accepted by FDA only through FDMS at *http://www.regulations.gov*.

Transcripts: Transcripts of the public workshop may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857, approximately 15 working days after the public workshop at a cost of 10 cents per page. A transcript of the public workshop will be available on the Internet at *http://www.fda.gov/cdrh/ocd/udi.index.html*.

Dated: January 6, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–784 Filed 1–14–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0656]

Secure Supply Chain Pilot Program; Notice of Pilot Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for sponsors and foreign manufacturers of finished drug products and active pharmaceutical ingredients (APIs) intended for human use imported by a secure supply chain to apply to participate in a voluntary Secure Supply Chain (SSC) pilot program to be conducted by FDA's Center for Drug Evaluation and Research (CDER) and Office of Regulatory Affairs (ORA). The goal of the pilot program is to allow FDA to determine the practicality of developing a secure supply chain program. The information obtained from this pilot program will assist FDA in its determination. A Secure Supply Chain program would assist the agency in its efforts to prevent the importation of adulterated, misbranded, or unapproved drugs by allowing the agency to focus its resources on imported drugs outside the program that may pose such risks. Such a program would increase the likelihood of expedited entry for specific finished drug products and APIs imported into the United States that meet the criteria for selection under the program.

DATES: Submit written or electronic comments on this pilot program by March 16, 2009. Submit written or electronic comments on the collection of information by March 16, 2009.

ADDRESSES: Submit written comments regarding this SSC pilot program to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments on the collection of information to *http://www.regulations.gov*. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Kathleen Anderson, Office of Compliance, Division of New Drugs and Labeling Compliance, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 51, rm. 5182, Silver Spring, MD 20993, 301–796–3110.

SUPPLEMENTARY INFORMATION:

I. Background

The SSC pilot program is part of FDA's risk-based approach to regulating drug imports, and it follows the President's charge to the Interagency Working Group on Import Safety to better assure that imported products are safe.

The goal of the pilot program is to allow FDA to determine the practicality of developing a secure supply chain program. The information obtained from this pilot program will assist FDA in its determination. A Secure Supply Chain program would assist the agency in its efforts to prevent the importation of adulterated, misbranded, or unapproved drugs by allowing the agency to focus its resources on imported drugs that fall outside the program and that may pose such risks. Such a program would increase the likelihood of expedited entry for specific finished drug products and APIs imported into the United States that meet the criteria for selection under the program.

II. Definitions for the Purposes of This Program

- *Affirmation of Compliance (AofC) Code*: A code designated by FDA for use by filers to convey information related to product or firm compliance with agency requirements, used to help expedite entry processing. Some AofC codes require a qualifier to provide additional information to aid in expedited processing.
- *Automated Broker Interface (ABI)*: An integral part of the Automated Commercial System, ABI is the means by which brokers or importers transmit entry data to the U.S. Customs and Border Protection (CBP).
- *Automated Commercial System (ACS)*: The system used by CBP to track, control, and process all commercial goods imported into the United States.
- *Broker/Customs Broker/Filer*: A licensed Customs broker hired to file entries for another party or a Customs ABI participant that files its own entries.
- *Customs-Trade Partnership Against Terrorism (CTPAT)*: CTPAT is the CBP initiative that partners with members of the trade community on a voluntary basis to better secure the international product supply chain to the United States.
- *Foreign Shipper*: The firm identified or declared as the shipper at time of entry into the United States.
- *Importer of Record*: The person, establishment, or representative responsible for making entry of imported goods in accordance with all laws affecting such importation.
- ''*May Proceed*'': This term means that an FDA-regulated imported product may proceed into domestic commerce after the electronic screening. This is not a decision by FDA about the product's regulatory status, and it does not preclude FDA action at a later time.
- *Manufacturer ID (MID)*: Manufacturer identification code constructed with specific segments of the manufacturer's or shipper's name and address. Refer to CBP Customs Directive Number 3550–055 (Old Number 3500–13), dated November 24, 1986, for instructions on determining the manufacturer ID.
- *Ultimate Consignee*: The party in the United States, at the time of entry or release, to whom the overseas shipper sold the imported merchandise. If at the time of entry the imported merchandise has not been sold, then the Ultimate Consignee at the time of entry or release is defined as the party in the United States to whom the overseas shipper consigned the imported merchandise.

III. SSC Pilot Program

A. Description

The SSC pilot program will be jointly administered by the Office of Compliance in CDER and the Division of Import Operations and Policy (DIOP) in ORA. To be selected to participate in the SSC pilot program, an application must meet the following criteria:

1. The applicant must submit a complete application, which is Form

FDA–3676. An applicant must be the holder of the New Drug Application (NDA) or Abbreviated New Drug Application (ANDA) or the foreign manufacturer of the imported finished drug product or API.

2. If the Ultimate Consignee identified in the SSC pilot application is an establishment subject to section 510 of the Federal Food, Drug, and Cosmetic Act (the act), then it must be in compliance with FDA's registration, drug listing, and current good manufacturing practice (cGMP) requirements and must have been in compliance over the past 3 years.

3. If the drug product identified in the SSC pilot application is a finished dosage form, then the firm identified as the Ultimate Consignee for the drug product must be identified in the NDA or ANDA.

4. If the drug product identified in the SSC pilot application is an API, then it must be used in the manufacture of an FDA approved drug product.

5. The importation of the finished drug product or API must: (a) Be from the foreign manufacturer identified in the SSC pilot application, (b) arrive through the identified port of entry and port of arrival, (c) use the identified Broker/Customs Broker/Filer, and (d) be intended for the identified Ultimate Consignee.

6. The foreign manufacturer identified in the SSC pilot application must be in compliance with requirements of the act relating to drugs.

7. The SSC applicant must have either a pending application or be certified with the CBP Customs-Trade Partnership Against Terrorism (CTPAT) Tier II certified secure supply chain. Both applicants to the SSC pilot program and firms identified in the SSC application must be CTPAT Tier II certified or Tier II pending certification at the time an application is submitted for participation in the pilot program.

8. The primary and secondary contacts identified in the SSC application must be able to answer questions and resolve issues raised by FDA.

9. The applicant must have a plan in place for promptly correcting any concerns that FDA identifies regarding its secure supply chain or specific importations.

10. The applicant must have a sufficient plan in place for recalling or correcting any finished drug products or APIs that do not meet, or are discovered not to have been manufactured in accordance with, FDA requirements. Deviations from the recall procedures for products associated with the SSC pilot program must be reported to FDA within 3 business days of identification by the applicant.

11. Applicants must comply with recordkeeping requirements of the act and its implementing regulations. For the purposes of participating in this pilot, applicants must make these records readily available to FDA upon request. Regardless of whether required by law, applicants must also maintain records that confirm the information provided in their SSC pilot applications, including documentation of their CTPAT certification status. These records must be maintained for the duration of the applicant's participation in the program and be readily available when requested by FDA. FDA requests, however, that these records be maintained and be readily available when requested by FDA for a period of at least 3 years after the pilot ends or the applicant's participation in the pilot ends. In addition, regardless of whether required by law, for each shipment of finished drug product or API, applicants must maintain records that document the product's movement through the secure supply chain from the point of manufacture to the point of receipt by the Ultimate Consignee. These records must be maintained for the duration of the applicant's participation in the program and be readily available when requested by FDA.

12. The Broker/Customs Broker/Filer identified in the SSC pilot application must be qualified for paperless entry filing to FDA's Operational and Administrative System for Import Support (OASIS).

Participation in the SSC pilot program described in this notice is voluntary. FDA plans to substantially increase the rate at which entries of the finished drug products and APIs selected for the SSC pilot program are given a ''May Proceed'' without human entry review or examination at the time of entry. As with all entries, FDA will, however, perform full electronic entry review of products included in the SSC pilot program. Some entries covered by the SSC pilot program will receive further FDA review or examination after the electronic entry review. In addition, FDA does not intend to issue a ''May Proceed'' after electronic entry review if it has information that a problem may exist with the product. Nothing in this notice restricts FDA, CBP, or any other agency from examining or inspecting any product or establishment, or affects the legal responsibilities of participants or the legal requirements of products that they are importing. FDA intends to regularly examine records and review whether participants in the SSC pilot program continue to meet the program's criteria.

FDA will assign a qualifier (a unique identifier) to each selected SSC pilot program application, and the Broker/Customs Broker/Filer will transmit the qualifier when filing entry for the product. The qualifier will accompany an AofC code, which FDA has designated as ''SSC.'' The AofC code identifies the drug product as being part of the SSC pilot program. In the event of any changes to the information contained in the SSC pilot program application, the pilot program applicant must submit a modified application detailing those changes and obtain FDA authorization of those changes in order to continue participation in the program. FDA will attempt to respond to the applicant's modified application within 15 business days after receipt.

The pilot program participants must be in full compliance with all requirements of the act relating to drug products. FDA may withdraw its selection of an application if the applicant, foreign manufacturer, or Ultimate Consignee receives a Warning Letter citing violations of the act relating to drug products or that FDA otherwise deems to have violated any requirements of the act relating to drug products. If the pilot program's criteria are no longer met, FDA intends to withdraw its selection of the relevant application. Termination of participation in the SSC pilot program will result in a return to the general rate at which entries of the finished drug products and APIs are given a ''May Proceed'' without human entry review or examination at the time of entry.

If FDA withdraws its selection of an application it will provide notice to the applicant. The applicant may provide information to show the program's criteria are met and, upon FDA review, participation in the SSC pilot program could continue or be resumed.

B. Selection of Participants for the Pilot

The Secure Supply Chain application form may not be submitted to FDA until the Office of Management and Budget (OMB) has approved the information collection associated with the SSC pilot program (see section IV of this document). After OMB approval, FDA will accept applications to participate in the program and FDA will select qualified applications. FDA will announce in the **Federal Register** OMB's approval, the date that applications may be submitted, and application submission procedures. FDA plans to select applications to participate in the SSC pilot program from not more than 100 qualified

applicants and not more than 5 drug products per applicant. FDA may, at its discretion, increase or decrease the number of applications that it selects or the number of products per applicant. The application to participate in the SSC pilot program is available for review and comment on the FDA Web site at*http://www.fda.gov/cder/fedreg/fda-3676.pdf*. Applications will be processed as they are received, on a first-come, first-served basis. All fields must be completed on the application; incomplete applications will be returned to the U.S. primary contact named in the application. Applicants will be notified in writing as to whether their applications have been selected.

C. Duration of the Pilot

The Secure Supply Chain application form may not be submitted to FDA until OMB has approved the information collection associated with the SSC pilot program. After OMB approval, FDA will accept applications to participate in the program and begin selecting applications for participation. FDA plans to finish selecting applications and begin the SSC pilot program 180 days after the date FDA announces that it is accepting applications. FDA plans to continue the SSC pilot program for 2 years after it begins. At its discretion, FDA may terminate the SSC pilot program before the close of the 2-year period, or FDA may extend the SSC pilot program beyond 2 years. Such decisions will be announced in the **Federal Register**.

D. Evaluation

FDA intends to evaluate the SSC pilot program based on several factors, including the following: Time frames for passage of goods through the entry process; the level of adherence by the SSC pilot program participants to the program's criteria; and the impact of the SSC pilot program. This evaluation will help FDA determine whether it should establish an SSC program and, if so, the parameters of such a program. FDA may also determine that it should extend the pilot program, perhaps with modifications, to continue its evaluation.

IV. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from OMB for each collection of information that they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA, 44 U.S.C. 3506(c)(2)(A), requires Federal agencies to provide a 60-day notice in the **Federal Register** for each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing this notice of the proposed collection of information set forth in this document.

With respect to the collection of information associated with the SSC pilot program, FDA invites comments on the following topics: (1) Whether the proposed information collected is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimated burden of the proposed information collected, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information collected; and (4) ways to minimize the burden of information collected on the respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

FDA is announcing an opportunity for sponsors and foreign manufacturers of finished drug products and APIs intended for human use imported via a secure supply chain to participate in a voluntary SSC pilot program. A limited number of applications that meet criteria established by FDA will be selected by FDA based largely on information submitted in the Secure Supply Chain application. Because there is an information collection under the PRA associated with the SSC pilot program, FDA must first obtain OMB approval to collect this information before accepting applications to participate in the program and before selecting qualified applications.

The information collection associated with the SSC pilot program consists of the following:

1. *Secure Supply Chain application form*. Proposed Form FDA–3676 will request:

(a) Identification and contact information for sponsors and foreign manufacturers wishing to participate in the SSC pilot program, (b) information about each drug to be imported, (c) logistical information associated with the importation and a description of the process by which the drug will be brought into the United States, and (d) A description of procedures that the applicant will follow to remedy any deficiencies that FDA may identify with the importation, including recall procedures. A draft of proposed Form FDA–3676 may be obtained at *http://www.fda.gov/cder/fedreg/fda–3676.pdf*, or by calling 301–827–1482. As explained previously, the Secure Supply Chain application form may not be submitted to FDA until OMB has approved the information collection associated with the SSC pilot program.

2. *Changes to information contained in SSC pilot program*. If there are changes to the information contained in the SSC pilot program application, then the applicant would be expected to submit to FDA a modified application detailing those changes and obtain FDA authorization before implementing them.

3. *FDA withdrawal of selection*. If FDA withdraws its selection of an application from participating in the SSC pilot program, the applicant would be given an opportunity to provide information to FDA to show that the program's criteria are met and participation should continue or be resumed. FDA will consider and act on this information at its sole discretion.

4. *Recordkeeping requirements*. Applicants will be expected to maintain records that confirm the information provided in their SSC pilot program applications, as well as records that document the drugs' movement through the secure supply chain from the point of manufacture to the point of receipt by the Ultimate Consignee, and make these records available to FDA if requested.

FDA intends to accept applications from no more than 100 qualified applicants and no more than 5 drugs per applicant to participate in the SSC pilot program. As indicated in table 1 of this document, FDA estimates that no more than 500 Secure Supply Chain application forms will be submitted by approximately 100 applicants, and that it will take approximately 3.5 hours to complete and submit each application form to FDA. FDA anticipates that approximately 5 applicants will need to submit a modified Secure Supply Chain application form, and that each modified application will take approximately 60 minutes to complete and submit to FDA. FDA anticipates that it will need to withdraw its selection of only one application under the SSC pilot program, and that it will take approximately 1 hour for an applicant to submit information in response. The reporting burden estimated in table 1 also includes the time for submitting the address where records associated with the SSC pilot program will be kept, and for submitting the FDA assigned qualifier code and Affirmation of Compliance code for each imported drug.

As indicated in table 2 of this document, FDA estimates that approximately 500 records associated with the SSC pilot program will be kept by approximately 100 applicants, and that each record will take about 15 minutes to maintain.

Because FDA intends to continue the SSC pilot program for 2 years, these burden estimates are for a one-time burden over a 2-year period.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED REPORTING BURDEN[1]

SSC Pilot Program	No. of Respondents	No. of Responses per Respondent	Total Responses	Hours per Response	Total Hours
Secure Supply Chain application form	100	5	500	3.5	1,750
Modified Secure Supply Chain application form	5	1	5	60 minutes	5
Information submitted in response to termination of participation	1	1	1	1	1
Total					1,755

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED RECORDKEEPING BURDEN[1]

SSC Pilot Program	No. of Recordkeepers	No. of Records per Recordkeeper	Total Records	Hours per Record	Total Hours
SSC Pilot Program records	100	5	500	15 minutes	125
Total					125

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic submissions will be accepted by FDA through FDMS only.

Dated: January 8, 2009.

Jeffrey Shuren,

Associate Comissioner for Policy and Planning.

[FR Doc. E9–791 Filed 1–14–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Request for Public Comment: 30-Day Proposed Information Collection: Indian Health Service Background Investigations of Individuals in Positions Involving Regular Contact With or Control Over Indian Children, OPM-306

Correction

In notice document E8–30330 beginning on page 78374 in the issue of Monday, December 22, 2008, make the following correction:

On page 78374, in the third column, under *Form Number*, in the 10th line ''IRS'' should read ''IHS''.

[FR Doc. Z8–30330 Filed 1–14–09; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Request for Public Comment: 30-Day Proposed Information Collection: Indian Health Service; HIV Knowledge/Attitudes/Practice Customer Survey

Correction

In notice document E8–30329 beginning on page 78375 in the issue of Monday, December 22, 2008, make the following corrections:

1. On page 78375, in the third column, under *Proposed Collection*, in the sixth line ''IRS'' should read ''IHS''.

2. On the same page, in the same column, in the same paragraph, six lines from the bottom ''IRS'' should read ''IHS''.

3. On the same page, in the same column, in the last paragraph, five lines from the bottom ''AIIAN'' should read ''AI/AN''.

4. On the same page, in the same column, in the same paragraph, four lines from the bottom ''lETS'' should read ''IHS''.

[FR Doc. Z8–30329 Filed 1–14–09; 8:45 am]

BILLING CODE 1505–01–D