

117TH CONGRESS
2D SESSION

S. 3509

To strengthen the authority of the Food and Drug Administration with respect to foreign drug facility inspections.

IN THE SENATE OF THE UNITED STATES

JANUARY 13 (legislative day, JANUARY 10), 2022

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

A BILL

To strengthen the authority of the Food and Drug Administration with respect to foreign drug facility inspections.

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 “Creating Efficiency
5 in Foreign Facility Inspections Act”.

6 **SEC. 2. STRENGTHENING FOREIGN DRUG FACILITY IN-**
7 **SPECTIONS.**

8 Section 704 of the Federal Food, Drug, and Cosmetic
9 Act (21 U.S.C. 374) is amended by adding at the end the
10 following:

1 “(i)(1) When the Secretary, and officers or employees
2 duly designated by the Secretary, conduct inspections
3 under this section of establishments engaged in the manu-
4 facturing, processing, packing, or holding of drugs that
5 are located outside of the United States, the Secretary
6 shall not notify the owner or operator of such establish-
7 ment of the planned inspection before the inspection oc-
8 curs unless—

9 “(A) notification to the establishment owner or
10 operator in advance of an inspection is mandated
11 under the laws of the country where the establish-
12 ment is located, in which case, the Secretary shall
13 provide not more than the minimum advanced notice
14 so mandated; or

15 “(B) the Secretary determines that notification
16 to the establishment owner or operator in advance of
17 an inspection is needed to protect the public health.

18 “(2)(A) With respect to all inspections described in
19 paragraph (1), the Secretary shall attempt to minimize the
20 time between advance notification to an establishment
21 owner or operator and the conduct of a surveillance in-
22 spection.

23 “(B) If the Secretary determines that notification to
24 an owner or operator of a foreign establishment of an in-
25 spection in advance of a surveillance inspection pursuant

1 to paragraph (1)(B) is needed, the Secretary shall provide
2 such notification only as far in advance as is needed to
3 protect the public health.

4 “(3) If an establishment is located in a country that,
5 on or after the date of enactment of this subsection, enacts
6 a law that prevents the Secretary from carrying out in-
7 spections as described in this subsection, the manufacturer
8 shall agree to waive any right to enforce any advanced-
9 notice requirement pursuant to such a law, to the extent
10 expressly permitted under applicable local law. If the man-
11 ufacturer does not agree to such a waiver, the manufac-
12 turer shall be deemed to have refused to permit entry or
13 inspection in violation of section 301(f).

14 “(4) The requirement of paragraph (1) shall not
15 apply to preapproval, prelicensure, or for-cause inspec-
16 tions.”.

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