 proved under subsection (c) or (j)” and insert-
 25 ing “The holder of an application approved
 26 under subsection (c) or (j) of section 505 of

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

3 (B) in paragraph (1), by inserting “(or, in
4 the case of a biological product, the proper
5 name)” after “established name”; and

6 (C) in paragraph (2), by striking “or ab-
7 breviated application number” and inserting “,
8 abbreviated application number, or biologics li-
9 cense application number”.

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

13 “(c) **ADDITIONAL ONE-TIME REPORT.**—Within 180
14 days of the date of enactment of the Biologics Market
15 Transparency Act of 2022, all holders of applications ap-
16 proved under subsection (a) or (k) of section 351 of the
17 Public Health Service Act shall review the information in
18 the list published under section 351(k)(9)(A) and shall
19 submit a written notice to the Secretary—

20 “(1) stating that all of the application holder’s
21 biological products in the list published under sec-
22 tion 351(k)(9)(A) that are not listed as discontinued
23 are available for sale; or

24 “(2) including the information required pursu-
25 ant to subsection (a) or (b), as applicable, for each

1 of the application holder’s biological products that
 2 are in the list published under section 351(k)(9)(A)
 3 and not listed as discontinued, but have been discon-
 4 tinued from sale or never have been available for
 5 sale.”.

6 (c) PURPLE BOOK.—Section 506I of the Federal
 7 Food, Drug, and Cosmetic Act (21 U.S.C. 356i) is amend-
 8 ed—

9 (1) in subsection (d)—

10 (A) by striking “or (c), the Secretary” and
 11 inserting the following: “or (c)—
 12 “(1) the Secretary”;

13 (B) by striking the period at the end and
 14 inserting “; and”; and

15 (C) by adding at the end the following:

16 “(2) the Secretary may identify the application
 17 holder’s biological products as discontinued in the
 18 list published under section 351(k)(9)(A) of the
 19 Public Health Service Act, except that the Secretary
 20 shall remove from the list, in accordance with sec-
 21 tion 351(k)(9)(B) of such Act, any biological prod-
 22 uct for which the license has been revoked or sus-
 23 pended for reasons of safety, purity, or potency.”;
 24 and

25 (2) in subsection (e)—

1 (A) by inserting after the first sentence the
2 following: “The Secretary shall update the list
3 published under section 351(k)(9)(A) of the
4 Public Health Service Act based on information
5 provided under subsections (a), (b), and (c) by
6 identifying as discontinued biological products
7 that are not available for sale, except that any
8 biological product for which the license has been
9 revoked or suspended for reasons of safety, pu-
10 rity, or potency shall be removed from the list
11 in accordance with section 351(k)(9)(B) of the
12 Public Health Service Act.”; and

13 (B) in the last sentence—

14 (i) by striking “updates to the list”
15 and inserting “updates to the lists pub-
16 lished under section 505(j)(7)(A) of this
17 Act and section 351(k)(9)(A) of the Public
18 Health Service Act”; and

19 (ii) by striking “update the list” and
20 inserting “update such lists”.

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