~~Title: To amend the Federal Food, Drug, and Cosmetic Act to ensure the safety of drug products, and for other purposes.~~

TITLE VII—DRUG SUPPLY CHAIN

~~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 "_____ Act of ____"].~~

~~SEC. 2. TABLE OF CONTENTS; REFERENCES IN ACT.~~

~~(a) Table of Contents.—The table of contents for this Act is as follows:~~

~~Sec.1.Short title.~~

~~Sec.2.Table of contents; references in Act.~~

~~Sec.3.Registration of domestic drug establishments.~~

~~Sec.4.Registration of foreign establishments.~~

~~Sec.5.Electronic system for registration and listing.~~

~~Sec.6.Risk-based inspection frequency.~~

~~Sec.7.Records for inspection.~~

~~Sec.8.Failure to allow foreign inspection.~~

~~Sec.9.Exchange of information.~~

~~Sec.10.Enhancing the safety and quality of the drug supply.~~

~~Sec.11.Accreditation of third-party auditors for drug establishments.~~

~~Sec.12.Standards for admission of imported drugs.~~

~~Sec.13.Notification.~~

~~Sec.14.Destruction of unsafe drugs.~~

~~Sec.15.Protection against intentional adulteration.~~

~~Sec.16.Enhanced criminal penalty for counterfeiting drugs.~~

~~Sec.17.Extraterritorial jurisdiction.~~

~~Sec.18.Drug distribution security.~~

~~(b) References in Act.—Except as otherwise specified, amendments made by this Act to a section or other provision of law are amendments to such section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).~~

~~SEC. 3~~ **SEC. 701**. REGISTRATION OF DOMESTIC DRUG ESTABLISHMENTS.

Section 510 (21 U.S.C. 360) is amended—

(1) in subsection (b)—

(A) in paragraph (1), by striking "On or before" and all ~~the~~ **that** follows through the period at the end and inserting the following "During the period beginning on October 1 and ending on December 31 of each year, every person who owns or operates any establishment in any State engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs shall register with the Secretary—

"(A) the name of such person, places of business of such person, all such establishments, the unique facility identifier of each such establishment, and a point of contact e-mail address; and

"(B) the name and place of business of each drug importer~~, and each manufacturer of drug excipients,~~ **or broker that takes physical possession of a finished drug product or active pharmaceutical ingredient** with which the person conducts business, including all establishments of each such drug importer ~~and excipient manufacturer~~ **or broker**, the unique facility identifier of each such establishment, and a point of contact e-mail address for each such drug importer ~~and excipient manufacturer.";~~ **or broker."; and**

(B) by adding at the end the following:

"(3) The Secretary may specify the unique facility identifier system that shall be used by registrants under paragraph (1)."; and

(2) in subsection (c), by striking ~~"his~~**"with the Secretary his** name, place of business, and such establishment" and inserting ~~"the~~**"with the Secretary—**

"(1) with respect to drugs, the information described under subsection ~~(b)."~~**(b)(1); and**

~~SEC. 4~~**"(2) with respect to devices, the information described under subsection (b)(2).".**

SEC. 702. REGISTRATION OF FOREIGN ESTABLISHMENTS.

(a) Enforcement of Registration of Foreign Establishments.—Section 502(o) (21 U.S.C. 352(o)) is amended by striking "in any State".

(b) Registration of Foreign Drug Establishments.—Section 510(i)~~(1)~~ (U.S.C. 360(i)~~(1))~~**)** is amended—

(1) **in paragraph (1)—**

(A) by amending the matter preceding subparagraph (A) to read as follows: "Every person who owns or operates any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or device that is imported or offered for import into the United States shall, through electronic means in accordance with the criteria of the Secretary—";

~~and~~

~~(2)~~**(B)** by amending subparagraph (A) to read as follows:

"(A) upon first engaging in any such activity, immediately submit a registration to the Secretary that includes—

"(i) with respect to drugs, the name and place of business of such person, all such establishments, the unique facility identifier of each such establishment, a point of contact e-mail address, the name of the United States agent of each such establishment, the name and place of business of each drug importer~~, and each manufacturer of drug excipients,~~ with which such person conducts business, including all establishments of each such drug importer ~~and excipient manufacturer~~, the unique facility identifier of each such establishment, and a point of contact e-mail address for each such drug importer ~~and excipient manufacturer~~; and

"(ii) with respect to devices, the name and place of business of the establishment, the name of the United States agent for the establishment, the name of each importer of such device in the United States that is known to the establishment, and the name of each person who imports or offers for import such device to the United States for purposes of importation; and"; and

~~(3)~~**(C)** by amending subparagraph (B) to read as follows:

"(B) each establishment subject to the requirements of subparagraph (A) shall thereafter register with the Secretary during the period beginning on October 1 and ending on December 31 of each year."**; and**~~.~~

~~SEC. 5~~**(2) by adding at the end the following:**

"(4) The Secretary may specify the unique facility identifier system that shall be used by registrants under paragraph (1) with respect to drugs.".

SEC. 703. REGISTRATION OF DRUG EXCIPIENT INFORMATION WITH PRODUCT LISTING.

Section 510(j)(1) (21 U.S.C. 360(j)(1)) is amended—

(1) in subparagraph (C), by striking "; and" and inserting a semicolon;

(2) in subparagraph (D), by striking the period at the end and inserting "; and"; and

(3) by adding at the end the following:

"(E) in the case of a drug contained in the applicable list and subject to section 505 or 512, the name and place of business of each manufacturer of an excipient of the drug with which the person so registered conducts business, including all establishments of each such excipient manufacturer, the unique facility identifier of each such establishment, and a point of contact e-mail address for each such excipient manufacturer.".

SEC. 704. ELECTRONIC SYSTEM FOR REGISTRATION AND LISTING.

Section 510(p) (21 U.S.C. 360(p)) is amended—

(1) by striking "(p) Registrations and listings" and inserting the following:

"(p) Electronic Registration and Listing.—

"(1) IN GENERAL.—Registration and listing"; and

(2) by adding at the end the following:

"(2) ELECTRONIC DATABASE.—Not later than ~~[2 years after XXX]~~ **2 years after the Secretary specifies a unique facility identifier system under subsections (b) and (i)**, the Secretary shall maintain an electronic database, which shall not be subject to inspection under subsection (f), populated with the information submitted as described under paragraph (1) that—

"(A) enables personnel of the Food and Drug Administration to search the database by any field of information submitted in a registration described under paragraph (1), or combination of such fields; and

"(B) ~~is interoperable and communicates~~ **uses the unique facility identifier system to link** with other relevant databases within the Food and Drug Administration, including the database for submission of information under section 801(r).

"(3) RISK-BASED INFORMATION AND COORDINATION.—The Secretary shall ensure the ~~interoperability,~~ accuracy~~,~~ and coordination of relevant Food and Drug Administration databases in order to identify and inform risk-based inspections under section 510(h).".

SEC. ~~6~~ **705**. RISK-BASED INSPECTION FREQUENCY.

Section 510(h) (21 U.S.C. 360(h)) is amended to read as follows:

"(h) Inspections.—

"(1) IN GENERAL.—Every establishment that is required to be registered with the Secretary under this section shall be subject to inspection pursuant to section 704.

"(2) RISK-BASED SCHEDULE.—The Secretary, acting through one or more officers or

employees duly designated by the Secretary, shall inspect ~~every establishment~~ **establishments** described in paragraph (1) that ~~is~~ **are** engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs (referred to in this subsection as a 'drug ~~establishment')~~ **establishments')** in accordance with a risk-based schedule established by the Secretary.

"(3) RISK FACTORS.—In establishing the risk-based scheduled under paragraph (2), the Secretary shall allocate resources to inspect establishments according to the known safety risks of such establishments, which shall be based on the following factors:

"(A) The compliance history of ~~an~~ **the** establishment.

"(B) The record, history, and nature of recalls linked to ~~an~~ **the** establishment.

"(C) The inherent risk of the drug manufactured, prepared, propagated, compounded, or processed at ~~an~~ **the** establishment.

"(D) The certifications described under ~~section 801(r)~~ **sections 801(r) and 809 for the establishment.**

~~"(E)~~**"(E) Whether the establishment has been inspected in the preceding 4-year period.**

"(F) Any other criteria deemed necessary and appropriate by the Secretary for purposes of allocating inspection resources.

"(4) EFFECT OF STATUS.—In determining the risk associated with an establishment for purposes of establishing a risk-based schedule under paragraph (2), the Secretary shall not consider whether the drugs manufactured, prepared, propagated, compounded, or processed by such establishment are drugs described in section 503(b).

"(5) ANNUAL REPORT ON INSPECTIONS OF ESTABLISHMENTS.—Not later than February 1 of each year, the Secretary shall submit a report to Congress regarding—

"(A)(i) the number of domestic and foreign establishments registered pursuant to this section in the previous fiscal year; and

"(ii) the number of such **domestic establishments and the number of such foreign** establishments that the Secretary inspected in the previous fiscal year;

"(B) with respect to establishments that manufacture, prepare, propagate, compound, or process an active ingredient of a drug, a finished drug product, or an excipient of a drug, the number of each such type of establishment; and

"(C) the percentage of the budget of the Food and Drug Administration used to fund the inspections described under subparagraph (A).

"(6) PUBLIC AVAILABILITY OF ANNUAL REPORTS.—The Secretary shall make the report required under paragraph (5) available to the public on the Internet Web site of the Food and Drug Administration.".

SEC. ~~7~~ **706**. RECORDS FOR INSPECTION.

Section 704(a) (21 U.S.C. 374(a)) is amended by adding at the end the following:

"(4)(A) Any records or other information that the Secretary is entitled to request **under this**

section from a person that owns or operates an establishment ~~located in any State or foreign country~~ that is engaged in the manufacture, preparation, propagation, compounding, or processing of a drug shall, upon the request of the Secretary, be provided to the Secretary by such person within a reasonable time frame, within reasonable limits and in a reasonable manner, and in ~~either~~ electronic ~~[or physical~~ form~~]~~, at the expense of such person. **The Secretary's request shall include a clear description of the records requested.**

"(B) Upon receipt of the records requested under subparagraph (A), the Secretary shall provide to the person ~~correspondence confirming~~ **confirmation of** the receipt of such records.

"(C) Nothing in this paragraph supplants the authority of the Secretary to conduct inspections otherwise permitted under this Act in order to ensure compliance by an establishment with this Act.".

SEC. ~~8~~ **707**. FAILURE TO ALLOW FOREIGN INSPECTION.

Section 801(a) (21 U.S.C. 381(a)) is amended by adding at the end the following: "Notwithstanding any other provision of this subsection, the Secretary of Homeland Security shall**, upon request from the Secretary of Health and Human Services** refuse to admit into the United States any article if the article was manufactured, **prepared, propagated, compounded,** processed, ~~packed,~~ or held at an establishment that has refused ~~or delayed an inspection by~~ **to permit** the Secretary of Health and Human ~~Services.".~~ **Services to enter or inspect the establishment in the same manner and to the same extent as the Secretary may inspect establishments under section 704.".**

~~SEC. 9~~ **SEC. 708**. EXCHANGE OF INFORMATION.

Section 708 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379) is amended—

(1) by striking "CONFIDENTIAL INFORMATION" and all that follows through "The Secretary" and inserting "confidential information.

"(a) Contractors.—The Secretary"; and

(2) by adding at the end the following:

"(b) Ability to Receive and Protect Confidential Information.—The Secretary shall not be required to disclose under section 552 of title 5, United States Code, or any other provision of law, any information relating to drugs obtained from a Federal, State or local government agency, or from a foreign government agency, if the agency has requested that the information be kept confidential, except pursuant to an order of a court of the United States. For purposes of section 552 of title 5, United States Code, this subsection shall be considered a statute described in section 552(b)(3)(B).

"(c) Authority to Enter Into Memoranda of Understanding for Purposes of Information Exchange.—The Secretary may enter into written agreements regarding the exchange of information referenced in section 301(j) subject to the following criteria:

"(1) CERTIFICATION.—The Secretary may only enter into written agreements under this subsection with foreign governments that the Secretary has certified as having the authority and demonstrated ability to protect trade secret information from disclosure. Responsibility for this certification shall not be delegated to any officer or employee other than the

Commissioner.

"(2) WRITTEN AGREEMENT.—The written agreement under this subsection shall include a commitment by the foreign government to protect information exchanged under this subsection from disclosure unless and until the sponsor gives written permission for disclosure or the Secretary makes a declaration of a public health emergency pursuant to section 319 of the Public Health Service Act that is relevant to the information.

"(3) INFORMATION EXCHANGE.—The Secretary may provide to a foreign government that has been certified under paragraph (1) and that has executed a written agreement under paragraph (2) information referenced in section 301(j) in the following circumstances:

"(A) Information concerning the inspection of a facility may be provided if—

"(i) the Secretary reasonably believes, or that the written agreement described in paragraph (2) establishes, that the government has authority to otherwise obtain such information; and

"(ii) the written agreement executed under paragraph (2) limits the recipient's use of the information to the recipient's civil regulatory purposes.

"(B) Information not described in subparagraph (A) may be provided as part of an investigation, or to alert the foreign government to the potential need for an investigation, if the Secretary has reasonable grounds to believe that a drug has a reasonable probability of causing serious adverse health consequences or death to humans or ~~animals.".~~ **animals.**

~~SEC. 10~~**"(4) EFFECT OF SUBSECTION.—Nothing in this subsection affects the ability of the Secretary to enter into any written agreement authorized by other provisions of law to share confidential information.".**

SEC. 709. ENHANCING THE SAFETY AND QUALITY OF THE DRUG SUPPLY.

Section 501 (21 U.S.C. 351) is amended by adding at the end the following flush text:

"For purposes of subsection (a)(2)(B), the term 'current good manufacturing practice' includes the implementation of oversight and controls over the manufacture of drugs to ensure quality, including managing the risk of and establishing the safety of raw materials, materials used in the manufacturing of drugs, and finished drug products.".

SEC. ~~11~~ **710**. ACCREDITATION OF THIRD-PARTY AUDITORS FOR DRUG ESTABLISHMENTS.

(a) In General.—Chapter VIII (21 U.S.C. 381 et seq.) is amended by adding at the end the following:

"SEC. 809. ACCREDITATION OF THIRD-PARTY AUDITORS FOR DRUG ESTABLISHMENTS.

"(a) Definitions.—In this section:

"(1) ACCREDITATION BODY.—The term 'accreditation body' means an authority that performs accreditation of third-party auditors.

"(2) ACCREDITED THIRD-PARTY AUDITOR.—The term 'accredited third-party auditor' means a third-party auditor (which may be an individual) accredited by an accreditation body to conduct drug safety **and quality** audits.

"(3) AUDIT AGENT.—The term 'audit agent' means an individual who is an employee or agent of an accredited third-party auditor and, although not individually accredited, is qualified to conduct drug safety **and quality** audits on behalf of an accredited third-party auditor.

"(4) CONSULTATIVE AUDIT.—The term 'consultative audit' means an audit of an eligible entity intended for internal purposes only to determine whether an establishment is in compliance with the provisions of this Act and applicable industry practices, or any other such service.

"(5) DRUG SAFETY **AND QUALITY** AUDIT.—The term 'drug safety **and quality** audit'—

"(A) means an audit of an eligible entity to certify that the eligible entity meets the requirements of this Act applicable to drugs, including the requirements of section 501 with respect to ~~the final dosage form of drugs and ingredients of~~ drugs; and

"(B) is not a consultative audit.

"(6) ELIGIBLE ENTITY.—The term 'eligible entity' means an entity, including a foreign drug establishment registered under section 510(c), in the drug supply chain that chooses to be audited by an accredited third-party auditor or the audit agent of such accredited third-party auditor.

"(7) THIRD-PARTY AUDITOR.—The term 'third-party auditor' means a foreign government, agency of a foreign government~~, foreign cooperative,~~ or any other third party (which may be an individual), as the Secretary determines appropriate in accordance with the criteria described in subsection (c)(1), that is eligible to be considered for accreditation to conduct drug safety **and quality** audits.

"(b) Accreditation System.—

"(1) RECOGNITION OF ACCREDITATION BODIES.—

"(A) IN GENERAL.—Not later than 2 years after date of enactment of the [insert short title], the Secretary shall establish a system for the recognition of accreditation bodies that accredit third-party auditors to conduct drug safety **and quality** audits.

"(B) DIRECT ACCREDITATION.—

"(i) IN GENERAL.—If, by the date that is 2 years after the date of establishment of the system described in subparagraph (A), the Secretary has not identified and recognized an accreditation body to meet the requirements of this section, the Secretary may directly accredit third-party auditors.

"(ii) CERTAIN DIRECT ACCREDITATIONS.—Notwithstanding subparagraph (A) or clause (i), the Secretary may directly accredit any foreign government or any agency of a foreign government as a third-party auditor at any time after the date

of enactment of the [insert short title].

"(2) NOTIFICATION.—Each accreditation body recognized by the Secretary shall submit to the Secretary—

"(A) a list of all accredited third-party auditors accredited by such body (including the name ~~and~~**,** contact information**, and scope and duration of accreditation** for each such auditor), and the audit agents of such auditors; and

"(B) updated lists as needed to ensure the list held by the Secretary is accurate.

"(3) REVOCATION OF RECOGNITION AS AN ACCREDITATION BODY.—The Secretary shall promptly revoke, after the opportunity for an informal hearing, the recognition of any accreditation body found not to be in compliance with the requirements of this section.

"(4) REINSTATEMENT.—The Secretary shall establish procedures to reinstate recognition of an accreditation body if the Secretary determines, based on evidence presented by such accreditation body, that revocation was inappropriate or that the body meets the requirements for recognition under this section.

"(5) MODEL ACCREDITATION STANDARDS.—

"(A) IN GENERAL.—Not later than 18 months after the date of enactment of the [insert short title], the Secretary shall develop model standards, including ~~requirements~~ **standards** for drug safety **and quality** audit **results,** reports**,** and certifications, and each recognized accreditation body shall ensure that third-party auditors and audit agents of such auditors meet such standards in order to qualify such third-party auditors as accredited third-party auditors under this section.

"(B) CONTENT.—The ~~requirements~~ **standards** developed under subparagraph (A) may—

"(i) include a description of required standards relating to the training procedures, ~~background qualifications~~ **competency**, management responsibilities, quality control, and conflict of interest requirements of accredited third-party auditors; and

"(ii) set forth procedures for the periodic renewal of the accreditation of accredited third-party auditors.

"(C) REQUIREMENT TO PROVIDE RESULTS **AND REPORTS** TO THE SECRETARY.—An accreditation body (or, in the case of direct accreditation under subsection (b)(1)(B), the Secretary) may not accredit a third-party auditor unless such third-party auditor agrees to provide to the Secretary, upon request, the results **and reports** of any drug safety **and quality** audit conducted pursuant to the accreditation provided under this section.

"(6) DISCLOSURE.—The Secretary shall maintain on the Internet Web site of the Food and Drug Administration a list of recognized accreditation bodies and accredited third-party auditors under this section.

"(c) Accredited Third-party Auditors.—

"(1) REQUIREMENTS FOR ACCREDITATION AS A THIRD-PARTY AUDITOR.—

"(A) FOREIGN GOVERNMENTS.—Prior to accrediting a foreign government or an agency of a foreign government as an accredited third-party auditor, the accreditation body (or, in the case of direct accreditation under subsection (b)(1)(B), the Secretary) shall perform such reviews and audits of drug safety programs, systems, and standards of the government or agency of the government as the Secretary deems necessary, including requirements under the standards developed under subsection (b)(5), to determine that the foreign government or agency of the foreign government is capable of adequately ensuring that eligible entities or drugs certified by such government or agency meet the requirements of this Act.

"(B) ~~FOREIGN COOPERATIVES AND OTHER~~ **OTHER** THIRD PARTIES.—Prior to accrediting any other third party to be an accredited third-party auditor, the accreditation body (or, in the case of direct accreditation under subsection (b)(1)(B), the Secretary) shall perform such reviews and audits of the training and qualifications of audit agents used by that party and conduct such reviews of internal systems and such other investigation of the party as the Secretary deems necessary, including requirements under the standards developed under subsection (b)(5), to determine that ~~each eligible entity certified by the party has systems and standards in use to ensure that such entity or drug~~ **the third party auditor is capable of adequately ensuring that an eligible entity or drug certified by such third party auditor** meets the requirements of this Act.

"(2) USE OF AUDIT AGENTS.—An accredited third-party auditor may conduct drug safety **and quality** audits and may employ or use audit agents to conduct drug safety **and quality** audits, but must ensure that such audit agents comply with all requirements the Secretary deems necessary, including requirements under subsections (c)(1) and (b)(5).

"(3) REVOCATION OF ACCREDITATION.—

"(A) IN GENERAL.—The Secretary shall promptly revoke, after the opportunity for an informal hearing, the accreditation of an accredited third-party auditor—

"(i) if, following an evaluation, the Secretary finds that the accredited third-party auditor is not in compliance with the requirements of this section; or

"(ii) following a refusal to allow United States officials to conduct such audits and investigations as may be necessary to ~~ensure continued~~ **determine** compliance with the requirements set forth in this section.

"(B) ADDITIONAL BASIS FOR REVOCATION OF ACCREDITATION.—The Secretary may revoke accreditation from an accredited third-party auditor in the case that such third-party auditor is accredited by an accreditation body for which recognition as an accreditation body under subsection (b)(3) is revoked, if the Secretary determines that there is good cause for the revocation of accreditation.

"(4) REACCREDITATION.—The Secretary shall establish procedures to reinstate the accreditation of a third-party auditor for which accreditation has been revoked under paragraph (3)—

"(A) if the Secretary determines, based on evidence presented, that—

"(i) the third-party auditor satisfies the requirements of this section; and

"(ii) adequate grounds for revocation no longer exist; and

"(B) in the case of a third-party auditor accredited by an accreditation body for which recognition as an accreditation body is revoked under subsection (b)(3)—

"(i) if the third-party auditor becomes accredited not later than 1 year after revocation of accreditation under paragraph (3), through direct accreditation under subsection (b)(1)(B), or by an accreditation body in good standing; or

"(ii) under such other conditions as the Secretary may require.

"(5) REQUIREMENT TO ISSUE CERTIFICATION OF ELIGIBLE ENTITIES FOR COMPLIANCE WITH CURRENT GOOD MANUFACTURING PRACTICE.—

"(A) IN GENERAL.—An accreditation body (or, in the case of direct accreditation under subsection (b)(1)(B), the Secretary) may not accredit a third-party auditor unless such third-party auditor agrees to issue a written and, as appropriate, electronic, **document or** certification**, as the Secretary may require under this Act,** regarding compliance with section 501 ~~to accompany each drug shipment for import into the United States from an eligible entity, subject to requirements set forth by the Secretary. Such written or electronic certification may be included with other documentation regarding such drug shipment. The Secretary shall consider certifications described~~**. The Secretary may consider any such document or certification to satisfy requirements** under section 801(r) and ~~when targeting~~ **to target** inspection resources under section 510(h).

"(B) REQUIREMENTS FOR ISSUING CERTIFICATION.—

"(i) IN GENERAL.—An accredited third-party auditor shall issue a drug certification described in subparagraph (A) and subsection (h) only after conducting a drug safety **and quality** audit and such other activities that may be necessary to establish compliance with the provisions of section 501.

"(ii) PROVISION OF CERTIFICATION.—Only an accredited third-party auditor or the Secretary may provide a drug certification described in subparagraph (A).

"(C) RECORDS.—Following any accreditation of a third-party auditor, the Secretary may, at any time, require the accredited third-party auditor or any audit agent of such auditor to submit to the Secretary a drug safety **and quality** audit report and such other reports or documents required as part of the drug safety **and quality** audit process, for any eligible entity for which the accredited third-party auditor or audit agent of such auditor performed a drug safety **and quality** audit. ~~Such report~~ **The Secretary** may ~~include~~ **require** documentation that the eligible entity is in compliance with any applicable registration requirements.

"(D) LIMITATION.—The requirement under subparagraph (C) shall not include any report or other documents resulting from a consultative audit, except that the Secretary may access the results of a consultative audit in accordance with section 704.

"(E) DECLARATION OF AUDIT TYPE.—Before an accredited third-party auditor begins any audit or provides any consultative service to an eligible entity, both the accredited third-party auditor and eligible entity shall establish in writing whether the audit is intended to be a drug safety **and quality** audit. Any audit, inspection, or consultative

service of any type provided by an accredited third-party auditor on behalf of an eligible entity shall be presumed to be a drug safety **and quality** audit in the absence of such a written agreement. Once a drug safety **and quality** audit is initiated, it shall be subject to the requirements of this section, and no person may withhold from the Secretary any document subject to subparagraph (C) on the grounds that the audit was a consultative audit or otherwise not a drug safety **and quality** audit.

"(F) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to limit the authority of the Secretary under section 704.

"(6) REQUIREMENTS REGARDING SERIOUS RISKS TO THE PUBLIC HEALTH.—If, at any time during a drug safety **and quality** audit, an accredited third-party auditor or an audit agent of such auditor discovers a condition that could cause or contribute to a serious risk to the public health, such auditor shall immediately notify the Secretary of—

"(A) the identity and location of the eligible entity subject to the drug safety **and quality** audit; and

"(B) such condition.

"(7) LIMITATIONS.—

"(A) IN GENERAL.—An audit agent of an accredited third party auditor may not perform a drug safety **and quality** audit of an eligible entity if such audit agent has performed a drug safety **and quality** audit or consultative audit of such eligible entity during the previous 13-month period.

"(B) WAIVER.—The Secretary may waive the application of subparagraph (A) if the Secretary determines that there is insufficient access to accredited third-party auditors in a country or region **or that the use of the same audit agent or accredited third party auditor is otherwise necessary**.

"(8) CONFLICTS OF INTEREST.—

"(A) **ACCREDITATION BODIES.—A recognized accreditation body shall—**

"(i) not be owned, managed, or controlled by any person that owns or operates an third-party auditor to be accredited by such body;

"(ii) in carrying out accreditation of third-party auditors under this section, have procedures to ensure against the use of any officer or employee of such body that has a financial conflict of interest regarding a third-party auditor to be accredited by such body; and

"(iii) annually make available to the Secretary disclosures of the extent to which such body and the officers and employees of such body have maintained compliance with clauses (i) and (ii) relating to financial conflicts of interest.

"(B) ACCREDITED THIRD-PARTY AUDITORS.—An accredited third-party auditor shall—

"(i) not be owned, managed, or controlled by any person that owns or operates an eligible entity to be certified by such auditor;

"(ii) in carrying out drug safety **and quality** audits of eligible entities under this section, have procedures to ensure against the use of any officer or employee of such auditor that has a financial conflict of interest regarding an eligible entity to be certified by such auditor; and

"(iii) annually make available to the Secretary disclosures of the extent to which such auditor and the officers and employees of such auditor have maintained compliance with clauses (i) and (ii) relating to financial conflicts of interest.

~~"(B)~~**"(C)** AUDIT AGENTS.—An audit agent shall—

"(i) not own or operate an eligible entity to be audited by such agent;

"(ii) in carrying out audits of eligible entities under this section, have procedures to ensure that such agent does not have a financial conflict of interest regarding an eligible entity to be audited by such agent; and

"(iii) annually make available to the Secretary disclosures of the extent to which such agent has maintained compliance with clauses (i) and (ii) relating to financial conflicts of interest.

~~"(C)~~**"(D)** REGULATIONS.—The Secretary shall promulgate regulations not later than 18 months after the date of enactment of the [insert short title] to implement this section and to ensure that there are protections against conflicts of interest between **a recognized accreditation body and the third-party auditor to be accredited by such accreditation body, and between** an accredited third-party auditor and the eligible entity to be ~~certified~~ **audited** by such auditor or audited by such audit agent. Such regulations shall include—

"(i) requiring that, to the extent practicable, drug safety **and quality** audits performed under this section be unannounced;

"(ii) a structure to decrease the potential for conflicts of interest, including timing and public disclosure, for fees paid by eligible entities to accredited third-party auditors; and

"(iii) appropriate limits on financial affiliations between an accredited third-party auditor or audit agents of such auditor and any person that owns or operates an eligible entity to be ~~certified~~ **audited** by such auditor, as described in subparagraphs (A) and (B).

"(d) False Statements.—Any statement or representation made—

"(1) by an employee or agent of an eligible entity to an accredited third-party auditor or audit agent; or

"(2) by an accreditation body, accredited third-party auditor, or audit agent of such auditor to the Secretary, shall be subject to section 1001 of title 18, United States Code.

"(e) Monitoring.—To ensure compliance with the requirements of this section, the Secretary—

"(1) shall periodically, or at least once every 4 years, reevaluate the accreditation bodies

described in subsection (b)(1);

"(2) shall periodically, or at least once every 4 years, evaluate the performance of each accredited third-party auditor, through the review of regulatory audit reports by such auditors, the compliance history as available of eligible entities certified by such auditors, and any other measures deemed necessary by the Secretary;

"(3) may at any time, conduct an onsite audit of any eligible entity certified by an accredited third-party auditor, with or without the auditor present; and

"(4) shall take any other measures deemed necessary by the Secretary.

"(f) Effect of Audit.—The results of a drug safety **and quality** audit by an accredited third-party auditor under this section—

"(1) may be used by the eligible entity—

"(A) as documentation of compliance with section 501(a)(2)(B) or section 801(r); and

"(B) for other purposes as determined appropriate by the Secretary; and

"(2) shall be used by the Secretary in establishing the risk-based inspection schedules under section 510(h).

"(g) ~~Neutralizing~~ Costs.—

"(1) AUTHORIZED FEES OF SECRETARY.—The Secretary may assess fees on accreditation bodies and accredited third-party auditors ~~for a fiscal year~~ in such an amount necessary to establish and administer the recognition and accreditation program under this section ~~in the fiscal year~~. The Secretary may require accredited third-party auditors and audit agents to reimburse the Food and Drug Administration for the work performed to carry out this section. The Secretary ~~shall make operating this program revenue-neutral and~~ shall not generate surplus revenue from such a reimbursement mechanism. Fees authorized under this paragraph shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriation Acts. Such fees are authorized to remain available until expended.

"(2) AUTHORIZED FEES ~~OF~~ **FOR** RECOGNIZED ACCREDITATION BODIES.—An accreditation body recognized by the Secretary under subsection (b) may assess a reasonable fee to accredit third-party auditors.

"(h) Limitations.—

"(1) NO EFFECT ON SECTION 704 INSPECTIONS.—The drug safety **and quality** audits performed under this section shall not be considered inspections under section 704.

"(2) NO EFFECT ON INSPECTION AUTHORITY.—Nothing in this section affects the authority of the Secretary to inspect any eligible entity pursuant to this Act.".

(b) Report on Accredited Third-party Auditors.—Not later than ~~[October 1, 20XX]~~ **January 20, 2017**, the Comptroller General of the United States shall submit to Congress a report that addresses the following, with respect to the period beginning on the date of implementation of section 809 of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)) and ending on the date of such report:

(1) The extent to which drug safety **and quality** audits completed by accredited third-party auditors under such section 809 are being used by the Secretary of Health and Human Services (referred to in this subsection as the "Secretary") in establishing or applying the risk-based inspection schedules under section 510(h) of such Act (as amended by section ~~7)~~ **705)**.

(2) The extent to which drug safety **and quality** audits completed by accredited third-party auditors **or agents** are assisting the Food and Drug Administration in evaluating compliance with sections 501(a)(2)(B) of such Act (21 U.S.C. 351(a)(2)(B)) and 801(r) of such Act (as added by section ~~12)~~ **711)**.

(3) Whether the Secretary has been able to access drug safety **and quality** audit reports completed by accredited third-party auditors under such section 809.

(4) Whether accredited third-party auditors accredited under such section 809 have adhered to the conflict of interest provisions set forth in such section.

(5) The extent to which the Secretary has audited recognized accreditation bodies or accredited third-party auditors to ensure compliance with the requirements of such section 809.

(6) The number of waivers under subsection (c)(7)(B) of such section 809 issued during the most recent 12-month period and the official justification by the Secretary for each determination that there was insufficient access to an accredited third-party auditor.

(7) The number of times a manufacturer has used the same accredited third-party auditor for 2 or more consecutive drug safety **and quality** audits under such section 809.

(8) Recommendations to Congress regarding the accreditation program under such section 809, including whether Congress should continue, modify, or terminate the program.

SEC. ~~12~~ **711**. STANDARDS FOR ADMISSION OF IMPORTED DRUGS.

~~(a) In General.—Section~~ **Section** 801 (21 U.S.C. 381) is amended—

(1) in subsection (o), by striking "drug or"; and

(2) by adding at the end the following:

"(r)(1) The Secretary may require, as a condition of granting admission to a drug imported or offered for import into the United States~~,~~ **(other than an unapproved drug imported or offered for import into the United States for use in preclinical research or in a clinical investigation under an investigational new drug exemption under section 505(i))** that the importer electronically submit information demonstrating that the drug complies with applicable requirements of this Act.

"(2) The information described under paragraph (1) may include—

"(A) information demonstrating the regulatory status of the drug, such as the new drug application, abbreviated new drug application, or investigational new drug or Drug Master File number;

"(B) facility information, such as proof of registration and the unique facility identifier;

"(C) indication of compliance with current good manufacturing practice, ~~such as satisfactory~~ testing results, certifications relating to satisfactory inspections, and compliance with the country of export regulations; and

"(D) any other information deemed necessary and appropriate by the Secretary to assess compliance of the article being offered for import.

"(3) Information requirements referred to in paragraph (2)(C) may ~~be satisfied~~**, at the discretion of the Secretary, be satisfied—**

"(A) by certifications from accredited third parties, as described under section 809**;**

"(B) through representation by a foreign government, if such inspection is conducted using standards and practices as agreed to by the Secretary; or

"(C) other appropriate documentation or evidence as described by the Secretary.

"(4) Not later than 18 months after the date of enactment of the [insert short title], the Secretary shall publish a notice of proposed rulemaking in the Federal Register to promulgate regulations with respect to the requirements described in paragraph (1). Such requirements shall not be effective before 180 days after the Secretary promulgates the final rule.".

SEC. ~~13~~ **712**. NOTIFICATION.

(a) Prohibited Acts.—Section 301 (21 U.S.C. 331) is amended by adding at the end the following:

"(aaa) The failure to notify the Secretary in violation of section 569.".

(b) Notification.—Subchapter E of chapter V (21 U.S.C. 360bbb et seq.) is amended by adding at the end the following:

"SEC. 569. NOTIFICATION.

"(a) Notification to Secretary.—With respect to a drug, the Secretary may require notification to the Secretary by a covered person if the covered person knows—

"(1) of a substantial loss or known theft of such drug **in the United States**; or

"(2) that such drug—

"(A) has been or is being counterfeited; and

"(B)(i) is the counterfeit product in commerce in the United States; or

"(ii) has been or is being imported into the United States.

"(b) Manner of Notification.—Notification under this section shall be made in a reasonable time, in such reasonable manner, and by such reasonable means as the Secretary may require by regulation or **specify in** guidance.

"(c) Definition.—In this section, the term 'covered person' means—

"(1) a person who is required to register under section 510 with respect to an establishment engaged in the manufacture, preparation, propagation, compounding, or

processing of a drug; ~~and~~ **or**

"(2) a person engaged in the wholesale distribution (as defined in section 503(e)(3)(B)) of a drug.".

SEC. ~~14~~ **713**. DESTRUCTION OF UNSAFE DRUGS.

(a) In General.—The sixth sentence of section 801(a) (21 U.S.C. 381(a)) is amended by inserting before the period at the end the following: ", except that the Secretary of **Health and Human Services, in collaboration with the Secretary of** Homeland Security ~~shall~~**, may** cause the destruction, without the opportunity for export, ~~upon referral from the Secretary of Health and Human Services, of any drug~~ **of any drug refused admission** that has reasonable probability of causing serious adverse health consequences or death to humans or animals, as determined by the Secretary of Health and Human Services, or that is valued at an amount that is $2,000 or less (or such higher amount as the Secretary of Homeland Security may set by regulation pursuant to section 1498 of title 19, United States Code)".

(b) Notice.—Subsection (a) of section 801 (21 U.S.C. 381), as amended by subsection (a), is further amended by inserting after the sixth sentence the following: "The Secretary of Health and Human Services shall issue regulations providing for notice and an opportunity for an informal hearing ~~for~~**, as described in the first sentence of this subsection, on** destruction of a drug under the sixth sentence of this subsection. ~~For a drug with a value less than and or equal to $2,000 (or, as described in the sixth sentence of this subsection, such higher amount as the Secretary of Homeland Security may set by regulation pursuant to section 1498 of title 19) such~~ **The** regulations shall provide ~~prompt~~ notice and an opportunity for an informal hearing to the owner or consignee ~~after the destruction has occurred. For a drug with a value greater than $2,000 (or, as described in the sixth sentence of this subsection, such higher amount as the Secretary of Homeland Security may set by regulation pursuant to section 1498 of title 19) that has reasonable probability of causing serious adverse health consequences or death to humans or animals, as determined by the Secretary of Health and Human Services, the regulations shall provide notice and an opportunity for an informal hearing to the owner or consignee~~ before the destruction occurs.".

(c) ~~Restitution.—In the regulations described in the sixth sentence of section 801(a) of the Federal Food, Drug, and Cosmetic Act (as added by subsection (b)), the Secretary of Health and Human Services shall establish an administrative process whereby an owner or consignee of a drug may obtain restitution for the value of the drug destroyed under the sixth sentence of such section upon demonstration that such drug was wrongfully destroyed.~~ **Applicability.—The amendment made by subsection (a) shall apply beginning on the effective date of the regulations promulgated under the amendment made by subsection (b).**

~~(d) Conforming Amendment.—The first sentence of subsection (a) of section 801 (21 U.S.C. 381) is amended by inserting after "to the owner or consignee," the following: "except as otherwise described in the sixth and seventh sentences of this subsection,".~~

~~(e) Effective Date.—The amendments made by subsections (a)~~

~~and (b) shall take effect [XX days] after the date of enactment of this Act.~~

~~SEC. 15~~ SEC. 714. PROTECTION AGAINST INTENTIONAL ADULTERATION.

Section 303(b) (21 U.S.C. 333(b)) is amended by adding at the end the following:

"(7) Notwithstanding subsection (a)**(2)**, any person that knowingly and intentionally adulterates a drug such that the drug is adulterated under subsection (a)(1), (b), (c), or (d) of section 501 and has a reasonable probability of causing serious adverse health consequences or death to humans or animals shall be imprisoned for not more than 20 years or fined not more than $1,000,000, or both.".

SEC. ~~16~~ 715. ENHANCED CRIMINAL PENALTY FOR COUNTERFEITING DRUGS.

Section 303(b) (21 U.S.C. 333(b)), as amended by section ~~15~~ **714**, is further amended by adding at the end the following:

"(8) Notwithstanding subsection (a)**(2)**, any person who knowingly and intentionally violates section 301(i) shall be imprisoned for not more than 20 years or fined not more than $4,000,000 or both.".

SEC. ~~17~~ 716. EXTRATERRITORIAL JURISDICTION.

Chapter III (21 U.S.C. 331 et seq.) is amended by adding at the end the following:

"SEC. 311. EXTRATERRITORIAL JURISDICTION.

"There is extraterritorial jurisdiction over any violation of this Act relating to any article regulated under this Act if such article was intended for import into the United States or if any act in furtherance of the violation was committed in the United States.".

~~[SEC. 18. DRUG DISTRIBUTION SECURITY.~~ SEC. 717. COMPLIANCE WITH INTERNATIONAL AGREEMENTS.

~~To be determined.]~~ **Nothing in this title (or an amendment made by this title) shall be construed in a manner inconsistent with the agreement establishing the World Trade Organization or any other treaty or international agreement to which the United States is a party.**