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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.

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''; and

(B) 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) 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''; and

(B) 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 withdrawn from sale or never have been available for sale.''.

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

(1) by striking ''the list published under subsection 505(j)(7)(A)'' and inserting ''the list published under section 505(j)(7)(A) of this Act or section 351(k)(9)(A) of the Public Health Service Act, as applicable,''; and

(2) by striking ''in accordance with subsection 505(j)(7)(C)'' and inserting ''in accordance with section 505(j)(7)(C) of this Act or section 351(k)(9)(B) of the Public Health Service Act (as applicable)''.