2018. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by May 31, 2018.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Artair Mallett at *Artair.Mallett@fda.hhs.gov* or 301–796–9638 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: May 10, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–10552 Filed 5–16–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–2347]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food and Cosmetic Export Certificate Application Process

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) 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 June 18, 2018.

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 0910–0793. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *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.

Food and Cosmetic Export Certificate Application Process

OMB Control Number 0910–0793—Revision

This information collection supports FDA's Center for Food Safety and Applied Nutrition's (CFSAN) export certificate application process. Some countries may require manufacturers of FDA-regulated products to provide certificates for products they wish to export to that country. Accordingly, firms exporting products from the United States often ask FDA to provide such a ''certificate.'' In many cases, foreign governments are seeking official assurance that products exported to their countries can be marketed in the United States, or that they meet specific U.S. requirements. In some cases, review of an FDA export certificate may be required as part of the process to register or import a product into another country. An export certificate generally indicates that the particular product is marketed in the United States or otherwise eligible for export and that the particular manufacturer has no unresolved enforcement actions pending before, or taken by, FDA.

Interested persons may request a certificate from CFSAN electronically via the Certificate Application Process (CAP), a component of FDA Industry Systems, or by contacting CFSAN for assistance. To facilitate the application process we have eliminated paper-based forms. For food products, we have expanded the electronic options for providing facility and product information. Respondents will now be able to identify facilities based on a food facility registration number, FDA Establishment Identification number, or Data Universal Numbering System number. The system uses these identifiers to locate and auto-populate name and address information, eliminating the need for users to manually enter this information and reducing the time to complete the application. Respondents can also upload product information via a spreadsheet, which reduces the time needed to enter product information, particularly for applications that include multiple products. All information is entered using electronic Forms FDA 3613d, 3613e, 3613g, and 3613*l* and used to evaluate certificate requests.

While burden associated with information collection activities for export certificates issued for other FDA-regulated products is approved under OMB control number 0910–0498, this collection specifically supports export certificates issued by CFSAN. Also, because we have eliminated paper-based forms, respondents who require assistance with completing export certificate applications online may contact CFSAN directly by email (*CFSANExportCertification@fda.hhs.gov*) or telephone (240–402–2307). Instructions for Form FDA 3613d are available online at *https://www.fda.gov/cosmetics/internationalactivities/exporters/ucm353912.htm* and instructions for Form FDA 3613e are available online at *https://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Exporting/ucm260280.htm.* Draft screenshots of Form FDA 3613g and 3613*l* are available for comment online at *https://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Exporting/default.htm.*

Description of Respondents: The respondents to this collection of information are firms interested in exporting U.S.-manufactured food and cosmetic products to foreign countries that require export certificates.

In the **Federal Register** of January 2, 2018 (83 FR 133), we published a notice soliciting public comment of the information collection. Two comments were received in support of the information collection. One comment included technical suggestions as well regarding respondents' ability to review and edit data that might have been entered improperly. We appreciate this comment and continue to seek ways to utilize improved information collection

technologies as our resources permit. FDA notes section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381) also provides that FDA may charge a fee of up to $175 if the Agency issues a certificate within 20 days of receipt of a complete request for such a certificate. This fee may vary depending on the product type, but it will not exceed $175.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Type of respondent	FDA Form No.[2]	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Cosmetics	3613d	270	3	810	0.5 (30 minutes)	405
Food	3613e, 3613g, 3613/ ...	881	5	4,405	0.5 (30 minutes)	2,203
Total						2,608

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] All forms are submitted electronically via CAP.

This estimate reflects a revision resulting from the elimination of paper-based forms. Specifically, and based on our experience with the information collection, we have reduced the estimated time to prepare a submission from 1.5 hours to 0.5 hour. The previous estimate was based on the time necessary to prepare a paper submission, but all firms requesting export certificates now provide submissions electronically via CAP. We believe that the time to prepare an electronic submission is under 0.25 hour, but are estimating 0.5 hour as a conservative approach to address all scenarios. We base our estimates of the total annual responses on our experience with certificate applications received in the past 3 fiscal years.

We expect that most firms requesting export certificates in the next 3 years will choose to take advantage of the option of electronic submission via CAP. If a firm is unable to submit their information via CAP, they may contact CFSAN and request assistance. CFSAN will assist firms in entering their information into the electronic system so that the firm may receive their export certificates in a timely manner. Our burden estimates in table 1 are based on the expectation of 100 percent participation in the electronic submission process. Providing the opportunity to submit the information in electronic format has reduced our previous estimates for the time to prepare each submission.

Dated: May 14, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–10551 Filed 5–16–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–new]

Agency Information Collection Request. 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before June 18, 2018.

ADDRESSES: Submit your comments to *OIRA_submission@omb.eop.gov* or via facsimile to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Sherrette Funn, *Sherrette.Funn@hhs.gov* or (202) 795–7714. When submitting comments or requesting information, please include the document identifier 0990–New–30D and project title for reference.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Evaluation of the Assisted Outpatient Treatment Grant Program for Individuals with Serious Mental Illness.

Type of Collection: New.

Abstract: The Office of the Assistant Secretary for Planning and Evaluation (ASPE) at the U.S. Department of Health and Human Services (HHS) is requesting Office of Management and Budget (OMB) approval for data collection activities to support the evaluation of the Substance Abuse and Mental Health Services Administration's (SAMHSA's) Assisted Outpatient Treatment (AOT) Grant Program for Individuals with Serious Mental Illness (SM–16–011). Enacted into law on April 1, 2014, Section 224 of the Protecting Access to Medicare Act (PAMA) (Pub. L. 113–93) mandated a 4-year pilot program of grants to implement AOT programs nationwide. Section 224(e) required a program evaluation to examine the impact of AOT on cost savings and public health outcomes, incarceration, homelessness, and patient and family satisfaction with program participation.

Focusing specifically on six of the 17 sites, the in-depth implementation and outcome evaluation of the SAMHSA AOT Grant Program for Individuals with Serious Mental Illness is being carried out by RTI International, in partnership with Duke University and Policy Research Associates. The completed implementation evaluation, conducted from November 2016 to August 2017, gathered information related to the processes and practices of AOT across the six in-depth sites. The information to be collected for the outcome evaluation will allow ASPE and partners SAMHSA and NIMH to assess which elements of AOT programs influence health and social outcomes for people under AOT orders, as well as the use of services, associated costs, and patient and family satisfaction with the AOT process.

Need and Proposed Use of the Information: Section 224(e) of PAMA requires annual reports to Congress that include evaluation of: Cost savings and