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(Original Signature of Member)

117TH CONGRESS
2D SESSION

H. R. 7035

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 HOUSE OF REPRESENTATIVES

M____ introduced the following bill; which was referred to the
Committee on _____

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”; and

14 (B) in paragraph (3), by striking “or ab-
15 breviated application number” and inserting “,
16 abbreviated application number, or biologics li-
17 cense application number”; and

18 (2) in subsection (b)—

19 (A) by striking “The holder of an applica-
20 tion approved under subsection (c) or (j)” and
21 inserting “The holder of an application ap-
22 proved under subsection (c) or (j) of section
23 505 of this Act or subsection (a) or (k) of sec-
24 tion 351 of the Public Health Service Act”; and

25 (B) in paragraph (2), by striking “or ab-
26 breviated application number” and inserting “,

1 abbreviated application number, or biologics li-
2 cense application number”.

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

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

13 “(1) stating that all of the application holder’s
14 biological products in the list published under sec-
15 tion 351(k)(9)(a) that are not listed as discontinued
16 are available for sale; or

17 “(2) including the information required pursu-
18 ant to subsection (a) or (b), as applicable, for each
19 of the application holder’s biological products that
20 are in the list published under section 351(k)(9)(a)
21 and not listed as discontinued, but have been with-
22 drawn from sale or never have been available for
23 sale.”.

1 (c) PURPLE BOOK.—Subsections (d) and (e) of sec-
2 tion 506I of the Federal Food, Drug, and Cosmetic Act
3 (21 U.S.C. 356i) are each amended—

4 (1) by striking “the list published under sub-
5 section 505(j)(7)(A)” and inserting “the list pub-
6 lished under section 505(j)(7)(A) of this Act or sec-
7 tion 351(k)(9)(A) of the Public Health Service Act,
8 as applicable,”; and

9 (2) by striking “in accordance with subsection
10 505(j)(7)(C)” and inserting “in accordance with sec-
11 tion 505(j)(7)(C) of this Act or section 351(k)(9)(B)
12 of the Public Health Service Act (as applicable)”.