4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2024-N-2032]

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, the 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: Submit written comments (including recommendations) 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 submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review--Open for Public Comments" or by using the search function. The OMB control number for this information collection is 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 helps support implementation of statutory and regulatory authorities governing the export of certain FDA-regulated products found in section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381), and in 21 CFR part 1, subpart E--Imports and Exports, of Agency regulations. 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.

Consistent with this authority, interested persons may request human food and cosmetic export certificates electronically via the Export Certification Application and Tracking System (eCATS) or Certificate Application Process (CAP), components of the FDA Industry Systems, or by contacting FDA for assistance. Health certificates are the exception and are requested via email. To facilitate the application process, we have eliminated paper-based forms. All information is currently submitted electronically using Forms FDA 3613d, 3613e, and 3613k. The eCATS Module is Form 3613k, where 3613e is the Certificate of Free Sale (https://www.fda.gov/food/food-export-certificates/online-applications-export-certificates-food). All "forms" are electronic and part of the eCATS or CAP portal accessed via https://www.access.fda.gov. To view representations of the forms, instructions must be downloaded and are accessible through the following links:

https://www.fda.gov/cosmetics/cosmetics-exporters/online-applications-export-certificates-cosmetics and https://www.fda.gov/food/food-export-certificates/online-applications-export-certificates-food.

While a burden associated with information collection activities for export certificates issued for other FDA regulated products is accounted for and approved under OMB control number 0910-0498, this collection specifically supports information collection activity attributable to export certificates issued for human food and cosmetic products. Also, because we have eliminated paper-based forms, respondents who require assistance with completing export certificate applications online may contact FDA directly by email (CFSANExportCertification@fda.hhs.gov) or telephone (240-402-2307). Instructions for requesting export certificates for cosmetics (Form FDA 3613d) are available online at https://www.fda.gov/cosmetics/cosmetics-exporters/online-applications-export-certificates-cosmetics and instructions for requesting export certificates for food (Forms FDA 3613e and Form 3613k) are available online at https://www.fda.gov/food/food-export-certificates/online-applications-export-certificates-food.

We are revising the information collection to include a web-based inquiry form, Form FDA 5077, entitled "U.S. Department of Health and Human Services Food and Drug Administration Export Certification Inquiry," intended to facilitate processing by cross-referencing the request with existing Agency data. A mockup of the proposed electronic form is posted to the docket to solicit public comment. For food products, respondents may identify facilities using their Food Facility Registration number, FDA Establishment Identifier number, or a 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. For some applications, 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.

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

In the *Federal Register* of May 15, 2024 (89 FR 42472), we published a 60-day notice requesting public comment on the proposed collection of information. Although two comments were received, neither appeared to be responsive to the information collection topics solicited in the notice, nor suggested FDA modify its burden estimates.

We therefore estimate the burden of the collections of information as follows:

Table 1.--Estimated Annual Reporting Burden[1]

Type of Certificate	Form No.[2]	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Cosmetics	FDA 3613d	66	3	198	0.5 (30 minutes)	99
Food	FDA 3613e, 3613k	454	10	4,540	0.5 (30 minutes)	2,270
Export Certification Inquiry	FDA 5077	520	18	9,360	0.25 (15 minutes)	2,340
Total						4,709

[1] There are no operating and maintenance costs associated with this collection of information.
[2] All forms are submitted electronically via FDA Industry Systems.

Since our last review of the information collection, we have adjusted our estimate of the number of respondents downward. At the same time, we have increased the number of responses per respondent and added new Form FDA 5077. Cumulatively these activities result in an estimated burden increase of 2,433 hours and 9,547 responses annually.

Dated: August 5, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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