

# Drug Supply Chain Integrity

HELP Draft for Stakeholder Discussion

Working Group: Senators Harkin, Enzi, Bennet, Burr, Grassley, Whitehouse

March 16, 2012

This discussion draft reflects bipartisan efforts to develop consensus policy proposals to accompany the FDA human medical product user fee legislation. The discussion drafts represent just that, draft language that should encourage discussion. These do not represent a completed product but rather the start of bipartisan work that will hopefully lead to consensus language to be marked up. Our goal is to solicit feedback on the policy merits, potential unintended consequences, and potential opportunities to improve the legislative language. We anticipate releasing additional drafts in other policy areas in the upcoming weeks. The discussion drafts will be available on the HELP Committee website. Please submit your written comments to both Kathleen Laird ([Kathleen\\_Laird@help.senate.gov](mailto:Kathleen_Laird@help.senate.gov)) in Senator Harkin's office and Grace Stuntz ([Grace\\_Stuntz@help.senate.gov](mailto:Grace_Stuntz@help.senate.gov)) in Senator Enzi's office by April 1, 2012. We will try to meet with as many stakeholders as possible starting March 26, 2012, but will give priority to those that have submitted written comments.



112TH CONGRESS  
1ST SESSION

**S.** \_\_\_\_\_

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

\_\_\_\_\_  
IN THE SENATE OF THE UNITED STATES

\_\_\_\_\_ introduced the following bill; which was read twice and referred to the Committee on \_\_\_\_\_

**A BILL**

To amend the Federal Food, Drug, and Cosmetic Act to ensure the safety of drug products, 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 “ \_\_\_\_\_ Act  
5 of \_\_\_\_\_”].

6 **SEC. 2. TABLE OF CONTENTS; REFERENCES IN ACT.**

7 (a) TABLE OF CONTENTS.—The table of contents for  
8 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.

1           (b) REFERENCES IN ACT.—Except as otherwise spec-  
2 ified, amendments made by this Act to a section or other  
3 provision of law are amendments to such section or other  
4 provision of the Federal Food, Drug, and Cosmetic Act  
5 (21 U.S.C. 301 et seq.).

6 **SEC. 3. REGISTRATION OF DOMESTIC DRUG ESTABLISH-**  
7 **MENTS.**

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

9           (1) in subsection (b)—

10           (A) in paragraph (1), by striking “On or  
11 before” and all the follows through the period  
12 at the end and inserting the following “During  
13 the period beginning on October 1 and ending  
14 on December 31 of each year, every person who  
15 owns or operates any establishment in any  
16 State engaged in the manufacture, preparation,  
17 propagation, compounding, or processing of a  
18 drug or drugs shall register with the Sec-  
19 retary—

1           “(A) the name of such person, places of busi-  
2           ness of such person, all such establishments, the  
3           unique facility identifier of each such establishment,  
4           and a point of contact e-mail address; and

5           “(B) the name and place of business of each  
6           drug importer, and each manufacturer of drug  
7           excipients, with which the person conducts business,  
8           including all establishments of each such drug im-  
9           porter and excipient manufacturer, the unique facil-  
10          ity identifier of each such establishment, and a point  
11          of contact e-mail address for each such drug im-  
12          porter and excipient manufacturer.”;

13          (2) in subsection (c), by striking “his name,  
14          place of business, and such establishment” and in-  
15          serting “the information described under subsection  
16          (b).”

17 **SEC. 4. REGISTRATION OF FOREIGN ESTABLISHMENTS.**

18          (a) ENFORCEMENT OF REGISTRATION OF FOREIGN  
19 ESTABLISHMENTS.—Section 502(o) (21 U.S.C. 352(o)) is  
20 amended by striking “in any State”.

21          (b) REGISTRATION OF FOREIGN DRUG ESTABLISH-  
22 MENTS.—Section 510(i)(1) (U.S.C. 360(i)(1)) is amend-  
23 ed—

24                 (1) by amending the matter preceding subpara-  
25                 graph (A) to read as follows: “Every person who

1 owns or operates any establishment within any for-  
2 eign country engaged in the manufacture, prepara-  
3 tion, propagation, compounding, or processing of a  
4 drug or device that is imported or offered for import  
5 into the United States shall, through electronic  
6 means in accordance with the criteria of the Sec-  
7 retary—”; and

8 (2) by amending subparagraph (A) to read as  
9 follows:

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

13 (i) with respect to drugs, the name and  
14 place of business of such person, all such estab-  
15 lishments, the unique facility identifier of each  
16 such establishment, a point of contact e-mail  
17 address, the name of the United States agent of  
18 each such establishment, the name and place of  
19 business of each drug importer, and each manu-  
20 facturer of drug excipients, with which such  
21 person conducts business, including all estab-  
22 lishments of each such drug importer and excip-  
23 ient manufacturer, the unique facility identifier  
24 of each such establishment, and a point of con-

1           tact e-mail address for each such drug importer  
2           and excipient manufacturer; and

3                   “(ii) with respect to devices, the name and  
4           place of business of the establishment, the name  
5           of the United States agent for the establish-  
6           ment, the name of each importer of such device  
7           in the United States that is known to the estab-  
8           lishment, and the name of each person who im-  
9           ports or offers for import such device to the  
10          United States for purposes of importation;  
11          and”); and

12          (3) by amending subparagraph (B) to read as  
13          follows:

14                   “(B) each establishment subject to the require-  
15          ments of subparagraph (A) shall thereafter register  
16          with the Secretary during the period beginning on  
17          October 1 and ending on December 31 of each  
18          year.”.

19   **SEC. 5. ELECTRONIC SYSTEM FOR REGISTRATION AND**  
20                   **LISTING.**

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

22                   (1) by striking “(p) Registrations and listings”  
23          and inserting the following:

24          “(p) ELECTRONIC REGISTRATION AND LISTING.—

1 “(1) IN GENERAL.—Registration and listing”;

2 and

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

4 “(2) ELECTRONIC DATABASE.—Not later than  
5 **[2 years after XXX]**, the Secretary shall maintain

6 an electronic database, which shall not be subject to  
7 inspection under subsection (f), populated with the

8 information submitted as described under paragraph  
9 (1) that—

10 “(A) enables personnel of the Food and  
11 Drug Administration to search the database by

12 any field of information submitted in a registra-  
13 tion described under paragraph (1), or com-

14 bination of such fields; and

15 “(B) is interoperable and communicates  
16 with other relevant databases within the Food

17 and Drug Administration, including the data-  
18 base for submission of information under sec-

19 tion 801(r).

20 “(3) RISK-BASED INFORMATION AND COORDI-  
21 NATION.—The Secretary shall ensure the interoper-

22 ability, accuracy, and coordination of relevant Food  
23 and Drug Administration databases in order to iden-

24 tify and inform risk-based inspections under section  
25 510(h).”.

1 **SEC. 6. RISK-BASED INSPECTION FREQUENCY.**

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

4 “(h) INSPECTIONS.—

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

9 “(2) RISK-BASED SCHEDULE.—The Secretary,  
10 acting through one or more officers or employees  
11 duly designated by the Secretary, shall inspect every  
12 establishment described in paragraph (1) that is en-  
13 gaged in the manufacture, preparation, propagation,  
14 compounding, or processing of a drug or drugs (re-  
15 ferred to in this subsection as a ‘drug establish-  
16 ment’) in accordance with a risk-based schedule es-  
17 tablished by the Secretary.

18 “(3) RISK FACTORS.—In establishing the risk-  
19 based schedule under paragraph (2), the Secretary  
20 shall allocate resources to inspect establishments ac-  
21 cording to the known safety risks of such establish-  
22 ments, which shall be based on the following factors:

23 “(A) The compliance history of an estab-  
24 lishment.

25 “(B) The record, history, and nature of re-  
26 calls linked to an establishment.

1           “(C) The inherent risk of the drug manu-  
2           factured, prepared, propagated, compounded, or  
3           processed at an establishment.

4           “(D) The certifications described under  
5           section 801(r)

6           “(E) Any other criteria deemed necessary  
7           and appropriate by the Secretary for purposes  
8           of allocating inspection resources.

9           “(4) EFFECT OF STATUS.—In determining the  
10          risk associated with an establishment for purposes of  
11          establishing a risk-based schedule under paragraph  
12          (2), the Secretary shall not consider whether the  
13          drugs manufactured, prepared, propagated, com-  
14          pounded, or processed by such establishment are  
15          drugs described in section 503(b).

16          “(5) ANNUAL REPORT ON INSPECTIONS OF ES-  
17          TABLISHMENTS.—Not later than February 1 of each  
18          year, the Secretary shall submit a report to Con-  
19          gress regarding—

20                 “(A)(i) the number of domestic and foreign  
21                 establishments registered pursuant to this sec-  
22                 tion in the previous fiscal year; and

23                 “(ii) the number of such establishments  
24                 that the Secretary inspected in the previous fis-  
25                 cal year;

1                   “(B) with respect to establishments that  
2                   manufacture, prepare, propagate, compound, or  
3                   process an active ingredient of a drug, a fin-  
4                   ished drug product, or an excipient of a drug,  
5                   the number of each such type of establishment;  
6                   and

7                   “(C) the percentage of the budget of the  
8                   Food and Drug Administration used to fund  
9                   the inspections described under subparagraph  
10                  (A).

11                  “(6) PUBLIC AVAILABILITY OF ANNUAL RE-  
12                  PORTS.—The Secretary shall make the report re-  
13                  quired under paragraph (5) available to the public  
14                  on the Internet Web site of the Food and Drug Ad-  
15                  ministration.”.

16 **SEC. 7. RECORDS FOR INSPECTION.**

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

19                  “(4)(A) Any records or other information that the  
20                  Secretary is entitled to request from a person that owns  
21                  or operates an establishment located in any State or for-  
22                  eign country that is engaged in the manufacture, prepara-  
23                  tion, propagation, compounding, or processing of a drug  
24                  shall, upon the request of the Secretary, be provided to  
25                  the Secretary by such person within a reasonable time

1 frame, within reasonable limits and in a reasonable man-  
2 ner, and in either electronic [or physical form], at the  
3 expense of such person.

4 “(B) Upon receipt of the records requested under  
5 subparagraph (A), the Secretary shall provide to the per-  
6 son correspondence confirming the receipt of such records.

7 “(C) Nothing in this paragraph supplants the author-  
8 ity of the Secretary to conduct inspections otherwise per-  
9 mitted under this Act in order to ensure compliance by  
10 an establishment with this Act.”

11 **SEC. 8. FAILURE TO ALLOW FOREIGN INSPECTION.**

12 Section 801(a) (21 U.S.C. 381(a)) is amended by  
13 adding at the end the following: “Notwithstanding any  
14 other provision of this subsection, the Secretary of Home-  
15 land Security shall refuse to admit into the United States  
16 any article if the article was manufactured, processed,  
17 packed, or held at an establishment that has refused or  
18 delayed an inspection by the Secretary of Health and  
19 Human Services.”

20 **SEC. 9. EXCHANGE OF INFORMATION.**

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

23 (1) by striking “CONFIDENTIAL INFORMATION”  
24 and all that follows through “The Secretary” and in-  
25 serting “**CONFIDENTIAL INFORMATION.**”

1 “(a) CONTRACTORS.—The Secretary”; and

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

3 “(b) ABILITY TO RECEIVE AND PROTECT CONFIDEN-  
4 TIAL INFORMATION.—The Secretary shall not be required  
5 to disclose under section 552 of title 5, United States  
6 Code, or any other provision of law, any information relat-  
7 ing to drugs obtained from a Federal, State or local gov-  
8 ernment agency, or from a foreign government agency, if  
9 the agency has requested that the information be kept con-  
10 fidential, except pursuant to an order of a court of the  
11 United States. For purposes of section 552 of title 5,  
12 United States Code, this subsection shall be considered a  
13 statute described in section 552(b)(3)(B).

14 “(c) AUTHORITY TO ENTER INTO MEMORANDA OF  
15 UNDERSTANDING FOR PURPOSES OF INFORMATION EX-  
16 CHANGE.—The Secretary may enter into written agree-  
17 ments regarding the exchange of information referenced  
18 in section 301(j) subject to the following criteria:

19 “(1) CERTIFICATION.—The Secretary may only  
20 enter into written agreements under this subsection  
21 with foreign governments that the Secretary has cer-  
22 tified as having the authority and demonstrated abil-  
23 ity to protect trade secret information from disclo-  
24 sure. Responsibility for this certification shall not be

1 delegated to any officer or employee other than the  
2 Commissioner.

3 “(2) WRITTEN AGREEMENT.—The written  
4 agreement under this subsection shall include a com-  
5 mitment by the foreign government to protect infor-  
6 mation exchanged under this subsection from disclo-  
7 sure unless and until the sponsor gives written per-  
8 mission for disclosure or the Secretary makes a dec-  
9 laration of a public health emergency pursuant to  
10 section 319 of the Public Health Service Act that is  
11 relevant to the information.

12 “(3) INFORMATION EXCHANGE.—The Secretary  
13 may provide to a foreign government that has been  
14 certified under paragraph (1) and that has executed  
15 a written agreement under paragraph (2) informa-  
16 tion referenced in section 301(j) in the following cir-  
17 cumstances:

18 “(A) Information concerning the inspection  
19 of a facility may be provided if—

20 “(i) the Secretary reasonably believes,  
21 or that the written agreement described in  
22 paragraph (2) establishes, that the govern-  
23 ment has authority to otherwise obtain  
24 such information; and

1                   “(ii) the written agreement executed  
2                   under paragraph (2) limits the recipient’s  
3                   use of the information to the recipient’s  
4                   civil regulatory purposes.

5                   “(B) Information not described in sub-  
6                   paragraph (A) may be provided as part of an  
7                   investigation, or to alert the foreign government  
8                   to the potential need for an investigation, if the  
9                   Secretary has reasonable grounds to believe  
10                  that a drug has a reasonable probability of  
11                  causing serious adverse health consequences or  
12                  death to humans or animals.”.

13 **SEC. 10. ENHANCING THE SAFETY AND QUALITY OF THE**  
14 **DRUG SUPPLY.**

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

17 “For purposes of subsection (a)(2)(B), the term ‘current  
18 good manufacturing practice’ includes the implementation  
19 of oversight and controls over the manufacture of drugs  
20 to ensure quality, including managing the risk of and es-  
21 tablishing the safety of raw materials, materials used in  
22 the manufacturing of drugs, and finished drug products.”.

1 **SEC. 11. ACCREDITATION OF THIRD-PARTY AUDITORS FOR**  
2 **DRUG ESTABLISHMENTS.**

3 (a) IN GENERAL.—Chapter VIII (21 U.S.C. 381 et  
4 seq.) is amended by adding at the end the following:

5 **“SEC. 809. ACCREDITATION OF THIRD-PARTY AUDITORS**  
6 **FOR DRUG ESTABLISHMENTS.**

7 “(a) DEFINITIONS.—In this section:

8 “(1) ACCREDITATION BODY.—The term ‘ac-  
9 creditation body’ means an authority that performs  
10 accreditation of third-party auditors.

11 “(2) ACCREDITED THIRD-PARTY AUDITOR.—  
12 The term ‘accredited third-party auditor’ means a  
13 third-party auditor (which may be an individual) ac-  
14 credited by an accreditation body to conduct drug  
15 safety audits.

16 “(3) AUDIT AGENT.—The term ‘audit agent’  
17 means an individual who is an employee or agent of  
18 an accredited third-party auditor and, although not  
19 individually accredited, is qualified to conduct drug  
20 safety audits on behalf of an accredited third-party  
21 auditor.

22 “(4) CONSULTATIVE AUDIT.—The term ‘con-  
23 sultative audit’ means an audit of an eligible entity  
24 intended for internal purposes only to determine  
25 whether an establishment is in compliance with the

1 provisions of this Act and applicable industry prac-  
2 tices, or any other such service.

3 “(5) DRUG SAFETY AUDIT.—The term ‘drug  
4 safety audit’—

5 “(A) means an audit of an eligible entity  
6 to certify that the eligible entity meets the re-  
7 quirements of this Act applicable to drugs, in-  
8 cluding the requirements of section 501 with re-  
9 spect to the final dosage form of drugs and in-  
10 gredients of drugs; and

11 “(B) is not a consultative audit.

12 “(6) ELIGIBLE ENTITY.—The term ‘eligible en-  
13 tity’ means an entity, including a foreign drug estab-  
14 lishment registered under section 510(c), in the drug  
15 supply chain that chooses to be audited by an ac-  
16 credited third-party auditor or the audit agent of  
17 such accredited third-party auditor.

18 “(7) THIRD-PARTY AUDITOR.—The term ‘third-  
19 party auditor’ means a foreign government, agency  
20 of a foreign government, foreign cooperative, or any  
21 other third party (which may be an individual), as  
22 the Secretary determines appropriate in accordance  
23 with the criteria described in subsection (c)(1), that  
24 is eligible to be considered for accreditation to con-  
25 duct drug safety audits.

1 “(b) ACCREDITATION SYSTEM.—

2 “(1) RECOGNITION OF ACCREDITATION BOD-  
3 IES.—

4 “(A) IN GENERAL.—Not later than 2 years  
5 after date of enactment of the [insert short  
6 title], the Secretary shall establish a system for  
7 the recognition of accreditation bodies that ac-  
8 credit third-party auditors to conduct drug  
9 safety audits.

10 “(B) DIRECT ACCREDITATION.—

11 “(i) IN GENERAL.—If, by the date  
12 that is 2 years after the date of establish-  
13 ment of the system described in subpara-  
14 graph (A), the Secretary has not identified  
15 and recognized an accreditation body to  
16 meet the requirements of this section, the  
17 Secretary may directly accredit third-party  
18 auditors.

19 “(ii) CERTAIN DIRECT ACCREDITA-  
20 TIONS.—Notwithstanding subparagraph  
21 (A) or clause (i), the Secretary may di-  
22 rectly accredit any foreign government or  
23 any agency of a foreign government as a  
24 third-party auditor at any time after the

1 date of enactment of the [insert short  
2 title].

3 “(2) NOTIFICATION.—Each accreditation body  
4 recognized by the Secretary shall submit to the Sec-  
5 retary—

6 “(A) a list of all accredited third-party  
7 auditors accredited by such body (including the  
8 name and contact information for each such  
9 auditor), and the audit agents of such auditors;  
10 and

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

13 “(3) REVOCATION OF RECOGNITION AS AN AC-  
14 CREDITATION BODY.—The Secretary shall promptly  
15 revoke, after the opportunity for an informal hear-  
16 ing, the recognition of any accreditation body found  
17 not to be in compliance with the requirements of this  
18 section.

19 “(4) REINSTATEMENT.—The Secretary shall es-  
20 tablish procedures to reinstate recognition of an ac-  
21 creditation body if the Secretary determines, based  
22 on evidence presented by such accreditation body,  
23 that revocation was inappropriate or that the body  
24 meets the requirements for recognition under this  
25 section.

1 “(5) MODEL ACCREDITATION STANDARDS.—

2 “(A) IN GENERAL.—Not later than 18  
3 months after the date of enactment of the [in-  
4 sert short title], the Secretary shall develop  
5 model standards, including requirements for  
6 drug safety audit reports and certifications, and  
7 each recognized accreditation body shall ensure  
8 that third-party auditors and audit agents of  
9 such auditors meet such standards in order to  
10 qualify such third-party auditors as accredited  
11 third-party auditors under this section.

12 “(B) CONTENT.—The requirements devel-  
13 oped under subparagraph (A) may—

14 “(i) include a description of required  
15 standards relating to the training proce-  
16 dures, background qualifications, manage-  
17 ment responsibilities, quality control, and  
18 conflict of interest requirements of accred-  
19 ited third-party auditors; and

20 “(ii) set forth procedures for the peri-  
21 odic renewal of the accreditation of accred-  
22 ited third-party auditors.

23 “(C) REQUIREMENT TO PROVIDE RESULTS  
24 TO THE SECRETARY.—An accreditation body  
25 (or, in the case of direct accreditation under

1 subsection (b)(1)(B), the Secretary) may not  
2 accredit a third-party auditor unless such third-  
3 party auditor agrees to provide to the Sec-  
4 retary, upon request, the results of any drug  
5 safety audit conducted pursuant to the accredi-  
6 tation provided under this section.

7 “(6) DISCLOSURE.—The Secretary shall main-  
8 tain on the Internet Web site of the Food and Drug  
9 Administration a list of recognized accreditation  
10 bodies and accredited third-party auditors under this  
11 section.

12 “(c) ACCREDITED THIRD-PARTY AUDITORS.—

13 “(1) REQUIREMENTS FOR ACCREDITATION AS A  
14 THIRD-PARTY AUDITOR.—

15 “(A) FOREIGN GOVERNMENTS.—Prior to  
16 accrediting a foreign government or an agency  
17 of a foreign government as an accredited third-  
18 party auditor, the accreditation body (or, in the  
19 case of direct accreditation under subsection  
20 (b)(1)(B), the Secretary) shall perform such re-  
21 views and audits of drug safety programs, sys-  
22 tems, and standards of the government or agen-  
23 cy of the government as the Secretary deems  
24 necessary, including requirements under the  
25 standards developed under subsection (b)(5), to

1 determine that the foreign government or agen-  
2 cy of the foreign government is capable of ade-  
3 quately ensuring that eligible entities or drugs  
4 certified by such government or agency meet  
5 the requirements of this Act.

6 “(B) FOREIGN COOPERATIVES AND OTHER  
7 THIRD PARTIES.—Prior to accrediting any  
8 other third party to be an accredited third-  
9 party auditor, the accreditation body (or, in the  
10 case of direct accreditation under subsection  
11 (b)(1)(B), the Secretary) shall perform such re-  
12 views and audits of the training and qualifica-  
13 tions of audit agents used by that party and  
14 conduct such reviews of internal systems and  
15 such other investigation of the party as the Sec-  
16 retary deems necessary, including requirements  
17 under the standards developed under subsection  
18 (b)(5), to determine that each eligible entity  
19 certified by the party has systems and stand-  
20 ards in use to ensure that such entity or drug  
21 meets the requirements of this Act.

22 “(2) USE OF AUDIT AGENTS.—An accredited  
23 third-party auditor may conduct drug safety audits  
24 and may employ or use audit agents to conduct drug  
25 safety audits, but must ensure that such audit

1 agents comply with all requirements the Secretary  
2 deems necessary, including requirements under sub-  
3 sections (c)(1) and (b)(5).

4 “(3) REVOCATION OF ACCREDITATION.—

5 “(A) IN GENERAL.—The Secretary shall  
6 promptly revoke, after the opportunity for an  
7 informal hearing, the accreditation of an ac-  
8 credited third-party auditor—

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

13 “(ii) following a refusal to allow  
14 United States officials to conduct such au-  
15 dits and investigations as may be necessary  
16 to ensure continued compliance with the  
17 requirements set forth in this section.

18 “(B) ADDITIONAL BASIS FOR REVOCATION  
19 OF ACCREDITATION.—The Secretary may re-  
20 voke accreditation from an accredited third-  
21 party auditor in the case that such third-party  
22 auditor is accredited by an accreditation body  
23 for which recognition as an accreditation body  
24 under subsection (b)(3) is revoked, if the Sec-

1           retary determines that there is good cause for  
2           the revocation of accreditation.

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

7           “(A) if the Secretary determines, based on  
8           evidence presented, that—

9                   “(i) the third-party auditor satisfies  
10                  the requirements of this section; and

11                  “(ii) adequate grounds for revocation  
12                  no longer exist; and

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

17                   “(i) if the third-party auditor becomes  
18                  accredited not later than 1 year after rev-  
19                  ocation of accreditation under paragraph  
20                  (3), through direct accreditation under  
21                  subsection (b)(1)(B), or by an accredita-  
22                  tion body in good standing; or

23                   “(ii) under such other conditions as  
24                  the Secretary may require.

1           “(5) REQUIREMENT TO ISSUE CERTIFICATION  
2           OF ELIGIBLE ENTITIES FOR COMPLIANCE WITH CUR-  
3           RENT GOOD MANUFACTURING PRACTICE.—

4           “(A) IN GENERAL.—An accreditation body  
5           (or, in the case of direct accreditation under  
6           subsection (b)(1)(B), the Secretary) may not  
7           accredit a third-party auditor unless such third-  
8           party auditor agrees to issue a written and, as  
9           appropriate, electronic, certification regarding  
10          compliance with section 501 to accompany each  
11          drug shipment for import into the United  
12          States from an eligible entity, subject to re-  
13          quirements set forth by the Secretary. Such  
14          written or electronic certification may be in-  
15          cluded with other documentation regarding such  
16          drug shipment. The Secretary shall consider  
17          certifications described under section 801(r)  
18          and when targeting inspection resources under  
19          section 510(h).

20          “(B) REQUIREMENTS FOR ISSUING CER-  
21          TIFICATION.—

22          “(i) IN GENERAL.—An accredited  
23          third-party auditor shall issue a drug cer-  
24          tification described in subparagraph (A)  
25          and subsection (h) only after conducting a

1 drug safety audit and such other activities  
2 that may be necessary to establish compli-  
3 ance with the provisions of section 501.

4 “(ii) PROVISION OF CERTIFICATION.—

5 Only an accredited third-party auditor or  
6 the Secretary may provide a drug certifi-  
7 cation described in subparagraph (A).

8 “(C) RECORDS.—Following any accredita-  
9 tion of a third-party auditor, the Secretary  
10 may, at any time, require the accredited third-  
11 party auditor or any audit agent of such audi-  
12 tor to submit to the Secretary a drug safety  
13 audit report and such other reports or docu-  
14 ments required as part of the drug safety audit  
15 process, for any eligible entity for which the ac-  
16 credited third-party auditor or audit agent of  
17 such auditor performed a drug safety audit.  
18 Such report may include documentation that  
19 the eligible entity is in compliance with any ap-  
20 plicable registration requirements.

21 “(D) LIMITATION.—The requirement  
22 under subparagraph (C) shall not include any  
23 report or other documents resulting from a con-  
24 sultative audit, except that the Secretary may

1 access the results of a consultative audit in ac-  
2 cordance with section 704.

3 “(E) DECLARATION OF AUDIT TYPE.—Be-  
4 fore an accredited third-party auditor begins  
5 any audit or provides any consultative service to  
6 an eligible entity, both the accredited third-  
7 party auditor and eligible entity shall establish  
8 in writing whether the audit is intended to be  
9 a drug safety audit. Any audit, inspection, or  
10 consultative service of any type provided by an  
11 accredited third-party auditor on behalf of an  
12 eligible entity shall be presumed to be a drug  
13 safety audit in the absence of such a written  
14 agreement. Once a drug safety audit is initi-  
15 ated, it shall be subject to the requirements of  
16 this section, and no person may withhold from  
17 the Secretary any document subject to subpara-  
18 graph (C) on the grounds that the audit was a  
19 consultative audit or otherwise not a drug safe-  
20 ty audit.

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

24 “(6) REQUIREMENTS REGARDING SERIOUS  
25 RISKS TO THE PUBLIC HEALTH.—If, at any time

1 during a drug safety audit, an accredited third-party  
2 auditor or an audit agent of such auditor discovers  
3 a condition that could cause or contribute to a seri-  
4 ous risk to the public health, such auditor shall im-  
5 mediately notify the Secretary of—

6 “(A) the identity and location of the eligi-  
7 ble entity subject to the drug safety audit; and

8 “(B) such condition.

9 “(7) LIMITATIONS.—

10 “(A) IN GENERAL.—An audit agent of an  
11 accredited third party auditor may not perform  
12 a drug safety audit of an eligible entity if such  
13 audit agent has performed a drug safety audit  
14 or consultative audit of such eligible entity dur-  
15 ing the previous 13-month period.

16 “(B) WAIVER.—The Secretary may waive  
17 the application of subparagraph (A) if the Sec-  
18 retary determines that there is insufficient ac-  
19 cess to accredited third-party auditors in a  
20 country or region.

21 “(8) CONFLICTS OF INTEREST.—

22 “(A) ACCREDITED THIRD-PARTY AUDI-  
23 TORS.—An accredited third-party auditor  
24 shall—

1                   “(i) not be owned, managed, or con-  
2                   trolled by any person that owns or operates  
3                   an eligible entity to be certified by such  
4                   auditor;

5                   “(ii) in carrying out drug safety au-  
6                   dits of eligible entities under this section,  
7                   have procedures to ensure against the use  
8                   of any officer or employee of such auditor  
9                   that has a financial conflict of interest re-  
10                  garding an eligible entity to be certified by  
11                  such auditor; and

12                  “(iii) annually make available to the  
13                  Secretary disclosures of the extent to  
14                  which such auditor and the officers and  
15                  employees of such auditor have maintained  
16                  compliance with clauses (i) and (ii) relat-  
17                  ing to financial conflicts of interest.

18                  “(B) AUDIT AGENTS.—An audit agent  
19                  shall—

20                         “(i) not own or operate an eligible en-  
21                         tity to be audited by such agent;

22                         “(ii) in carrying out audits of eligible  
23                         entities under this section, have procedures  
24                         to ensure that such agent does not have a  
25                         financial conflict of interest regarding an

1 eligible entity to be audited by such agent;  
2 and

3 “(iii) annually make available to the  
4 Secretary disclosures of the extent to  
5 which such agent has maintained compli-  
6 ance with clauses (i) and (ii) relating to fi-  
7 nancial conflicts of interest.

8 “(C) REGULATIONS.—The Secretary shall  
9 promulgate regulations not later than 18  
10 months after the date of enactment of the [in-  
11 sert short title] to implement this section and  
12 to ensure that there are protections against  
13 conflicts of interest between an accredited third-  
14 party auditor and the eligible entity to be cer-  
15 tified by such auditor or audited by such audit  
16 agent. Such regulations shall include—

17 “(i) requiring that, to the extent prac-  
18 ticable, drug safety audits performed under  
19 this section be unannounced;

20 “(ii) a structure to decrease the po-  
21 tential for conflicts of interest, including  
22 timing and public disclosure, for fees paid  
23 by eligible entities to accredited third-party  
24 auditors; and

1                   “(iii) appropriate limits on financial  
2                   affiliations between an accredited third-  
3                   party auditor or audit agents of such audi-  
4                   tor and any person that owns or operates  
5                   an eligible entity to be certified by such  
6                   auditor, as described in subparagraphs (A)  
7                   and (B).

8           “(d) FALSE STATEMENTS.—Any statement or rep-  
9           resentation made—

10                   “(1) by an employee or agent of an eligible enti-  
11                   ty to an accredited third-party auditor or audit  
12                   agent; or

13                   “(2) by an accreditation body, accredited third-  
14                   party auditor, or audit agent of such auditor to the  
15                   Secretary, shall be subject to section 1001 of title  
16                   18, United States Code.

17           “(e) MONITORING.—To ensure compliance with the  
18           requirements of this section, the Secretary—

19                   “(1) shall periodically, or at least once every 4  
20                   years, reevaluate the accreditation bodies described  
21                   in subsection (b)(1);

22                   “(2) shall periodically, or at least once every 4  
23                   years, evaluate the performance of each accredited  
24                   third-party auditor, through the review of regulatory  
25                   audit reports by such auditors, the compliance his-

1 tory as available of eligible entities certified by such  
2 auditors, and any other measures deemed necessary  
3 by the Secretary;

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

8 “(4) shall take any other measures deemed nec-  
9 essary by the Secretary.

10 “(f) EFFECT OF AUDIT.—The results of a drug safe-  
11 ty audit by an accredited third-party auditor under this  
12 section—

13 “(1) may be used by the eligible entity—

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

16 “(B) for other purposes as determined ap-  
17 propriate by the Secretary; and

18 “(2) shall be used by the Secretary in estab-  
19 lishing the risk-based inspection schedules under sec-  
20 tion 510(h).

21 “(g) NEUTRALIZING COSTS.—

22 “(1) AUTHORIZED FEES OF SECRETARY.—The  
23 Secretary may assess fees on accreditation bodies  
24 and accredited third-party auditors for a fiscal year  
25 in such an amount necessary to establish and ad-

1 minister the recognition and accreditation program  
2 under this section in the fiscal year. The Secretary  
3 may require accredited third-party auditors and  
4 audit agents to reimburse the Food and Drug Ad-  
5 ministration for the work performed to carry out  
6 this section. The Secretary shall make operating this  
7 program revenue-neutral and shall not generate sur-  
8 plus revenue from such a reimbursement mecha-  
9 nism. Fees authorized under this paragraph shall be  
10 collected and available for obligation only to the ex-  
11 tent and in the amount provided in advance in ap-  
12 propriation Acts. Such fees are authorized to remain  
13 available until expended.

14 “(2) AUTHORIZED FEES OF RECOGNIZED AC-  
15 CREDITATION BODIES.—An accreditation body rec-  
16 ognized by the Secretary under subsection (b) may  
17 assess a reasonable fee to accredit third-party audi-  
18 tors.

19 “(h) LIMITATIONS.—

20 “(1) NO EFFECT ON SECTION 704 INSPEC-  
21 TIONS.—The drug safety audits performed under  
22 this section shall not be considered inspections under  
23 section 704.

24 “(2) NO EFFECT ON INSPECTION AUTHOR-  
25 ITY.—Nothing in this section affects the authority of

1 the Secretary to inspect any eligible entity pursuant  
2 to this Act.”.

3 (b) REPORT ON ACCREDITED THIRD-PARTY AUDI-  
4 TORS.—Not later than [October 1, 20XX], the Comp-  
5 troller General of the United States shall submit to Con-  
6 gress a report that addresses the following, with respect  
7 to the period beginning on the date of implementation of  
8 section 809 of the Federal Food, Drug, and Cosmetic Act  
9 (as added by subsection (a)) and ending on the date of  
10 such report:

11 (1) The extent to which drug safety audits com-  
12 pleted by accredited third-party auditors under such  
13 section 809 are being used by the Secretary of  
14 Health and Human Services (referred to in this sub-  
15 section as the “Secretary”) in establishing or apply-  
16 ing the risk-based inspection schedules under section  
17 510(h) of such Act (as amended by section 7).

18 (2) The extent to which drug safety audits com-  
19 pleted by accredited third-party auditors are assist-  
20 ing the Food and Drug Administration in evaluating  
21 compliance with sections 501(a)(2)(B) of such Act  
22 (21 U.S.C. 351(a)(2)(B)) and 801(r) of such Act (as  
23 added by section 12).

1           (3) Whether the Secretary has been able to ac-  
2           cess drug safety audit reports completed by accred-  
3           ited third-party auditors under such section 809.

4           (4) Whether accredited third-party auditors ac-  
5           credited under such section 809 have adhered to the  
6           conflict of interest provisions set forth in such sec-  
7           tion.

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

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

18          (7) The number of times a manufacturer has  
19          used the same accredited third-party auditor for 2 or  
20          more consecutive drug safety audits under such sec-  
21          tion 809.

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

1 **SEC. 12. STANDARDS FOR ADMISSION OF IMPORTED**  
2 **DRUGS.**

3 (a) IN GENERAL.—Section 801 (21 U.S.C. 381) is  
4 amended—

5 (1) in subsection (o), by striking “drug or”;  
6 and

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

8 “(r)(1) The Secretary may require, as a condition of  
9 granting admission to a drug imported or offered for im-  
10 port into the United States, that the importer electroni-  
11 cally submit information demonstrating that the drug  
12 complies with applicable requirements of this Act.

13 “(2) The information described under paragraph (1)  
14 may include—

15 “(A) information demonstrating the regulatory  
16 status of the drug, such as the new drug application,  
17 abbreviated new drug application, or investigational  
18 new drug or Drug Master File number;

19 “(B) facility information, such as proof of reg-  
20 istration and the unique facility identifier;

21 “(C) indication of compliance with current good  
22 manufacturing practice, such as satisfactory testing  
23 results, certifications relating to satisfactory inspec-  
24 tions, and compliance with the country of export  
25 regulations; and

1           “(D) any other information deemed necessary  
2           and appropriate by the Secretary to assess compli-  
3           ance of the article being offered for import.

4           “(3) Information requirements referred to in para-  
5           graph (2)(C) may be satisfied by certifications from ac-  
6           credited third parties, as described under section 809.

7           “(4) Not later than 18 months after the date of en-  
8           actment of the [insert short title], the Secretary shall  
9           publish a notice of proposed rulemaking in the Federal  
10          Register to promulgate regulations with respect to the re-  
11          quirements described in paragraph (1). Such requirements  
12          shall not be effective before 180 days after the Secretary  
13          promulgates the final rule.”.

14          **SEC. 13. NOTIFICATION.**

15          (a) PROHIBITED ACTS.—Section 301 (21 U.S.C.  
16          331) is amended by adding at the end the following:

17               “(aaa) The failure to notify the Secretary in violation  
18               of section 569.”.

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

22          **“SEC. 569. NOTIFICATION.**

23               “(a) NOTIFICATION TO SECRETARY.—With respect  
24               to a drug, the Secretary may require notification to the

1 Secretary by a covered person if the covered person  
2 knows—

3 “(1) of a substantial loss or known theft of  
4 such drug; or

5 “(2) that such drug—

6 “(A) has been or is being counterfeited;

7 and

8 “(B)(i) is the counterfeit product in com-  
9 merce in the United States; or

10 “(ii) has been or is being imported into the  
11 United States.

12 “(b) MANNER OF NOTIFICATION.—Notification  
13 under this section shall be made in a reasonable time, in  
14 such reasonable manner, and by such reasonable means  
15 as the Secretary may require by regulation or guidance.

16 “(c) DEFINITION.—In this section, the term ‘covered  
17 person’ means—

18 “(1) a person who is required to register under  
19 section 510 with respect to an establishment en-  
20 gaged in the manufacture, preparation, propagation,  
21 compounding, or processing of a drug; and

22 “(2) a person engaged in the wholesale distribu-  
23 tion (as defined in section 503(e)(3)(B)) of a drug.”.

1 **SEC. 14. DESTRUCTION OF UNSAFE DRUGS.**

2 (a) IN GENERAL.—The sixth sentence of section  
3 801(a) (21 U.S.C. 381(a)) is amended by inserting before  
4 the period at the end the following: “, except that the Sec-  
5 retary of Homeland Security shall cause the destruction,  
6 without the opportunity for export, upon referral from the  
7 Secretary of Health and Human Services, of any drug that  
8 has reasonable probability of causing serious adverse  
9 health consequences or death to humans or animals, as  
10 determined by the Secretary of Health and Human Serv-  
11 ices, or that is valued at an amount that is \$2,000 or less  
12 (or such higher amount as the Secretary of Homeland Se-  
13 curity may set by regulation pursuant to section 1498 of  
14 title 19, United States Code)”.

15 (b) NOTICE.—Subsection (a) of section 801 (21  
16 U.S.C. 381), as amended by subsection (a), is further  
17 amended by inserting after the sixth sentence the fol-  
18 lowing: “The Secretary of Health and Human Services  
19 shall issue regulations providing for notice and an oppor-  
20 tunity for an informal hearing for destruction of a drug  
21 under the sixth sentence of this subsection. For a drug  
22 with a value less than and or equal to \$2,000 (or, as de-  
23 scribed in the sixth sentence of this subsection, such high-  
24 er amount as the Secretary of Homeland Security may  
25 set by regulation pursuant to section 1498 of title 19)  
26 such regulations shall provide prompt notice and an oppor-

1 tunity for an informal hearing to the owner or consignee  
2 after the destruction has occurred. For a drug with a value  
3 greater than \$2,000 (or, as described in the sixth sentence  
4 of this subsection, such higher amount as the Secretary  
5 of Homeland Security may set by regulation pursuant to  
6 section 1498 of title 19) that has reasonable probability  
7 of causing serious adverse health consequences or death  
8 to humans or animals, as determined by the Secretary of  
9 Health and Human Services, the regulations shall provide  
10 notice and an opportunity for an informal hearing to the  
11 owner or consignee before the destruction occurs.”.

12 (c) RESTITUTION.—In the regulations described in  
13 the sixth sentence of section 801(a) of the Federal Food,  
14 Drug, and Cosmetic Act (as added by subsection (b)), the  
15 Secretary of Health and Human Services shall establish  
16 an administrative process whereby an owner or consignee  
17 of a drug may obtain restitution for the value of the drug  
18 destroyed under the sixth sentence of such section upon  
19 demonstration that such drug was wrongfully destroyed.

20 (d) CONFORMING AMENDMENT.—The first sentence  
21 of subsection (a) of section 801 (21 U.S.C. 381) is amend-  
22 ed by inserting after “to the owner or consignee,” the fol-  
23 lowing: “except as otherwise described in the sixth and  
24 seventh sentences of this subsection,”.

1 (e) EFFECTIVE DATE.—The amendments made by  
2 subsections (a) and (b) shall take effect [XX days] after  
3 the date of enactment of this Act.

4 **SEC. 15. PROTECTION AGAINST INTENTIONAL ADULTERA-**  
5 **TION.**

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

8 “(7) Notwithstanding subsection (a), any person that  
9 knowingly and intentionally adulterates a drug such that  
10 the drug is adulterated under subsection (a)(1), (b), (c),  
11 or (d) of section 501 and has a reasonable probability of  
12 causing serious adverse health consequences or death to  
13 humans or animals shall be imprisoned for not more than  
14 20 years or fined not more than \$1,000,000, or both.”.

15 **SEC. 16. ENHANCED CRIMINAL PENALTY FOR COUNTER-**  
16 **FEITING DRUGS.**

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

20 “(8) Notwithstanding subsection (a), any person who  
21 knowingly and intentionally violates section 301(i) shall be  
22 imprisoned for not more than 20 years or fined not more  
23 than \$4,000,000 or both.”.

1 **SEC. 17. EXTRATERRITORIAL JURISDICTION.**

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

4 **"SEC. 311. EXTRATERRITORIAL JURISDICTION.**

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

10 **[SEC. 18. DRUG DISTRIBUTION SECURITY.**

11 To be determined.]