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117TH CONGRESS
2D SESSION

H. R. 7006

To amend the Federal Food, Drug, and Cosmetic Act to improve inspections of foreign drug manufacturing establishments, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 9, 2022

Mr. GRIFFITH (for himself and Mr. WELCH) 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 improve inspections of foreign drug manufacturing establishments, 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 ''Improving the Nation's Safe Pharmaceuticals and Excipients by Creating Tools for Inspecting and Overseeing Needed Supplies Act'' or the ''INSPECTIONS Act''.

SEC. 2. IMPROVING FDA INSPECTIONS.

(a) RISK FACTORS FOR ESTABLISHMENTS.—Section 510(h)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(h)(4)) is amended—

(1) by redesignating subparagraph (F) as subparagraph (G); and

(2) by inserting after subparagraph (E) the following:

''(F) The compliance history of establishments in the country or region in which the establishment is located that are subject to regulation under this Act, including the history of violations related to products exported from such country or region that are subject to such regulation.''.

(b) USE OF RECORDS.—Section 704(a)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374) is amended—

(1) by redesignating subparagraph (C) as subparagraph (D); and

(2) by inserting after subparagraph (B) the following:

''(C) The Secretary may use any records or other information that the Secretary may inspect under this section to satisfy requirements for a preapproval or risk-based surveillance in-

spection, including resolving the findings of such inspections, if applicable and appropriate.''.

(c) RECOGNITION OF FOREIGN GOVERNMENT INSPECTIONS.—Section 809 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384e) is amended—

(1) in subsection (a)(1), by inserting ''preapproval or'' before ''risk-based inspections''; and

(2) by adding at the end the following:

''(c) PERIODIC REVIEW.—

''(1) IN GENERAL.—Beginning not later than 1 year after the date of the enactment of the INSPECTIONS Act the Secretary shall periodically assess whether additional arrangements and agreements with a foreign government or an agency of a foreign government, as allowed under this section, are appropriate.

''(2) REPORTS TO CONGRESS.—Beginning not later than 4 years after the date of the enactment of the INSPECTIONS Act, and every 4 years thereafter, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor and Pensions a report describing the

findings and conclusions of each review conducted under paragraph (1).''.

SEC. 3. GAO REPORT ON INSPECTIONS OF FOREIGN ESTABLISHMENTS MANUFACTURING DRUGS.

(a) IN GENERAL.—Not later than 18 months after the date of the enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor and Pensions of the Senate a report on inspections of foreign establishments conducted by the Secretary of Health and Human Services pursuant to subsections (h) and (i) of section 510 and section 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360, 374) (or a foreign government or an agency of a foreign government pursuant to section 809 of such Act (21 U.S.C. 384e)).

(b) CONTENTS.—The report conducted under subsection (a) shall include—

(1) what alternative tools, including remote inspections, other countries are utilizing to facilitate inspections of foreign establishments;

(2) how frequently trusted foreign regulators conduct inspections of foreign facilities that could be

useful to the Food and Drug Administration to review in lieu of its own inspections;

(3) how frequently and under what circumstances, including for what types of inspections, the Secretary utilizes existing agreements or arrangements under section 809 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384e) and whether the use of such agreements could be appropriately expanded;

(4) whether the Secretary has accepted reports of inspections of facilities in China and India conducted by entities with which they have entered into such an agreement or arrangement;

(5) what additional foreign governments or agencies of foreign governments the Secretary has considered entering into a mutual recognition agreement with and, if applicable, reasons why the Secretary declined to enter into a mutual recognition agreement with such foreign governments or agencies;

(6) what tools, if any, the Secretary used to facilitate inspections of domestic facilities that could also be effectively utilized to appropriately inspect foreign facilities;

(7) what steps the Secretary has taken to identify and evaluate tools and strategies the Secretary may use to continue oversight with respect to inspections when in-person inspections are disrupted;

(8) how the Secretary is considering incorporating alternative tools into the inspection activities conducted pursuant to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.); and

(9) what steps the Secretary has taken to identify and evaluate how the Secretary may use alternative tools to address workforce shortages to carry out such inspection activities.

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