**ACTION:** Notice of meeting.

**DATES:** Thursday, February 19, 2015 from 9:00 a.m. to 4:30 p.m.; and Friday, February 20, 2015 from 9:00 a.m. to 2:00 p.m. (EST)

These meetings will be open to the general public.

**ADDRESSES:** These meetings will be held in the U.S. Department of Health and Human Services/Hubert H. Humphrey Building located at 200 Independence Avenue SW., Conference Room 505A, Washington, DC 20201.

Individuals who would like to participate via conference call may do so by dialing toll-free 888–935–0260, when prompted enter pass code: 3656064. Individuals whose full participation in the meeting will require special accommodations (*e.g.,* sign language interpreting services, assistive listening devices, materials in alternative format such as large print or Braille) should notify Dr. MJ Karimi, PCPID Team Lead, via email at *MJ.Karimie@acl.hhs.gov*, or via telephone at 202–357–3588, no later than Friday, February 13, 2015. The PCPID will attempt to accommodate requests made after that date, but cannot guarantee the ability to grant requests received after this deadline. All meeting sites are barrier free, consistent with the Americans with Disabilities Act (ADA) and the Federal Advisory Committee Act (FACA).

*Agenda:* The Committee Members will discuss preparation of the PCPID 2015 Report to the President, including its content and format, and related data collection and analysis required to complete the writing of the Report. They will also receive presentations from selected experts in the field of Technology for People with Intellectual and Developmental Disabilities.

*Additional Information:* For further information, please contact Dr. MJ Karimi, Team Lead, President's Committee for People with Intellectual Disabilities, One Massachusetts Avenue NW., Room 4206, Washington, DC 20201. Telephone: 202–357–3588. Fax: 202–205–8037. Email: *MJ.Karimie@acl.hhs.gov*.

**SUPPLEMENTARY INFORMATION:** The PCPID acts in an advisory capacity to the President and the Secretary of Health and Human Services, through the Administration on Intellectual and Developmental Disabilities, on a broad range of topics relating to programs, services and supports for persons with intellectual disabilities. The PCPID Executive Order stipulates that the Committee shall: (1) Provide such advice concerning intellectual disabilities as the President or the Secretary of Health and Human Services may request; and (2) provide advice to the President concerning the following for people with intellectual disabilities: (A) Expansion of educational opportunities; (B) promotion of homeownership; (C) assurance of workplace integration; (D) improvement of transportation options; (E) expansion of full access to community living; and (F) increasing access to assistive and universally designed technologies.

Dated: January 28, 2015.

**Aaron Bishop,**

*Commissioner, Administration on Intellectual and Developmental Disabilities (AIDD).*

[FR Doc. 2015–02514 Filed 2–5–15; 8:45 am]

**BILLING CODE P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2010–N–0161]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Export of Food and Drug Administration Regulated Products: Export Certificates

**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.

**DATES:** Fax written comments on the collection of information by March 9, 2015.

**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 OMB control number 0910–0498. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

**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.

**Export of Food and Drug Administration Regulated Products: Export Certificates—(OMB Control Number 0910–0498)—Extension**

In April 1996, a law entitled ''The FDA Export Reform and Enhancement Act of 1996'' (FDAERA) amended sections 801(e) and 802 of the FD&C Act (21 U.S.C. 381(e) and 382). It was designed to ease restrictions on exportation of unapproved pharmaceuticals, biologics, and devices regulated by FDA. Section 801(e)(4) of the FDAERA provides that persons exporting certain FDA regulated products may request FDA to certify that the products meet the requirements of 801(e) and 802 or other requirements of the FD&C Act. This section of the law requires FDA to issue certification within 20 days of receipt of the request and to charge firms up to $175 for the certifications.

This section of the FD&C Act authorizes FDA to issue export certificates for regulated pharmaceuticals, biologics, and devices that are legally marketed in the United States, as well as for these same products that are not legally marketed but are acceptable to the importing country, as specified in sections 801(e) and 802 of the FD&C Act. FDA has developed four types of certificates that satisfy the requirements of section 801(e)(4)(B) of the FD&C Act: (1) Certificates to Foreign Governments, (2) Certificates of Exportability, (3) Certificates of a Pharmaceutical Product, and (4) Non-Clinical Research Use Only Certificates. Table 1 of this document lists the different certificates and details their use:

TABLE 1—CERTIFICATES AND USES

| Type of certificate | Use |
|---|---|
| ''Supplementary Information Certificate to Foreign Government Requests''. | For the export of products legally marketed in the United States. |
| ''Exporter's Certification Statement Certificate to Foreign Government''. | |
| ''Exporter's Certification Statement Certificate to Foreign Government (For Human Tissue Intended for Transplantation)''. | |
| ''Supplementary Information Certificate of Exportability Requests''. | For the export of products not approved for marketing in the United States (unapproved products) that meet the requirements of sections 801(e) or 802 of the FD&C Act. |
| Exporter's Certification Statement Certificate of Exportability''. | |
| ''Supplementary Information Certificate of a Pharmaceutical Product''. | Conforms to the format established by the World Health Organization and is intended for use by the importing country when the product in question is under consideration for a product license that will authorize its importation and sale or for renewal, extension, amending, or reviewing a license. |
| ''Exporter's Certification Statement Certificate of a Pharmaceutical Product''. | |
| ''Supplementary Information Non-Clinical Research Use Only Certificate''. | For the export of a non-clinical research use only product, material, or component that is not intended for human use which may be marketed in, and legally exported from the United States under the FD&C Act. |
| ''Exporter's Certification Statement (Non-Clinical Research Use Only)''. | |

FDA will continue to rely on self-certification by manufacturers for the first three types of certificates listed in table 1 of this document. Manufacturers are requested to self-certify that they are in compliance with all applicable requirements of the FD&C Act, not only at the time that they submit their request to the appropriate center, but also at the time that they submit the certification to the foreign government.

The appropriate FDA centers will review product information submitted by firms in support of their certificate and any suspected case of fraud will be referred to FDA's Office of Criminal Investigations for follow up. Making or submitting to FDA false statements on any documents may constitute violations of 18 U.S.C. 1001, with penalties including up to $250,000 in fines and up to 5 years imprisonment.

In the **Federal Register** of November 14, 2014 (79 FR 68277), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

| FDA center and FDA form | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| Center for Biologics Evaluation and Research | 2,114 | 1 | 2,114 | 1 | 2,114 |
| FDA 3613. | | | | | |
| FDA 3613a. | | | | | |
| FDA 3613b. | | | | | |
| FDA 3613c. | | | | | |
| Center for Devices and Radiological Health | 10,528 | 1 | 10,528 | 2 | 21,056 |
| FDA 3613. | | | | | |
| FDA 3613a. | | | | | |
| FDA 3613c. | | | | | |
| Center for Veterinary Medicine | 855 | 1 | 855 | 1 | 855 |
| FDA 3613. | | | | | |
| FDA 3613a. | | | | | |
| FDA 3613b. | | | | | |
| Total | | | | | 24,025 |

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

Dated: January 30, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015–02348 Filed 2–5–15; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2014–N–1168]**

### Generic Drug User Fee Amendments of 2012; September 2014 Public Hearing on Policy Development; Reopening of Docket; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; reopening of docket; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the reopening of the docket to solicit public comment on certain topics related to implementation of the Generic Drug User Fee Amendments of 2012 (GDUFA) and the GDUFA Commitment Letter that accompanies the legislation. A public hearing in September 2014 provided an opportunity for public input on future