



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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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 [oir\\_submission@omb.eop.gov](mailto:oir_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, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@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 3613l 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 3613l 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<sup>1</sup>

| Type of Respondent | FDA Form No. <sup>2</sup> | No. of Respondents | No. of Responses per Respondent | Total Annual Responses | Average Burden per Response (in hours) | Total Hours |
|--------------------|---------------------------|--------------------|---------------------------------|------------------------|--|-------------|
| Cosmetics          | 3613d                     | 270                | 3                               | 810                    | 0.5<br>(30 minutes)                    | 405         |
| Food               | 3613e, 3613g,<br>3613l    | 881                | 5                               | 4,405                  | 0.5<br>(30 minutes)                    | 2,203       |
| Total              |                           |                    |                                 |                        |  | 2,608       |

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

<sup>2</sup>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.

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