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

public health outcomes such as mortality, suicide, substance abuse, hospitalization, and use of services; rates of incarceration by patients; rates of homelessness among patients; and patient and family satisfaction with program participation. The data collected under this submission will help ASPE address the evaluation questions listed above and inform the required reports to Congress.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS TO RESPONDENTS

Forms	Respondents	Number of respondents	Number of responses per respondent	Average burden per response (hours)	Total annual burden (hours)
Client Interview Instrument	Program Participant	520	3	1.00	1560.00
	Comparison Subjects	520	3	1.00	1560.00
Family Satisfaction Survey	Program Participant's Family Member.	173	1	15/60	43.25
Cost Questionnaire	Program Administrator	6	1	1.25	7.50
	Other Site Representatives	12	1	1.25	15.00
Docket Case Monitoring Form	AOT Local Evaluator	6	390	6/60	234.00
AOT Characteristics Form	AOT Local Evaluator	6	12	30/60	36.00
Total		1,243	411	0.76	3,455.75

Terry Clark,

Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.

[FR Doc. 2018–10512 Filed 5–16–18; 8:45 am]

BILLING CODE 4150–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket No. FDA–2016–D–1605]

Institutional Review Board Written Procedures: Guidance for Institutions and Institutional Review Boards; Availability

AGENCY: The Office for Human Research Protections, Office of the Assistant Secretary for Health, Office of the Secretary, and the Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Office for Human Research Protections (OHRP), Office of the Assistant Secretary for Health, and the Food and Drug Administration (FDA) are announcing the availability of a guidance entitled ''Institutional Review Board (IRB) Written Procedures: Guidance for Institutions and IRBs.'' The guidance is intended for institutions and IRBs responsible for review and oversight of human subject research under the Department of Health and Human Services (HHS) and FDA regulations. The purpose of this guidance is to assist staff at institutions and IRBs who are responsible for preparing and maintaining written procedures. The guidance announced in this notice finalizes the draft guidance of the same title dated August 2016.

DATES: The announcement of the guidance is published in the **Federal Register** on May 17, 2018.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–D–1605 for ''Institutional Review Board (IRB) Written Procedures: Guidance for Institutions and IRBs.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed