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Dated: June 14, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–14989 Filed 6–19–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0656]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Secure Supply Chain Pilot Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Fax written comments on the collection of information by July 20, 2012.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov*. All comments should be identified with the title Secure Supply Chain Pilot Program. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Juanmanuel Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr. PIFO–400W, Rockville, MD 20850, (301) 796–7651.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance: ''Secure Supply Chain Pilot Program.''

The Secure Supply Chain Pilot Program (SSCPP) is intended to assist FDA 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.

Title: Secure Supply Chain Pilot Program.

Description of Respondents: Respondents to this collection of information are sponsors and foreign manufacturers of finished drug products and active pharmaceutical ingredients (APIs) intended for human use.

Burden Estimate: In the **Federal Register** of January 15, 2009 (74 FR 2605) (the January 2009 notice), FDA announced an opportunity for sponsors and foreign manufacturers of finished drug products and APIs intended for human use imported via a secure supply chain to apply to participate in a voluntary SSCPP to be conducted by FDA's Center for Drug Evaluation and Research (CDER) and Office of Regulatory Affairs (ORA). The goal of the SSCPP 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. An SSCPP 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. A limited number of applications that meet criteria established by FDA will be selected by FDA based largely on information submitted in the SSCPP application.

Because there is information collection under the PRA associated with the SSCPP, this **Federal Register** notice is being issued as part of the process for OMB approval to collect this information. After OMB approval, FDA will accept applications to participate in the program and 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 has considered all PRA and Non-PRA comments received. This FR notice responds only to the PRA-related comments.

The information collection associated with the SSCPP consists of the following:

(1) Secure Supply Chain Pilot Program application form. Proposed Form FDA 3676 will request the following: (a) Identification and contact information for sponsors and foreign manufacturers wishing to participate in the SSCPP; (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) 796–7651. The SSCPP application form may not be submitted to FDA until OMB has approved the information collection associated with the SSCPP.

(2) Changes to information contained in the SSCPP. If there are changes to the information contained in the SSCPP 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 SSCPP, 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 SSCPP applications and make these records available to FDA if requested. While these records must be maintained for the duration of the applicant's participation in the program, FDA requests that they 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 their 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. FDA intends to accept applications from no more than 100 qualified applicants and for no more than 5 drugs per applicant to participate in the SSCPP. As indicated in Table 1 of this document, FDA estimates that no more than 500 SSCPP 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 SSCPP, and that each modified application will take approximately 60 minutes to complete and submit to FDA (this estimate includes the time for an applicant to also submit a copy of its Customs Trade Partnership Against Terrorism (C–TPAT) application). FDA anticipates that it will need to withdraw its selection of only one SSCPP application, 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 SSCPP 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 SSCPP will be kept by approximately 100 applicants, and that each record will take about 60 minutes to maintain.

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

In the January 2009 notice, FDA requested public comment on the proposed collection of information. We received comments from 11 different companies that pertained to the information collection resulting from the SSCPP. A summary of the comments and FDA's response are as follows:

(1) Several comments stated that foreign manufacturers, with the exception of manufactures in Canada and Mexico, are not eligible for Customs Trade Partnership Against Terrorism (C–TPAT) program and therefore would be unable to meet the criteria in the SSCPP.

To clarify the C–TPAT program eligibility requirements, only business entities who handle cargo that enter the United States are eligible to be a member of the C–TPAT program. Foreign manufacturers, with the exception of those located in Canada and Mexico, cannot apply to be members of the C–TPAT program, but would be visited by the C–TPAT program as part of the validation process for a C–TPAT partner. C–TPAT partners must adhere to the security requirements and ensure that requirements are met by their business partners throughout the international supply chain. The January 2009 notice states that firms identified in the SSCPP application must be either C–TPAT Tier II certified or Tier II pending certification at the time the application is submitted. After further review and discussion with the U.S. Customs and Border Protection (CBP) about the C–TPAT program, FDA is revising the C–TPAT criteria to permit firms to participate in the SSCPP if the supply chain has been validated as Tier II or Tier III. Tier II validated means that CBP has visited a site in the firm's supply chain and has validated its security procedures as meeting the requirements set forth by C–TPAT. Tier III means that a firm has exceeded C–TPAT's security criteria and implemented their own best practices. FDA intends to revise the SSCPP application to reflect the change in the criteria from Tier II certified or Tier II pending to require validated as Tier II or Tier III.

(2) Several comments stated that the January 2009 notice does not contain sufficient detail to determine how FDA will identify the ultimate consignee for purposes of this pilot program, and that further clarification is needed.

The January 2009 notice specifically defines ''ultimate consignee,'' for the purposes of the SSCPP, as ''[t]he 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.''

(3) Several comments stated that clarification is needed regarding the data that will be required for individual shipments by program participants, the automated systems that will be used, and the modifications participants must make to those systems for imported drugs under the program.

FDA will be using the current systems for receiving and reviewing entry information. FDA will assign a unique identifier to each selected SSCPP application, and the Broker/Customs—Broker/Filer will transmit the identifier when filing entry for the product, which will enable FDA to verify the drug product as being part of the SSCPP. Otherwise, the FDA data requirements to submit a drug import entry will not change.

(4) Several comments expressed concern that the SSCPP requires the primary and secondary points of contact to respond directly to all questions posed by FDA regarding an applicant's status in the SSCPP. In addition, comments made suggest that FDA identify primary and secondary points of contact, within the Agency, with whom the applicants can raise concerns and discuss issues.

The intent in the SSCPP is to identify appropriate individuals who can obtain information to respond to Agency questions and requests for information. Those contacts can obtain assistance within the firm and then contact the Agency with the response. This will eliminate contacting multiple people potentially within several firms to obtain a response. FDA intends to identify primary and secondary points of contact within the Agency and will publish this information in a subsequent **Federal Register** notice.

(5) Several comments stated that under the Primary and Secondary contacts requirement on the SSCPP application, the term ''any concerns'' is too broad and the scope should be limited to ''concerns.'' In addition, the comments suggested that the applicant provide a corrective action plan ''if needed,'' but that this should not be a necessary requirement.

FDA will change ''any concerns'' to ''concerns'' with the understanding that the Agency will raise concerns related to the SSCPP. FDA believes a corrective action plan should be kept as a required element for participation in this program.

(6) Several comments request that prior notification be given to applicants when an audit check analysis is performed.

FDA does not agree with this position. Audits of the SSCPP will not be announced in advance and will be administered in intervals chosen by the agency.

(7) Several comments stated that the Secure Supply Chain (SSC) Affirmation of Compliance (A of C) code should be submitted in place of (and not in addition to) the A of C codes currently transmitted during entry processing.

There will be one code for products subject to the SSCPP. This will be an SSC A of C, which will be required at the time of entry and will identify the drug product as being part of the SSCPP.

(8) Several comments requested clarification as to whether multiple dosage forms of a drug covered under a single new drug application (NDA) are considered one SSCPP application.

Each individual dosage form will require a separate application for the SSCPP. One API used in multiple drug products' NDAs would require the submission of one application.

(9) Some comments requested clarification regarding the product entry process when an application, which has been modified to reflect a change in information, is under review by FDA for continued participation in the program.

The firm must notify FDA of the change before its implementation. If the firm implements the change before FDA authorizes the change, FDA will revert to the normal drug entry process for the product.

(10) Several comments requested that the SSCPP criteria for use of one port of entry be amended to allow for multiple ports of entry because of changes associated with airline landing requirements.

At this time, the Agency will not consider amending this requirement. Any deviations from the applicant's SSC distribution practices, as identified in the SSCPP application, would cause that individual shipment to be screened under general import processing procedure. Included in such deviations are changes to airline landings, which would require a different port of arrival and entry from that which is defined in a participant's SSCPP application.

(11) Several comments suggested that selection for participation in the pilot program should be based on the Agency's satisfaction that the importer will not deviate from the details of its application and that the importer will continue to abide by applicable regulations, and not based on a regular examination of relevant records. The comments suggested that there would be no benefit to regular examination but that examinations of records on a random basis would ensure compliance.

The Agency believes that the pilot is consistent with the approach recommended by this comment. As part of this pilot program, the Agency believes it is important to have the ability to examine records on a random basis as determined by the Agency.

(12) Several comments expressed concern with the manner in which FDA will determine that an applicant should be withdrawn from the SSCPP. Several comments further suggested that withdrawing an applicant if they receive a ''Warning Letter citing violations of the act relating to drug products'' (see the January 2009 notice) is too broad because the Warning Letter may be unrelated to the products covered by the SSCPP application or to imports in general. The comments suggested narrowing the statement and making it specific to Warning Letters related to the product covered by the application.

FDA disagrees. The Agency intends to fully evaluate an applicant's compliance status and associated risk posed by violations relating to drug products.

(13) Several comments stated that the SSCPP should be evaluated in terms of FDA resource conservation, impact on consumer safety, economic benefit to the trade community, and supply chain facilitation. Some comments further suggested expanding the program to be account-based (along the lines of a ''Qualified Trusted Importer Program'') rather than product-based.

FDA agrees with this comment with respect to evaluating the program. Evaluation of the SSCPP will be based on several factors including, but not limited to, those identified in the comment. However, we have decided that this voluntary program should be product-based at this time.

(14) Several comments requested clarification on the question of whether an API source is required to be disclosed for applicants importing finished dosage form drug products in their SSCPP applications.

Yes, the SSCPP application (Section E, Details of Your Secure Supply Chain) requests this information for both applicants importing finished dosage form drug products and/or APIs.

(15) Several comments suggested changing the language in Box 15, Logistics, on the SSCPP application to read, ''U.S. Port(s) of Entry'' and in Box 16, Logistics, to read, ''U.S. Port(s) of Arrival (if different from Port(s) of Entry).'' In addition, in Box 22, Other Information, it was suggested that it is important for FDA to recognize current normal transportation and trade compliance practice, because some transportation records are kept at a foreign shipping location and not in the United States.

FDA disagrees with changing the language to allow for multiple ports at this time; therefore, the pilot program will be limited to the one port of entry and one port of arrival (if different) listed in the application. In addition, the transportation records must be readily available, regardless of where they are physically located. The Agency will revise the SSCPP application form to clearly state that transportation records may be located either in the United States or outside the country, provided the records are made readily available to FDA upon request.

(16) Some comments asked whether the data collected during the pilot program as described in Section D of the SSCPP application will be shared with participants and the public, and if so, at what frequency. In addition, the comments questioned how industry participants in the program establish themselves as having best practices for securing a supply chain.

The Agency recognizes that at this time there is no industry-wide standard for best practices to secure the drug supply chain. However, there is a draft Good Importer Practices guidance document that was issued in January of 2009 that may be of assistance. Although participation in this pilot program will not establish a firm as having those best practices, at the end of the SSCPP, FDA intends to make summary information about the program publicly available. The Agency does not intend to publicly disclose information submitted in Section D of the SSCPP application that can be associated with a specific individual or entity, unless doing so is required by law.

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

TABLE 1—ESTIMATED REPORTING BURDEN [1]

Secure Supply Chain Pilot Program	Number of respondents	Number of responses per respondent	Total responses	Average burden 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	1	5
Information submitted in response to termination of participation	1	1	1	1	1

TABLE 1—ESTIMATED REPORTING BURDEN [1]—Continued

Secure Supply Chain Pilot Program	Number of respondents	Number of responses per respondent	Total responses	Average burden per response	Total hours
Total					1,756

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

TABLE 2—ESTIMATED RECORDKEEPING BURDEN [1]

Secure Supply Chain Pilot Program	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours/ week	Total hours per year
Secure Supply Chain Pilot Program Records	100	5	500	1	500	26,000

[1] There are no capital or operating costs associated with this recordkeeping.

Dated: June 14, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–14990 Filed 6–19–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA 2012–D–0304]

Draft Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Implanted Blood Access Devices for Hemodialysis; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Class II Special Controls Guidance Document: Implanted Blood Access Devices for Hemodialysis.'' This draft guidance document describes a means by which implanted blood access devices may comply with the requirement of special controls for class II devices. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by September 18, 2012.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Class II Special Controls Guidance Document: Implanted Blood Access Devices for Hemodialysis'' to the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Melissa Burns, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1646, Silver Spring, MD 20993–0002, 301–796–5616.

I. Background

This draft guidance document was developed as a special control guidance to support the reclassification of implanted blood access devices into class II (special controls). This draft guidance document will serve as the special control for implanted blood access devices. Section 513(f)(3) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) provides that the Agency may initiate the reclassification of a device. This classification will be a reclassification of the device. FDA must publish a notice in the **Federal Register** announcing this reclassification. Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule to reclassify this device type from class III into class II (special controls), under section 513(e) of the FD&C Act (21 U.S.C. 360c(e)).

FDA is issuing this guidance document as a level 1 draft guidance document. FDA will consider any comments that are received within 90 days of the issuance of this notice to determine whether to revise the guidance document.

II. Significance of Special Controls Guidance Document

FDA believes that adherence to the recommendations described in this draft guidance document, when finalized, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of implanted blood access devices classified under § 876.5540(b)(1) (21 CFR 876.5540(b)(1)). If classified as a class II device under § 876.5540(b)(1), implanted blood access devices will need to comply with the requirement for special controls; manufacturers will need to address the issues requiring special controls as identified in the guidance document or by some other means that provides equivalent assurances of safety and effectiveness.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov.* To receive ''Class II Special Controls Guidance Document: Implanted Blood Access Devices for Hemodialysis,'' you may either send an email request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 301–847–8149 to receive