Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research

SECURE SUPPLY CHAIN (SSC) PILOT PROGRAM APPLICATION

For FDA Use Only	*Form Approved*
SSC Pilot Program Application Number	OMB Control Number: 0910-XXXX
	Expiration Date: Xxxxxx xx, 20XX
	See OMB Statement on page 5.

A. APPLICANT INFORMATION

1. Business Information

Business Name		Address		
Telephone Number	DUNS Number	City	State	ZIP

2. U.S. Primary Contact	3. U.S. Secondary Contact
Name	Name
Telephone Number	Telephone Number
E-mail Address	E-mail Address

4. Importer of Record

Importer Name	Address
DUNS Number	

5. Importer of Record's IRS Number *(Optional)* -OR- Importer of Record's FDA Establishment Identifier (FEI) (FEI verified by FDA)

6. Customs Trade Partnership Against Terrorism (C-TPAT)

Supply Chain Validated as C-TPAT Tier II or Tier III? *(Select one)* ☐ Tier II ☐ Tier III	Status Verification Interface (SVI) Number *(When available)*	Application Date *(When available)*

B. PRODUCT INFORMATION

7. New Drug Application (NDA)/Abbreviated New Drug Application (ANDA) Number	8. National Drug Code (NDC) Number	9. FDA Product Code

10. Commercial Invoice Description

(Continuation page will be provided.)

11. Foreign Manufacturer

Name	Address
DUNS Number	

12. CBP Manufacturer ID (MID) *(For manufacturer)*	13. Foreign Manufacturer FEI or Central File Number (CFN)

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14. Describe methods of product identification, lot designation, and product tracing through the supply chain.

(Continuation page will be provided.)

C. LOGISTICS

15. U.S. Port of Entry

16. U.S. Port of Arrival *(If different from Port of Entry)*

17. Broker/Customs - Broker/Filer Information

Broker/Customs - Broker/Filer Name

Address

Telephone Number

DUNS Number

E-mail Address

18. Ultimate Consignee Information

Ultimate Consignee Name

Address

DUNS Number

19. Ultimate Consignee IRS Number *(Optional)* -OR- Ultimate Consignee FEI (FEI verified by FDA)

20. Foreign Shipper Information

Foreign Shipper Name

Address

DUNS Number

21. CBP Manufacturer ID (MID) *(For shipper)*

FEI

D. OTHER INFORMATION

22. Provide the full name and address of the location of records confirming the application information and documentation for all shipments of the product that the applicant is submitting for inclusion in the SSC pilot program. Provide point of contact including an e-mail address and telephone number.

23. Describe Recall/Correction Plans, including the following: point of contact; method of communication; method for product identification; procedures for returned products; and procedures for controlling and disposing of returned product.

(Continuation page will be provided.)

24. Describe your plan for promptly correcting concerns that FDA identifies regarding specific importations or your secure supply chain.

(Continuation page will be provided.)

E. DETAILS OF YOUR SECURE SUPPLY CHAIN

Please provide a detailed narrative of the process by which the active pharmaceutical ingredient (API) and/or finished drug product will be brought into the United States, from the point of product manufacture to delivery to the ultimate consignee. This narrative must include, at a minimum, the following information:

A. API source, including DUNS number;

B. Source of finished drug product;

C. Master file number (if applicable);

D. Overview of the supply chain including facilities where manufacturing, packaging, labeling, and storage occur; and their DUNS number when available or if not already provided above;

E. Transport from packager to port of lading;

F. Port of lading process from delivery to un-lading of vessel;

G. Transport process to the United States, including stops before arrival in the United States; and

H. Transport from port of arrival to ultimate consignee.

(Continuation page will be provided.)

[FDA Use Only] SSC Pilot Program Application Number:

F. ACKNOWLEDGEMENT

The undersigned acknowledges that it wishes to participate in the Food and Drug Administration (FDA) Secure Supply Chain (SSC) pilot program. The undersigned understands the criteria for acceptance in the SSC pilot program, as set forth in the third FEDERAL REGISTER notice, published on _____ titled "Secure Supply Chain Pilot Program," and that FDA will determine participation based on the date of application and whether the program criteria are met. If accepted for participation in the SSC pilot program, the undersigned understands that FDA will monitor its entries to check for compliance with the program's criteria.

mm/dd/yyyy

To participate in the SSC pilot program, the undersigned will maintain records that confirm the information provided in this application for the duration of the applicant's participation in the program, and will ensure that these records will be readily available when requested by FDA. FDA requests that these records be maintained for a period of at least 3 years after the pilot ends or the applicant's participation in the pilot ends.

The undersigned agrees to submit a modified application detailing any changes to the information contained in this secure supply chain application and obtain FDA authorization of these changes to continue participation.

The undersigned understands that FDA plans to run the SSC pilot program from _____ to _____ although FDA may terminate the program sooner or extend the ending date.

*mm/dd/yyyy** *mm/dd/yyyy^*

* Insert date 180 days after date of publication in the *FEDERAL REGISTER* announcing that FDA is accepting applications.
^ Insert date 30 months after date of publication in the *FEDERAL REGISTER* announcing that FDA is accepting applications.

Signature of applicant or applicant's authorized representative	Date
DRAFT	

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.

The burden time for this collection of information is estimated to average 3.5 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
1350 Piccard Drive, Room 400
Rockville, MD 20850

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Designer note: This is the new PRA burden statement, keeping the 3.5 hours estimated response time noted previously for this specific form.

Instructions for Completion of FORM FDA 3676
SECURE SUPPLY CHAIN (SSC) PILOT PROGRAM APPLICATION

Note: Applicants must file a separate application for each finished product or active pharmaceutical ingredient (API) for which inclusion in the SSC pilot program is sought.

A. Applicant Information

1. This is the legal name of the applicant to the SSC pilot program. Provide the full name, address, DUNS number, and telephone number of the applicant.

2. Provide the U.S. primary contact full name, phone number, and e-mail address.

3. Provide the U.S. secondary contact full name, phone number, and e-mail address.

4. Provide the full firm name, DUNS number, and address for the Importer of Record. The importer of record is the person, establishment, or representative responsible for making entry of imported goods in accordance with all laws affecting such importation.

5. The IRS Number is optional. If not provided, contact FDA to determine the appropriate FEI.

6. Customs Trade Partnership Against Terrorism (C-TPAT) – Indicate in the space provided if the supply chain is C-TPAT Tier II or Tier III Validated (either Yes or No).

   For more information on C-TPAT see *http://www.cbp.gov/xp/cgov/trade/cargo_security/ctpat/*

   Status Verification Interface (SVI) Number – Indicate the SVI number of the space provided when available.

   Application Date – Indicate in the space provided the date that the applicant applied for C-TPAT Tier II or Tier III status when available.

B. Product Information

7. New Drug Application (NDA)/Abbreviated New Drug Application (ANDA) Number – Provide the NDA and/or ANDA number for the product that the applicant is submitting for inclusion in the SSC pilot program. For APIs, submit the NDA/ANDA number for the approved products in which the API will be used.

8. National Drug Code (NDC) Number – Provide the NDC number for the product that the applicant is submitting for inclusion in the SSC pilot program.

9. Provide the FDA product code for the product that the applicant is submitting for inclusion in the SSC pilot program.

10. Commercial Invoice Description (also known as the Product Description) – Provide the complete product name (trade name and chemical name), dosage strength, dosage unit, dosage description (special markings, color, and tablet), and dosage package for the product that the applicant is submitting for inclusion in the SSC pilot program.

11. Provide the full firm name and site-specific address of the foreign manufacturer of the product that the applicant is submitting for inclusion in the SSC pilot program.

12. Provide the U.S. Customs and Border Protection (CBP) Manufacturer Identification Code (MID) for the foreign manufacturer of the product that the applicant is submitting for inclusion in the SSC pilot program.

13. Provide the FDA Establishment Identifier (FEI) or facility Central File Number (CFN) for the foreign manufacturer of the product that the applicant is submitting for inclusion in the SSC pilot program.

14. Describe the methods of product identification, lot designation, and product tracing through the supply chain of the product that the applicant is submitting for inclusion in the SSC pilot program.

C. Logistics

15. Provide the U.S. port of entry where a consumption entry will be filed with CBP for the product that the applicant is submitting for inclusion in the SSC pilot program.

16. Provide the U.S. port of arrival (if different from the U.S. port of entry) for the product that the applicant is submitting for inclusion in the SSC pilot program.

17. Provide the full firm name, DUNS number, address, and e-mail of the firm (Broker/Customs - Broker/Filer) that will be filing entry of the product identified in the application with CBP.

18. Provide the full firm name, DUNS number, and address of the Ultimate Consignee of the product that the applicant is submitting for inclusion in the SSC pilot program.

19. The IRS Number is optional. If not provided, contact FDA to determine the appropriate FEI.

20. Provide the full firm name, DUNS number, and address for the foreign shipper of the product that the applicant is submitting for inclusion in the SSC pilot program.

21. Provide the U.S. Customs and Border Protection (CBP) Manufacturer Identification Code (MID) for the foreign shipper of the product that the applicant is submitting for inclusion in the SSC pilot program. Also, provide the FEI.

D. Other Information

22. Provide the full name and address of the location of records confirming the application information and documentation for all shipments of the product that the applicant is submitting for inclusion in the SSC pilot program. Provide a point of contact including an e-mail address and telephone number.

23. Provide Recall/Correction Plans that would be used for returned products and procedures for controlling and disposing of returned products that the applicant is submitting for inclusion in the SSC pilot program.

24. Provide a plan that would be used to correct deficiencies identified by FDA regarding specific importations or the firm's secure supply chain process.

E. Details of YourSecure Supply Chain

Provide a detailed narrative of the process by which the active pharmaceutical ingredient (API) and/or finished drug product that the applicant is submitting for inclusion in the SSC pilot program will be brought into the United States, from the point of product manufacture to delivery to the ultimate consignee. The narrative must include at least the following information:

- API source;
- Source of finished drug product;
- Master file number (if applicable);
- Overview of the supply chain including facilities where manufacturing, packaging, labeling, and storage occur;
- Transport from packager to port of lading;
- Port of lading process from delivery to un-lading of vessel;
- Transport process to the United States, including stops before arrival in the United States;
- Transport from port of arrival to ultimate consignee; and
- Include DUNS number for each business entity identified in the application when available.

F. Acknowledgement

Sign the acknowledgement if you wish to participate in the SSC pilot program. The applicant, by signing the acknowledgement, understands the criteria for acceptance in the SSC pilot, as set forth in the third FEDERAL REGISTER notice, published on (insert Month, Day, Year) titled "Secure Supply Chain Pilot Program," and that FDA will determine participation in the pilot program. The acknowledgement also contains terms for participation in the SSC pilot program that include maintaining and making records available to FDA, and notifying FDA with information about any changes to the secure supply process.