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115TH CONGRESS
1ST SESSION

# H. R. 1736

To amend the Federal Food, Drug, and Cosmetic Act to improve the process for inspections of device establishments and for granting export certifications.

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IN THE HOUSE OF REPRESENTATIVES

MARCH 27, 2017

Mr. BUCSHON (for himself, Mrs. BROOKS of Indiana, Mr. PETERS, and Mr. BUTTERFIELD) 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 the process for inspections of device establishments and for granting export certifications.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

**SECTION 1. FINDINGS.**

Congress finds as follows:

(1) There is a lack of transparency and consistency concerning inspections by the Food and Drug Administration of medical device establishments around the world, which leads to inefficiencies and

inconsistencies and undermines confidence in United States standards.

(2) Inspections by the Food and Drug Administration of foreign device establishments are often conducted more efficiently than inspections of domestic device establishments.

(3) The frequency and nature of inspections of device establishments are not consistently risk-based, and a comprehensive, transparent, risk-based approach to inspections would result in greater focus on the more significant risks to public health while reducing the burdens on establishments with a strong track record of compliance.

(4) There is a lack of transparency and consistency among United States-based regional inspection offices with respect to the frequency of inspections of device establishments and the activities and concerns that trigger for-cause inspections of such establishments.

(5) Greater transparency concerning the timing and nature of routine inspections of device establishments would improve the quality and efficiency of the inspection process.

(6) Enhancing communications before, during, and after inspections in which deficiencies are identi-

fied, would assist the Secretary of Health and Human Services and the device industry in maintaining the safety and effectiveness of devices.

(7) Guidance for device establishments is necessary to provide transparency and consistency concerning inspection-related communications.

(8) Enhanced training opportunities for device establishment investigators would improve the consistency and efficiency of the device inspection process.

(9) There is a lack of transparency in the export certification process with respect to device establishments for which FDA Form 483 has been used to document issues noticed during an inspection conducted pursuant to section 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374) or establishments that have received Warning Letters in connection with such an inspection, and between domestic and foreign establishments, resulting in devices that are lawfully marketed for United States patients being denied certification for marketing in other countries.

(10) Device establishments that have attempted to address deficiencies identified by inspections carried out by the Food and Drug Administration lack

sufficient opportunities to confirm that such corrective actions are appropriate.

**SEC. 2. RISK-BASED INSPECTIONS FOR DEVICES.**

Paragraph (2) of section 510(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(h)) is amended to read as follows:

''(2) RISK-BASED SCHEDULE FOR DEVICES.—

''(A) IN GENERAL.—The Secretary, acting through one or more officers or employees duly designated by the Secretary, shall inspect establishments described in paragraph (1) that are engaged in the manufacture, propagation, compounding, or processing of a device or devices (referred to in this subsection as 'device establishments') in accordance with one risk-based inspection schedule established by the Secretary, applied consistently across regional offices.

''(B) FACTORS AND CONSIDERATIONS.—In establishing the risk-based schedule under subparagraph (A), the Secretary shall—

''(i) apply, to the extent applicable for device establishments, the factors identified in paragraph (4); and

''(ii) consider the participation of the device establishment, as applicable, in international device audit programs in which the United States participates or the United States recognizes for purposes of inspecting.''.

**SEC. 3. IMPROVEMENTS TO INSPECTIONS PROCESS FOR DEVICE ESTABLISHMENTS.**

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

''(h)(1) The Secretary shall adopt a uniform process and uniform standards applicable to inspections of domestic and foreign device establishments. Such process shall include—

''(A) notifying the owner, operator, or agent in charge of the establishment of the type and nature of the inspection;

''(B) announcing the inspection the establishment within a reasonable time before such inspection;

''(C) in the case of inspections other than for-cause inspections, providing a reasonable estimate of the timeframe for the inspection, an opportunity for advance communications between the officers or em-

ployees carrying out the inspection under subsection (a)(1) and the owner, operator, or agent in charge of the establishment concerning appropriate working hours during the inspection, and, to the extent feasible, advance notice of records that will be requested in order to expedite the inspection; and

''(D) daily communications with the owner, operator, or agent in charge of the establishment regarding inspection status, which may be recorded by either party with advance notice.

''(2) In the case of device establishments that have received a report pursuant to subsection (b), and for which the owner, operator, or agent in charge of such establishment submits a timely response to such report that includes a request for feedback to the actions proposed in such response, the Secretary shall provide nonbinding feedback regarding such proposed actions within 45 days of receipt of such request.

''(3) Nothing in this subsection limits the authority of the Secretary to conduct inspections otherwise permitted under this Act in order to ensure compliance with this Act.

''(4)(A) Not later than 1 year after the date of enactment of this subsection, the Secretary shall issue draft guidance that—

''(i) specifies how the Food and Drug Administration will implement the process described in paragraph (1) and the requirements described in paragraph (2);

''(ii) provides for standardized templates for communications described in such paragraphs;

''(iii) establishes a standard timeframe over consecutive days that is applicable to both domestic and foreign inspections, to which each inspector shall adhere unless an investigator can identify to the establishment a reason that more time is needed; and

''(iv) identifies practices for investigators and device establishments to facilitate the continuity of inspections.

''(B) Not later than 18 months after the date of enactment of this subsection, after notice and opportunity for public comment on the draft guidance described in subparagraph (A), the Secretary shall issue final guidance consistent with this subsection.''.

**SEC. 4. CERTIFICATES TO FOREIGN GOVERNMENTS FOR DEVICES.**

Subsection (e)(4) of section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(e)(4)) is amended—

(1) by adding at the end the following:

''(E)(i) If the Secretary denies a request for certification with respect to a device pursuant to subparagraph (A)(ii), the Secretary shall provide in writing to the person seeking such certification the basis for such denial, and specifically identify the finding upon which such denial is based.

''(ii) If the denial of a request as described in clause (i) is based on grounds other than an injunction proceeding pursuant to section 302, seizure action pursuant to section 304, or a recall designated Class I or Class II pursuant to part 7, title 21, Code of Federal Regulations, the Secretary shall provide a substantive summary of the specific deficiencies identified.

''(iii) With respect to a device manufactured in an establishment that has received a report under section 704(b), the Secretary shall not deny a request for certification with respect to a device pursuant to subparagraph (A)(ii) if the Secretary and the owner, operator, or agent in charge of such establishment have agreed to a plan of correction in response to such report.

''(F)(i) The Secretary shall provide a process for a person who is denied a certification as described in subparagraph (E)(i) to request a review that conforms to the standards of section 517A(b).

''(ii) Notwithstanding any previous review conducted pursuant to clause (i), a person who has been denied a certification as described in subparagraph (E)(i) may at any time request a review in order to present new information relating to actions taken by such person to address the reasons identified by the Secretary for the denial of certification, including corrective actions to address deficiencies identified by the Secretary.

''(iii) Not later than 1 year after date of enactment of this subparagraph, the Secretary shall issue guidance providing for a process to carry out this subparagraph.

''(G)(i) Subparagraphs (E) and (F) apply to requests for certification on behalf of any device establishment registered under section 510, whether the establishment is located in the United States or another country.

''(ii) The Secretary may charge a fee for the issuance of a certification described in clause (i), and such fee is subject to the conditions and requirements of subparagraph (B).''; and

(2) by moving the margins of subparagraphs (C) and (D) 4 ems to the left.

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