AMENDMENT

OFFERED BY M__. _____

At the appropriate place, insert the following sections:

TITLE ____—IMPROVING THE PROCESS FOR INSPECTIONS OF DEVICE ESTABLISHMENTS

SEC. ___1. 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 a risk-based schedule established by the Secretary.

''(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 device establishments.''; and

SEC. ___2. RECOGNITION OF FOREIGN GOVERNMENT INSPECTIONS.

Subsection (a)(1) of section 809 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384e(a)(1)) is amended by inserting ''or 510(h)(2) (as applicable)''? before the semicolon at the end.

SEC. ___3. IMPROVEMENTS TO INSPECTIONS PROCESS FOR DEVICE ESTABLISHMENTS.

(a) IN GENERAL.—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) In the case of inspections other than for-cause inspections, the Secretary shall review processes and

standards applicable to inspections of domestic and foreign device establishments in effect as of the date of the enactment of this subsection, and update such processes and standards through the adoption of uniform processes and standards applicable to such inspections. Such processes and standards shall provide for—

''(A) exceptions to such processes and standards, as appropriate;

''(B) announcing the inspection of the establishment within a reasonable time before such inspection occurs, including by providing to the owner, operator, or agent in charge of the establishment a notification regarding the type and nature of the inspection;

''(C) a reasonable estimate of the timeframe for the inspection, an opportunity for advance communications between the officers or employees 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 some records that will be requested in order to expedite the inspection; and

''(D) regular communications during the inspection with the owner, operator, or agent in charge of

the establishment regarding inspection status, which may be recorded by either party with advance notice and mutual consent.

''(2)(A) The Secretary shall, with respect to a request described in subparagraph (B), provide nonbinding feedback with respect to such request not later than 45 days after the Secretary receives such request.

''(B) A request described in this subparagraph is a request for feedback—

''(i) that is made by the owner, operator, or agent in charge of such establishment in a timely manner; and

''(ii) with respect to actions proposed to be taken by a device establishment in a response to a report received by such establishment pursuant to subsection (b) that involve a public health priority, that implicate systemic or major actions, or relate to emerging safety issues (as determined by the Secretary).

''(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.''.

(b) GUIDANCE.—

(1) DRAFT GUIDANCE.—Not later than 18 months after the date of enactment of this section, the Secretary of Health and Human Services shall issue draft guidance that—

(A) specifies how the Food and Drug Administration will implement the process described in paragraph (1) of subsection (h) of section 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374), as added by subsection (a), and the requirements described in paragraph (2) of such subsection;

(B) provides for standardized methods for communications described in such paragraphs;

(C) establishes, with respect to inspections of both domestic and foreign device establishments (as referred to in section 510(h)(2) of the Federal Food, Drug, and Cosmetic Act, as amended by section 1), a standard timeframe for such inspections that—

(i) occurs over consecutive days;

(ii) to which each investigator conducting such an inspection shall adhere unless the investigator identifies to the establishment involved a reason that more time

is needed to conduct such investigation; and

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

(2) FINAL GUIDANCE.—Not later than 1 year after providing notice and opportunity for public comment on the draft guidance issued under paragraph (1), the Secretary of Health and Human Services shall issue final guidance to implement subsection (h) of section 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374), as added by subsection (a).

SEC. ___4. CERTIFICATES TO FOREIGN GOVERNMENTS FOR DEVICES.

(a) IN GENERAL.—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 made under subparagraph (A)(ii) for certification with respect to a device, 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—

''(I) 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, and

''(II) an establishment being considered out of compliance with part 820, title 21, Code of Federal Regulations,

the Secretary shall provide a substantive summary of the specific grounds for noncompliance so identified, if such grounds have not been previously communicated to the manufacturer.

''(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 under subparagraph (A)(ii) based exclusively on the issuance of that report if the owner, operator, or agent in charge of such establishment has

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 for a device as described in subparagraph (E)(i) may, at any time, request a review of that denial in order to present new information relating to actions taken by such person to address the reasons identified by the Secretary for such denial, including evidence that corrective actions are being or have been implemented to address the grounds for noncompliance identified by the Secretary under subparagraph (E)(ii).

''(G)(i) This paragraph applies 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 same conditions and requirements as a fee charged under subparagraph (B) for a certification issued under such subparagraph. ''; and

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

(b) GUIDANCE.—Not later than 1 year after date of the enactment of this section, the Secretary of Health and Human Services shall issue guidance providing for a process to carry out subparagraph (F) of section 801(e)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(e)(4)), as added by subsection (a). Not later than 12 months after the comment period closes for the draft guidance, the Secretary shall issue final guidance.

SEC. ___5. FACILITATING INTERNATIONAL HARMONIZATION.

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

''(15) Notwithstanding any other provision of this subsection, for purposes of conducting inspections of establishments that manufacture, prepare, propagate, compound, or process devices except

types of devices licensed under section 351 of the Public Health Service Act, which inspections are required under section 510(h) or are inspections of such establishments required to register pursuant to section 510(i), the Secretary may recognize auditing organizations that are recognized by organizations established by governments to facilitate international harmonization. Nothing in this paragraph affects the authority of the Secretary to inspect any device establishment pursuant to this Act. Nothing in this paragraph affects the authority of the Secretary to determine the official classification of an inspection. ''.