

117TH CONGRESS
2D SESSION

S. 3449

To require foreign establishments engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or device to register with the Food and Drug Administration regardless of whether the drug or device undergoes further manufacture, preparation, propagation, compounding, or processing at a separate establishment outside the United States prior to being imported into the United States.

IN THE SENATE OF THE UNITED STATES

JANUARY 10, 2022

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

A BILL

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1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Registration of Certain
3 Foreign Establishments Act”.

4 **SEC. 2. REGISTRATION OF CERTAIN FOREIGN ESTABLISH-**
5 **MENTS.**

6 (a) REGISTRATION OF CERTAIN FOREIGN ESTAB-
7 LISHMENTS.—Section 510(i) of the Federal Food, Drug,
8 and Cosmetic Act (21 U.S.C. 360(i)) is amended by add-
9 ing at the end the following:

10 “(5) The requirements of paragraphs (1) and (2)
11 shall apply regardless of whether the drug or device under-
12 goes further manufacture, preparation, propagation,
13 compounding, or processing at a separate establishment
14 outside the United States prior to being imported or of-
15 fered for import into the United States.”.

16 (b) UPDATING REGULATIONS.—Not later than 2
17 years after the date of enactment of this Act, the Sec-
18 retary of Health and Human Services shall update regula-
19 tions, as appropriate, to implement the amendment made
20 by subsection (a).

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