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117TH CONGRESS
2D SESSION

# H. R. 6483

To amend the Federal Food, Drug, and Cosmetic Act to clarify reporting requirements for establishments within a foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of an active pharmaceutical ingredient, and for other purposes.

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IN THE HOUSE OF REPRESENTATIVES

JANUARY 25, 2022

Ms. ESHOO introduced the following bill; which was referred to the Committee on Energy and Commerce

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# A BILL

To amend the Federal Food, Drug, and Cosmetic Act to clarify reporting requirements for establishments within a foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of an active pharmaceutical ingredient, 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 ''Improved Transparency of Foreign Drug Manufacturing Act of 2022''.

**SEC. 2. REPORTING REQUIREMENT FOR DRUG MANUFACTURERS.**

(a) ESTABLISHMENTS IN A FOREIGN COUNTRY.—Section 510(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(i)) is amended by inserting at the end the following:

''(5) The requirements of paragraphs (1) and (2) shall apply to establishments within a foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of any drug, including the active pharmaceutical ingredient, that is required to be listed pursuant to subsection (j). Such requirements shall apply regardless of whether the drug or active pharmaceutical ingredient undergoes further manufacture, preparation, propagation, compounding, or processing at a separate establishment or establishments outside the United States prior to being imported or offered for import into the United States.''.

(b) LISTING OF DRUGS.—Section 510(j)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(j)(1)) is amended—

(1) in subparagraph (D), by striking ''and'' at the end;

(2) in subparagraph (E), by striking the period at the end and inserting ''; and''; and

(3) by adding at the end the following:

''(F) in the case of a drug contained in the applicable list, a certification that the registrant has—

''(i) identified every other known establishment where manufacturing is performed for the drug; and

''(ii) notified each known foreign establishment engaged in the manufacture, preparation, propagation, compounding, or processing of the drug, including the active pharmaceutical ingredient, of the inclusion of the drug in the list and the obligation to register.''.

(c) QUARTERLY REPORTING ON AMOUNT OF DRUGS MANUFACTURED.—Section 510(j)(3)(A) of the Federal Food, Drug, and Cosmetic Act (as added by section 3112 of the CARES Act (Public Law 116–136)) is amended by striking ''annually'' and inserting ''once during the month of March of each year, once during the month of June of each year, once during the month of September of each year, and once during the month of December of each year''.

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