# Secure Supply Chain Pilot Program (SSCPP)

0910-[NEW]

SUPPORTING STATEMENT

## A. Justification

1. Circumstances Making the Collection of Information Necessary

   The SSCPP will permit entry into the United States of selected low-risk finished drug products and active pharmaceutical ingredients (APIs) with minimal delay at designated ports of entry. The goal is to create incentives for drug manufacturers to develop secure routes to import finished drugs and APIs and allow FDA field personnel to focus on higher-risk drug products, including diverted and counterfeit drugs.

   The legal basis for this initiative is 21 U.S.C. §381, Section 801(d)(1) and 21 U.S.C. §384, Section 804 of the Federal Food, Drug, and Cosmetic Act. Section 801(d)(1) states that "Except as provided in paragraph (2) and section 804, no drug subject to section 503(b) or composed wholly or partly of insulin which is manufactured in a State and exported may be imported into the United States unless the drug is imported by the manufacturer of the drug." Section 804 allows for the importation of prescription drugs into the United States if certain regulations, as promulgated by the Secretary, are met.

2. Purpose and Use of the Information Collection

   The SSCPP will permit selected pre-qualified firms to import specified finished drug products and APIs with minimal delay at designated ports of entry. The SSCPP will be jointly administered by the Office of Compliance in CDER and the Division of Import Operations and Policy (DIOP) in ORA.

   FDA will accept not more than 100 applicants and not more than five products per applicant to participate in the SSCPP. FDA may, at its discretion, increase the number of applications that it will accept or the number of products allowed per applicant. Applications will be accepted once the third FRN is posted announcing the start of the program. Applications will be processed as they are received, on a first come, first served basis. The first 100 applicants who submit complete applications (i.e., applications that contain all required information and that otherwise comply with the terms of the SSCPP) will be selected as participants.

   Upon approval of the firm's application, FDA will assign a qualifier – a unique product and site-specific identifier – to each drug product in an approved SSCPP application and the SCC pilot program participant will transmit the qualifier when it offers a product for entry under the SSCPP. The qualifier will accompany an Affirmation of Compliance

(AofC) code, which FDA has designated as "SSC." The AofC code classifies the importing firm as a participant in the SSCPP.

At its discretion, FDA may terminate an applicant's participation in the SSCPP based on factors that include: deviation from the terms of the SSC pilot; public safety; failure of a firm in the secure supply chain to qualify or continue to qualify for CTPAT-Tier II certification; failure of the applicant's Customs broker or filer to continue to qualify for paperless entry; issuance of a Warning Letter or other regulatory action by FDA; or other reasons that FDA considers appropriate.

This involves the collection of both new and current information.

3. Use of Improved Information Technology and Burden Reduction

All applications must be submitted to FDA via email to the following email address: SSCPILOT@fda.hhs.gov. FDA will periodically perform full electronic entry review to ensure the integrity of the process.

4. Efforts to Identify Duplication and Use of Similar Information

The form will collect the DUNS numbers which are currently collected on other forms within the Agency. However, we are requesting this information as a validation criterion in our programs.

5. Impact on Small Businesses or Other Small Entities

The government does not believe that there will be an impact on small businesses.

6. Consequences of Collecting the Information Less Frequently

N/A, the information is collected once (annually) per drug product.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

The information in the application will be treated as confidential commercial information, and some of the required information is proprietary.

The firm must not have received an FDA Warning Letter citing violations of the FD&C Act relating to drug products within three years preceding the date of application to the SSC pilot.

The firm must also be an active member of Customs C-TPAT (Customs Trade Partnership Against Terrorism) Program, validated as either CTPAT Tier II or Tier III.

Applicants must maintain, for five years, records that confirm the information provided in their SSC pilot applications, including documentation of their CTPAT certification status.

If the FDA requests these records, applicants must make them available to FDA within five business days.

If there are any changes to the information contained in the SSCPP application, the applicant must submit a modified application detailing those changes and obtain FDA authorization prior to implementing them and prior to offering their drug product for importation to the U.S.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

The 60-day notice was published in the FEDERAL REGISTER on January 15, 2009.

In accordance with 5 CFR 1320.8(d), FDA published a 60 day notice for public comment in the FEDERAL REGISTER of 01/15/2009 (Vol. 74, No. 10 FR 2605). FDA 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:

i. 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.

ii. 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."

iii. 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.

iv. 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.

v. 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.

vi. 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.

vii. 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.

viii. 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.

ix. 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.

x. 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.

xi. 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.

xii. 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.

xiii. 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.

xiv. 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.

xv. 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.

xvi. 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.

9. Explanation of Any Payment or Gift to Respondents

N/A, no payment or gifts will be provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

The information will be treated as confidential commercial information to the extent permitted by the law.

11. Justification for Sensitive Questions

The confidential statement addresses the concern of sensitive questions. The statement in the FR notice reads as follows: FDA intends to treat information submitted in the SSC pilot program application as confidential commercial information to the extent permitted by the law.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

Table 1. --Estimated Reporting Burden[1]

| Secure Supply Chain Pilot Program | No. of Respondents | No. of Responses per Respondent | Total Responses | Average Burden per Response | Total Hours |
|---|---|---|---|---|---|
| Secure Supply Chain application form | 100 | 5 | 500 | 3.5 | 1,750 |

[1]

| | | | | | |
|---|---|---|---|---|---|
| Modified Secure Supply Chain application form | 5 | 1 | 5 | 1 | 5 |
| Information submitted in response to termination of participation | 1 | 1 | 1 | 1 | 1 |
| 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 | No. of Record keepers | No. 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.

12b. Annualized Cost Burden Estimate

| Type of Respondent | Total Burden Hours | Hourly Wage Rate | Total Respondent Costs |
|---|---|---|---|
| Director | 26 | $100.00 | $2,600 |
| Import Ops Officer | 52 | $48.00 | $2,496 |
| Total | | | $5,096 |

This estimate is based on the annual effort of respondents based on overall burden hours.

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

The information we are requesting should currently be collected as part of their business practices and should not be require any new processes.

14. Annualized Cost to the Federal Government

The annual cost to the Federal government is estimated at $600,000. This is based on the cost of operating the program with staff from headquarters and the field. It also includes the cost of monitoring, implementation, and project development.

15. Explanation for Program Changes or Adjustments

    This is a new data collection.

16. Reason(s) Display of OMB Expiration Date is Inappropriate

    N/A

17. Exceptions to Certification for Paperwork Reduction Act Submissions

    There are no exceptions to the certification.