• Information gathered will not be used for the purpose of substantially informing influential policy decisions; [2] and

• Information gathered will yield qualitative findings; the collections will not be designed or expected to yield statistical data or used as though the results are generalizable to the population of study.

To obtain approval for a collection that meets the conditions of this generic clearance, an abbreviated supporting statement will be submitted to OMB along with supporting documentation (*e.g.,* a copy of the survey or experimental design and stimuli for testing).

FDA will submit individual quantitative collections under this generic clearance to OMB. Individual quantitative collections will also undergo review by FDA's Research Involving Human Subjects Committee, senior leadership in the Center for Food Safety and Applied Nutrition, and PRA specialists.

Respondents to this collection of information may include a wide range of consumers and other FDA stakeholders such as producers and manufacturers who are regulated under FDA-regulated food and cosmetic products, dietary supplements, and animal food and feed.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN BY ANTICIPATED DATA COLLECTION METHODS [1]

Survey type	Number of respondents	Number of responses per respondent	Total annual responses	Total hours
Cognitive Interviews Screener	720	1	720	60
Cognitive Interviews	144	1	144	144
Pre-test Study Screener	2,400	1	2,400	199
Pre-testing Study	480	1	480	120
Self-administered Surveys/Experimental Studies Screener	75,000	1	75,000	6,225
Self-Administered Surveys/Experimental Studies	15,000	1	15,000	3,750
Total				10,498

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

The total estimated annual burden is 10,498 hours. Current estimates are based on both historical numbers of participants from past projects as well as estimates for projects to be conducted in the next 3 years. The number of participants to be included in each new survey will vary, depending on the nature of the compliance efforts and the target audience.

Dated: August 28, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–19088 Filed 8–31–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–2700]

Food for Human Consumption; Export Certificates; Food and Drug Administration Food Safety Modernization Act of 2011; Certification Fees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the fees we will assess for issuing export certificates for food for human consumption, with the exception of dietary supplements, medical foods, and foods for special dietary use. The FDA Food Safety Modernization Act (FSMA) of 2011 authorizes us to charge fees to cover our costs associated with issuing export certificates for food. This notice provides the fee schedule for issuing these certificates and the basis for the fees. We have not previously exercised our FSMA authority to collect fees for export certificates issued for food for human consumption.

DATES: The fees described in this document for export certificates for food for human consumption, with the exception of dietary supplements, medical foods, and foods for special dietary use, will be effective October 1, 2018.

FOR FURTHER INFORMATION CONTACT: Kate Meck, International Affairs Staff, Center for Food Safety and Applied Nutrition (HFS–550), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2307, *CFSANExportCertification@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In April 1996, the ''FDA Export Reform and Enhancement Act of 1996'' (Pub. L. 104–134, amended by Pub. L. 104–180) amended sections 801 and 802 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 381 and 382). As a result of the 1996 amendments, section 801(e)(4) of the FD&C Act provides that persons exporting a drug, animal drug, or device may request FDA to certify that the product meets the requirements of section 801(e)(1), section 802, or other applicable requirements of the FD&C Act. Upon a showing that the product meets the applicable requirements, the law provides that FDA shall issue export certification within 20 days of the receipt of a request for such certification. The law also authorizes us to charge up to $175 for each certification issued within the 20-day period.

In January 2011, section 801(e)(4) of the FD&C Act was further amended by FSMA (Pub. L. 111–353) to authorize FDA to issue, and charge fees for, export certificates for food. Under section 801(e)(4)(C) of the FD&C Act, an export certification can be made in such form (including a publicly available listing) as FDA determines appropriate.

This notice focuses on the fees to be assessed with respect to export certificates issued by the Center for Food Safety and Applied Nutrition (CFSAN) for food for human

[2] As defined in OMB and agency Information Quality Guidelines, ''influential'' means that ''an agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact on important public policies or important private sector decisions.''

consumption, with the exception of dietary supplements, medical foods, and foods for special dietary use. This notice applies to foods such as produce, grains, processed foods, food additives, color additives, food contact substances, generally regarded as safe ingredients, infant formula, and all other foods not specifically excluded. Dietary supplements, medical foods, and foods for special dietary use are excluded from this notice.

II. Fees To Be Assessed for Export Certificates

CFSAN estimates the annual costs of the export certification program for food for human consumption, with the exception of dietary supplements, medical foods, and foods for special dietary use, to be approximately $975,000 per year for preparing and issuing export certificates. The costs are due to payroll and operating expenses. Specifically, there are four cost categories for preparing and issuing export certificates in general: (1) Direct personnel for research, review, tracking, writing, and assembly; (2) an information technology system used for tracking and processing certificates; (3) billing and collection of fees; and (4) overhead and administrative support. In fiscal year (FY) 2017 CFSAN issued approximately 4,072 export certificates for food for human consumption, with the exception of dietary supplements, medical foods, and foods for special dietary use. Because CFSAN has not been charging fees for issuing these export certificates, the program has been covered by appropriated funds.

As mentioned previously, FDA may charge up to $175 for each certificate. Certificates for some of the foods that are the subject of this notice cost us more than $175 to prepare. Subsequent certificates issued for the same product(s) in response to the same request generally cost FDA less than $175 to prepare. The fee for all subsequent certificates for the same product(s) issued in response to the same request reflects reduced FDA costs for preparing those certificates.

The following fees will be assessed starting October 1, 2018, for export certificates for food for human consumption, with the exception of dietary supplements, medical foods, and foods for special dietary use:

TABLE 1—CFSAN FEES FOR FIRST, SECOND, AND SUBSEQUENT EXPORT CERTIFICATES

Type of certificate	Fee (dollars)
First certificate	175
Second certificate for the same product(s) issued in response to the same request	155
Subsequent certificates for the same product(s) issued in response to the same request	100

The fee for issuing the first export certificate for food for human consumption, with the exception of dietary supplements, medical foods, and foods for special dietary use, will be at the maximum allowable amount and consistent with the export certification fees assessed since FY 1997 by other FDA Centers that provide export certification for drugs and devices. It is also consistent with the export certification fees assessed by the Center for Veterinary Medicine (CVM) for certificates for animal food, which CVM began assessing in FY 2016 because the FSMA amendments to section 801(e)(4) of the FD&C Act also apply to animal food. The fees for issuing subsequent certificates continue to differ among the Centers, based on varying costs.

Dated: August 28, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–19064 Filed 8–31–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–4040–0014]

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 October 4, 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 4040–0014–30D 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 Collections: Federal Financial Report (SF–425) and Federal Financial Report Attachment (SF–425A).

Type of Collection: Extension.

OMB No.: 4040–0014.

Abstract: Federal Financial Report (SF–425) and Federal Financial Report Attachment (SF–425A) are OMB-approved collections (4040–0014). These information collections are used by grant awardees. The ICs expire on January 31, 2019. We are requesting a three-year clearance of these collections.

ESTIMATED ANNUALIZED BURDEN TABLE

Forms	Type of respondent	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Federal Financial Report (SF–425)	Grant Applicant	100,000	1	1	100,000
Federal Financial Report Attachment (SF–425A)	Grant Applicant	100,000	1	1	100,000
Total		200,000			200,000