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(Original Signature of Member)

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.

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## IN THE HOUSE OF REPRESENTATIVES

M. \_\_\_\_\_ introduced the following bill; which was referred to the  
Committee on \_\_\_\_\_

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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.

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 “Improving the Nation’s  
5 Safe Pharmaceuticals and Excipients by Creating Tools  
6 for Inspecting and Overseeing Needed Supplies Act” or  
7 the “INSPECTIONS Act”.

1 **SEC. 2. IMPROVING FDA INSPECTIONS.**

2 (a) RISK FACTORS FOR ESTABLISHMENTS.—Section  
3 510(h)(4) of the Federal Food, Drug, and Cosmetic Act  
4 (21 U.S.C. 360(h)(4)) is amended—

5 (1) by redesignating subparagraph (F) as sub-  
6 paragraph (G); and

7 (2) by inserting after subparagraph (E) the fol-  
8 lowing:

9 “(F) The compliance history of establish-  
10 ments in the country or region in which the es-  
11 tablishment is located that are subject to regu-  
12 lation under this Act, including the history of  
13 violations related to products exported from  
14 such country or region that are subject to such  
15 regulation.”.

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

19 (1) by redesignating subparagraph (C) as sub-  
20 paragraph (D); and

21 (2) by inserting after subparagraph (B) the fol-  
22 lowing:

23 “(C) The Secretary may use any records  
24 or other information that the Secretary may in-  
25 spect under this section to satisfy requirements  
26 for a preapproval or risk-based surveillance in-

1           speciation, including resolving the findings of  
2           such inspections, if applicable and appro-  
3           priate.”.

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

7           (1) in subsection (a)(1), by inserting  
8           “preapproval or” before “risk-based inspections”;  
9           and

10          (2) by adding at the end the following:

11          “(c) PERIODIC REVIEW.—

12           “(1) IN GENERAL.—Beginning not later than 1  
13          year after the date of the enactment of the IN-  
14          SPECTIONS Act the Secretary shall periodically as-  
15          sess whether additional arrangements and agree-  
16          ments with a foreign government or an agency of a  
17          foreign government, as allowed under this section,  
18          are appropriate.

19           “(2) REPORTS TO CONGRESS.—Beginning not  
20          later than 4 years after the date of the enactment  
21          of the INSPECTIONS Act, and every 4 years there-  
22          after, the Secretary shall submit to the Committee  
23          on Energy and Commerce of the House of Rep-  
24          resentatives and the Committee on Health, Edu-  
25          cation, Labor and Pensions a report describing the

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

3 **SEC. 3. GAO REPORT ON INSPECTIONS OF FOREIGN ESTAB-**  
4 **LISHMENTS MANUFACTURING DRUGS.**

5 (a) IN GENERAL.—Not later than 18 months after  
6 the date of the enactment of this Act, the Comptroller  
7 General of the United States shall submit to the Com-  
8 mittee on Energy and Commerce of the House of Rep-  
9 resentatives and the Committee on Health, Education,  
10 Labor and Pensions of the Senate a report on inspections  
11 of foreign establishments conducted by the Secretary of  
12 Health and Human Services pursuant to subsections (h)  
13 and (i) of section 510 and section 704 of the Federal  
14 Food, Drug, and Cosmetic Act (21 U.S.C. 360, 374) (or  
15 a foreign government or an agency of a foreign govern-  
16 ment pursuant to section 809 of such Act (21 U.S.C.  
17 384e)).

18 (b) CONTENTS.—The report conducted under sub-  
19 section (a) shall include—

20 (1) what alternative tools, including remote in-  
21 spections, other countries are utilizing to facilitate  
22 inspections of foreign establishments;

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

1 useful to the Food and Drug Administration to re-  
2 view in lieu of its own inspections;

3 (3) how frequently and under what cir-  
4 cumstances, including for what types of inspections,  
5 the Secretary utilizes existing agreements or ar-  
6 rangements under section 809 of the Federal Food,  
7 Drug, and Cosmetic Act (21 U.S.C. 384e) and  
8 whether the use of such agreements could be appro-  
9 priately expanded;

10 (4) whether the Secretary has accepted reports  
11 of inspections of facilities in China and India con-  
12 ducted by entities with which they have entered into  
13 such an agreement or arrangement;

14 (5) what additional foreign governments or  
15 agencies of foreign governments the Secretary has  
16 considered entering into a mutual recognition agree-  
17 ment with and, if applicable, reasons why the Sec-  
18 retary declined to enter into a mutual recognition  
19 agreement with such foreign governments or agen-  
20 cies;

21 (6) what tools, if any, the Secretary used to fa-  
22 cilitate inspections of domestic facilities that could  
23 also be effectively utilized to appropriately inspect  
24 foreign facilities;

1           (7) what steps the Secretary has taken to iden-  
2           tify and evaluate tools and strategies the Secretary  
3           may use to continue oversight with respect to inspec-  
4           tions when in-person inspections are disrupted;

5           (8) how the Secretary is considering incor-  
6           porating alternative tools into the inspection activi-  
7           ties conducted pursuant to the Federal Food, Drug,  
8           and Cosmetic Act (21 U.S.C. 321 et seq.); and

9           (9) what steps the Secretary has taken to iden-  
10          tify and evaluate how the Secretary may use alter-  
11          native tools to address workforce shortages to carry  
12          out such inspection activities.