notice provides the public meeting date of the GTAC: September 3, 2013. The meeting is open to the public via teleconference.

DATES: The meeting will be held on Tuesday, September 3, 2013, beginning at 9:00 a.m. Eastern Standard Time, and ending no later than 4:00 p.m. Eastern Standard Time.

FOR FURTHER INFORMATION CONTACT: Ms. Marcerto Barr, Designated Federal Officer (DFO), Government-wide Travel Advisory Committee (GTAC), Office of Government-wide Policy, General Services Administration, 1800 F Street NW., Washington, DC 20405, 202–208–7654 or by email to: *gtac@gsa.gov.*

SUPPLEMENTARY INFORMATION:

Authority: The GSA Office of Asset and Transportation Management, Travel and Relocation Division, establishes policy that governs travel by Federal civilian employees and others authorized to travel at Government expense on temporary duty travel through the Federal Travel Regulation.

Agenda: The Committee will continue any outstanding discussion on lodging per diem. It is expected the Committee will discuss private sector business practices of internal controls for attendance at conferences, training sessions, and travel associated with such events. The Committee may discuss other topics to be determined at a later date associated with the Federal Travel Regulations.

Meeting Access: The meeting is open to the public via teleconference. Members of the public wishing to listen in on the GTAC discussion are recommended to visit the GTAC Web site at: *www.gsa.gov/gtac* to obtain registration details. Members of the public will not have the opportunity to ask questions or otherwise participate in the meeting. However, members of the public wishing to comment on the discussion or topics outlined in the agenda should follow the steps detailed in Procedures for Providing Public Comments.

Availability of Materials for the Meeting: Please see the GTAC Web site *www.gsa.gov/gtac* for any available materials and detailed meeting notes after the meeting.

Procedures for Providing Public Comments: In general, public comments will be posted to *www.gsa.gov/gtac.* Non-electronic documents will be made available for public inspection and copying at GSA, 1800 F Street NW., Washington, DC 20405, on official business days between the hours of 10:00 a.m. Eastern Standard Time and 4:00 p.m. Eastern Standard Time. The public can make an appointment to inspect comments by telephoning the DFO at 202–208–7654. All comments, including attachments and other supporting materials received, are part of the public record and subject to public disclosure. Any comments submitted in connection with the GTAC meeting will be made available to the public under the provisions of the Federal Advisory Committee Act.

The public is invited to submit written comments after the closing of this meeting until 4:00 p.m. Eastern Standard Time on Tuesday, September 10, 2013, by either of the following methods and cite Meeting Notice-GTAC–2013–02.

Electronic or Paper Comments: (1) submit electronic comments to *gtac@gsa.gov;* or (2) submit paper comments to the attention of Ms. Marcerto Barr at GSA, 1800 F Street NW., Washington, DC 20405.

Dated: August 14, 2013.

Carolyn Austin-Diggs,

Acting Deputy Associate Administrator, Office of Asset and Transportation Management, Office of Government-wide Policy.

[FR Doc. 2013–20197 Filed 8–19–13; 8:45 am]

BILLING CODE 6820–14–P

GENERAL SERVICES ADMINISTRATION

[Notice-WWICC–2013–01; Docket No. 2013–0007; Sequence 1]

World War I Centennial Commission; Notification of Upcoming Public Advisory Meeting; Sunshine Act Meetings

TIME AND DATE: Open: 9:30 a.m.–5:30 p.m. (Central Time) on Friday, September 13, 2013.

PLACE: The meeting will be held at the National World War 1 Museum at Liberty Memorial, 100 W. 26th Street, Kansas City, MO 64108.

STATUS: This meeting will be open to the public.

MATTERS TO BE CONSIDERED:

Agenda

September 13, 2013

- Introductions and plans for today's meeting—DFO
- Swearing in of Commissioners—GSA HR
- Ethics Brief for Commissioners—GSA Legal
- Election of Chairperson and Vice Chairperson—DFO
- 30 minute public comment period for individuals pre-registered per instructions below. Each individual will be able to speak for no more than 5 minutes.
- Project/Activity discussion
- Foundation brief
- Other business
- Closing comments

Procedures for Public Participation

Contact Daniel S. Dayton at 202–254–5607 to register to comment during the meeting's 30 minute public comment period. Registered speakers/organizations will be allowed 5 minutes and will need to provide written copies of their presentations. Requests to comment at the meeting must be received by 5:00 p.m. Eastern time, September 10, 2013. Written comments may be provided to Mr. Dayton at *daniel.dayton@dhs.gov* until 5:00 p.m. Eastern time, September 10, 2013. Please contact Mr. Dayton at the email address above to obtain meeting materials.

Contact Person for More Information: Daniel S. Dayton, Designated Federal Officer, Department of Homeland Security, Science and Technology Directorate, 245 Murry Lane, Mailstop 0203, Washington, DC 20528, telephone 202–254–5607 (note: this is not a toll-free number).

Dated: August 8, 2013.

Daniel S. Dayton,

Designated Federal Official.

[FR Doc. 2013–20327 Filed 8–16–13; 11:15 am]

BILLING CODE 6820–95–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0656]

Secure Supply Chain Pilot Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the start of the Secure Supply Chain Pilot Program (SSCPP). The 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 may pose risks. Such a program would increase the likelihood of expedited entry for specific finished drug products and active pharmaceutical ingredients (APIs) imported into the United States that meet the criteria for selection under the program. This notice outlines the

eligibility requirements and the process for applying for participation in the SSCPP.

DATES: FDA will be accepting applications for participation in the SSCPP beginning September 16, 2013, and continuing through December 31, 2013. The SSCPP will be piloted for 2 years, from February 2014 through February 2016.

FOR FURTHER INFORMATION CONTACT: Katharine Neckers, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3339, email: *katharine.neckers@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Participation in the SSCPP described in this notice is voluntary. FDA plans to increase the rate at which entries of the finished drug products and APIs selected for the pilot program are given a ''May Proceed'' without human entry review or examination; thus, the Agency anticipates that participation in the program will increase the likelihood of expedited entry when products covered by the program are offered for importation into the United States.

This pilot program is closely related to section 713(4)(B)(i) of the recently enacted Food and Drug Administration Safety and Innovation Act (FDASIA). Section 713 of FDASIA authorizes FDA to require the submission of drug compliance information as a condition of granting admission to imported drugs, and subsection (4)(B)(i) specifically states that in issuing the implementing regulations FDA ''may, as appropriate, take into account differences among importers and types of imports, and based on the level of risk posed by the imported drug, provide for expedited clearance for those importers that volunteer to participate in partnership programs for highly compliant companies and pass a review of internal controls. . . .'' Thus, the information provided through this pilot program will help inform the Agency's approach to implementing the program mentioned in section 713(4)(B) of FDASIA.

To the extent allowed by law, and in a manner consistent with applicable laws and policies, the Agency intends to share the names of the participants and information related to these companies with other Federal Agencies, such as Customs and Border Protection (CBP). FDA is collaborating with CBP regarding the Customs-Trade Partnership Against Terrorism (C–TPAT) portion of the application. 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 announced this pilot program in the **Federal Register** of January 15, 2009 (74 FR 2605), requesting comments on the program and proposed collection of information. A subsequent request for comments on the collection of information was issued June 20, 2012 (77 FR 37055). The 2009 and 2012 notices contain further background and clarification regarding the pilot program. FDA has made a few changes to the pilot program announced in 2009, and this notice describes the requirements to participate and other aspects of the program.

To help determine whether participants in the SSCPP continue to meet the program's criteria and help evaluate the program, FDA intends to periodically examine records and conduct random field examinations to audit shipments. FDA may withdraw its selection of an application if the applicant, foreign manufacturer, or Ultimate Consignee: (1) Receives communications, such as an Untitled Letter, Cyber Letter, or Warning Letter, that cite violations of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) relating to drug products that FDA otherwise deems to have violated any requirements of the FD&C Act relating to drug products or (2) fails to comply with the SSCPP. Termination of participation in the SSCPP will result in a return to the routine manual drug entry review process.

II. Secure Supply Chain Pilot Program Requirements

To be selected to participate in the SSCPP, an applicant must meet the following criteria:

1. The applicant must submit a complete application using Form FDA 3676 and be the sponsor of the New Drug Application (NDA) or the Abbreviated New Drug Application (ANDA), or be the foreign manufacturer of the imported finished drug product or API.

2. If the Ultimate Consignee identified in the SSCPP application is an establishment subject to section 510 of the FD&C Act (21 U.S.C. 360), then it must be in compliance with FDA's registration, drug listing, and current good manufacturing practice requirements, and must have been in compliance over the past 3 years.

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

4. If the drug identified in the SSCPP application is an API, then the source must be an acceptable source per the approved NDA or ANDA, and the API must be used in the manufacture of the FDA-approved drug product.

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

6. The foreign manufacturer and the finished drug product or API identified in the SSCPP application must be in compliance with requirements of the FD&C Act relating to drugs.

7. The SSCPP importer of record must have a validated Tier II or Tier III secure supply chain per the CBP Customs–C–TPAT Program.

8. The primary and secondary contacts identified in the SSCPP application must be able to answer questions and resolve issues raised by FDA. The primary contact must be the sponsor or the U.S. agent for the sponsor.

9. The applicant must have a plan in place for promptly correcting 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 SSCPP must be reported to FDA within 3 business days of identification by the applicant.

11. Applicants must comply with recordkeeping requirements of the FD&C 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 SSCPP applications, including documentation of their C–TPAT validation 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, for the duration of the applicant's participation, 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.

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

III. 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.
- *Automated Commercial System (ACS):* The system used by CBP to track, control, and process all commercial goods imported into the United States.
- *Customs House Broker/Entry 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:* C–TPAT 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:* 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.

IV. Process for Applying To Participate in the Pilot

Due to resource constraints, FDA intends to limit the SSCPP to no more than 100 qualified applicants, with no 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 (Form FDA 3676) to participate in the SSCPP can be found at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm.*

The SSCPP application should be submitted electronically as a document in Portable Document Format (PDF) and using the Electronic Common Technical Document (eCTD) format and the Electronic Submissions Gateway (ESG). The SSCPP application form should be referenced and placed in the 1.2 Cover Letter section. The PDF file name should contain ''3676'' as part of the file name, and the eCTD leaf title should include ''3676,'' the sponsor name, and the drug name, e.g., ''3676 Form—ABC Drug Company for XYZ Pain Pill.'' If a firm is unable to submit the application electronically, it should submit a hard copy of the application form via mail to: U.S. Food and Drug Administration, Attention: OC Office of Drug Security, Integrity, and Recalls, Central Document Room, 5901B Ammendale Rd., Beltsville, MD 20705–1266.

For further information regarding eCTD, please refer to the Web site at *http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm153574.htm.* For communications other than the submission of the SSCPP application (Form FDA 3676), please contact the CDER SSCPP mailbox at *SSCPPMailBox@fda.hhs.gov.*

FDA will be accepting applications for participation in the SSCPP (see **DATES**). Applications will be processed as they are received, on a first-come, first-served basis. FDA anticipates finishing its review of the applications and selection of the participants by February 2014. All required fields must be completed on the application; incomplete applications will be returned to the U.S. primary contact named in the application. Please do not attach additional documents to the application submission. For the narrative sections of the application, please use the space provided to respond to the question. Applicants will be notified in writing as to whether their application has been selected.

FDA will assign a qualifier to each selected SSCPP application. Each Customs House Broker/Entry Filer will transmit the qualifier when filing the entry for the product. The qualifier will accompany an AofC code, which FDA has designated as a Secure Supply Chain (SSC). Once accepted into the SSCPP, the applicant must notify FDA of any changes to the information contained in Form FDA 3676 by email to the SSCPP mailbox at *SSCPPMailBox@fda.hhs.gov.* FDA anticipates responding to the applicant's modified application within 15 business days after receipt. Continued participation in the SSCPP is dependent on FDA's authorization of those changes.

V. Evaluation

FDA intends to evaluate the SSCPP based on several factors, including, but not limited to, the following: Timeframes for passage of drugs through the imports entry process, the level of adherence by the program participants to the program's criteria, and the impact of the SSCPP. This evaluation will help FDA determine whether establishment of an SSC program is supported and, if so, the parameters of such a program. FDA may also determine that it should extend the pilot program to continue its evaluation, or may terminate the pilot program before the close of the 2-year period. Such decisions will be announced in the **Federal Register**.

Dated: August 14, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–20215 Filed 8–19–13; 8:45 am]

BILLING CODE 4160–01–P