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

SECURE SUPPLY CHAIN 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 (Optional)	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 *(Optional)*	

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)

Certified as C-TPAT Tier II?	Certification/Application Date
☐ Yes ☐ No	

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 *(Optional)*	

12. Foreign Manufacturer Registration Number	13. CBP Manufacturer ID (MID) *(For manufacturer)*

PSC Graphics (301) 443-1090 EF

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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 *(Optional)*

E-mail Address

18. Ultimate Consignee Information

Ultimate Consignee Name

Address

DUNS Number *(Optional)*

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

20. Foreign Shipper Information

Foreign Shipper Name

Address

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

DUNS Number *(Optional)*

D. OTHER INFORMATION

22. Provide the full name and address in the United States where the records that confirm information provided in the applicant's SSC pilot program application and information for all shipments of product that the applicant is submitting for the SSC pilot program are located. Provide point of contact including an email 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 any concerns that FDA identifies regarding specific importations or your secure supply chain.

(Continuation page will be provided.)

E. LOGISTICS

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;

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;

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, as set forth in the FEDERAL REGISTER notice 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, the undersigned understands that FDA will monitor its entries to check for compliance with the program's criteria.

To participate in the SSC pilot, 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 in order to continue participation.

The undersigned understands that FDA plans to run the SSC pilot from _____ to _____
*mm/dd/yyyy** *mm/dd/yyyy^*
although FDA may terminate the program sooner or extend the ending date.

* 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

OMB Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 3.5 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information. Including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of the Chief Information Officer (HFA-710)
5600 Fishers Lane
Rockville, MD 20857

"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 control number."

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, and telephone number of the applicant.
2. Provide the U.S. primary contact full name, phone number, and email address.
3. Provide the U.S. secondary contact full name, phone number and email address.
4. Provide the full firm name 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 applicant is C-TPAT Tier II Certified (either Yes or No).

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

   Certification/Application Date – Indicate in the space provided the date that the applicant either applied for or was approved for C-TPAT Tier II status.

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 foreign manufacturer registration number.
13. 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. Also, as an optional entry, provide the DUNS Number.
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 and 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 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 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, as an optional entry, provide the DUNS Number.

D. Other Information

22. Provide the full name and address in the United States where records confirming application information are located and documentation is located 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 email address and telephone number.

23. Provide Recall/Correction Plans that would be used for returned products and procedures for controlling and disposing of returned product 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. Description of Secure 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; and
- Transport from port of arrival to ultimate consignee.

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 FEDERAL REGISTER notice 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 that include maintaining and making records available to FDA, and notifying FDA with information about any changes to the secure supply process.