

115TH CONGRESS
1ST SESSION

S. 404

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

IN THE SENATE OF THE UNITED STATES

FEBRUARY 15, 2017

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

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.

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. FINDINGS.**

4 Congress finds as follows:

5 (1) There is a lack of transparency and consist-
6 ency concerning inspections by the Food and Drug
7 Administration of medical device establishments
8 around the world, which leads to inefficiencies and

1 inconsistencies and undermines confidence in United
2 States standards.

3 (2) Inspections by the Food and Drug Adminis-
4 tration of foreign device establishments are often
5 conducted more efficiently than inspections of do-
6 mestic device establishments.

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

14 (4) There is a lack of transparency and consist-
15 ency among United States-based regional inspection
16 offices with respect to the frequency of inspections
17 of device establishments and the activities and con-
18 cerns that trigger for-cause inspections of such es-
19 tablishments.

20 (5) Greater transparency concerning the timing
21 and nature of routine inspections of device establish-
22 ments would improve the quality and efficiency of
23 the inspection process.

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

1 fied, would assist the Secretary of Health and
2 Human Services and the device industry in main-
3 taining the safety and effectiveness of devices.

4 (7) Guidance for device establishments is nec-
5 essary to provide transparency and consistency con-
6 cerning inspection-related communications.

7 (8) Enhanced training opportunities for device
8 establishment investigators would improve the con-
9 sistency and efficiency of the device inspection proc-
10 ess.

11 (9) There is a lack of transparency in the ex-
12 port certification process with respect to device es-
13 tablishments for which FDA Form 483 has been
14 used to document issues noticed during an inspec-
15 tion conducted pursuant to section 704 of the Fed-
16 eral Food, Drug, and Cosmetic Act (21 U.S.C. 374)
17 or establishments that have received Warning Let-
18 ters in connection with such an inspection, and be-
19 tween domestic and foreign establishments, resulting
20 in devices that are lawfully marketed for United
21 States patients being denied certification for mar-
22 keting in other countries.

23 (10) Device establishments that have attempted
24 to address deficiencies identified by inspections car-
25 ried out by the Food and Drug Administration lack

1 sufficient opportunities to confirm that such correc-
2 tive actions are appropriate.

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

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

7 “(2) RISK-BASED SCHEDULE FOR DEVICES.—

8 “(A) IN GENERAL.—The Secretary, acting
9 through one or more officers or employees duly
10 designated by the Secretary, shall inspect estab-
11 lishments described in paragraph (1) that are
12 engaged in the manufacture, propagation,
13 compounding, or processing of a device or de-
14 vices (referred to in this subsection as ‘device
15 establishments’) in accordance with one risk-
16 based inspection schedule established by the
17 Secretary, applied consistently across regional
18 offices.

19 “(B) FACTORS AND CONSIDERATIONS.—In
20 establishing the risk-based schedule under sub-
21 paragraph (A), the Secretary shall—

22 “(i) apply, to the extent applicable for
23 device establishments, the factors identified
24 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-

1 ployees carrying out the inspection under subsection
2 (a)(1) and the owner, operator, or agent in charge
3 of the establishment concerning appropriate working
4 hours during the inspection, and, to the extent fea-
5 sible, advance notice of records that will be re-
6 quested in order to expedite the inspection; and

7 “(D) daily communications with the owner, op-
8 erator, or agent in charge of the establishment re-
9 garding inspection status, which may be recorded by
10 either party with advance notice.

11 “(2) In the case of device establishments that have
12 received a report pursuant to subsection (b), and for which
13 the owner, operator, or agent in charge of such establish-
14 ment submits a timely response to such report that in-
15 cludes a request for feedback to the actions proposed in
16 such response, the Secretary shall provide nonbinding
17 feedback regarding such proposed actions within 45 days
18 of receipt of such request.

19 “(3) Nothing in this subsection limits the authority
20 of the Secretary to conduct inspections otherwise per-
21 mitted under this Act in order to ensure compliance with
22 this Act.

23 “(4)(A) Not later than 1 year after the date of enact-
24 ment of this subsection, the Secretary shall issue draft
25 guidance that—

1 “(i) specifies how the Food and Drug Adminis-
2 tration will implement the process described in para-
3 graph (1) and the requirements described in para-
4 graph (2);

5 “(ii) provides for standardized templates for
6 communications described in such paragraphs;

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

13 “(iv) identifies practices for investigators and
14 device establishments to facilitate the continuity of
15 inspections.

16 “(B) Not later than 18 months after the date of en-
17 actment of this subsection, after notice and opportunity
18 for public comment on the draft guidance described in
19 subparagraph (A), the Secretary shall issue final guidance
20 consistent with this subsection.”.

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

23 Subsection (e)(4) of section 801 of the Federal Food,
24 Drug, and Cosmetic Act (21 U.S.C. 381(e)(4)) is amend-
25 ed—

1 (1) by adding at the end the following:

2 “(E)(i) If the Secretary denies a request for certifi-
3 cation with respect to a device pursuant to subparagraph
4 (A)(ii), the Secretary shall provide in writing to the person
5 seeking such certification the basis for such denial, and
6 specifically identify the finding upon which such denial is
7 based.

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

15 “(iii) With respect to a device manufactured in an
16 establishment that has received a report under section
17 704(b), the Secretary shall not deny a request for certifi-
18 cation with respect to a device pursuant to subparagraph
19 (A)(ii) if the Secretary and the owner, operator, or agent
20 in charge of such establishment have agreed to a plan of
21 correction in response to such report.

22 “(F)(i) The Secretary shall provide a process for a
23 person who is denied a certification as described in sub-
24 paragraph (E)(i) to request a review that conforms to the
25 standards of section 517A(b).

1 “(ii) Notwithstanding any previous review conducted
 2 pursuant to clause (i), a person who has been denied a
 3 certification as described in subparagraph (E)(i) may at
 4 any time request a review in order to present new informa-
 5 tion relating to actions taken by such person to address
 6 the reasons identified by the Secretary for the denial of
 7 certification, including corrective actions to address defi-
 8 ciencies identified by the Secretary.

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

12 “(G)(i) Subparagraphs (E) and (F) apply to requests
 13 for certification on behalf of any device establishment reg-
 14 istered under section 510, whether the establishment is
 15 located in the United States or another country.

16 “(ii) The Secretary may charge a fee for the issuance
 17 of a certification described in clause (i), and such fee is
 18 subject to the conditions and requirements of subpara-
 19 graph (B).”; and

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

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