UNITED STATES FOOD & DRUG ADMINISTRATION

Food and Cosmetic Export Certificate Applications Process

OMB Control No. 0910-0793

SUPPORTING STATEMENT – **Part A: Justification**:

1. Circumstances Making the Collection of Information Necessary

This information collection request pertains to issuance of food and cosmetic export certificates under the Federal Food, Drug, and Cosmetic Act (the FD&C Act). Under the FD&C Act, firms exporting products from the United States often ask FDA to provide export certificates. 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. While the FD&C Act does not require us to issue certificates for cosmetics, foreign governments may require certificates for these types of products and the agency continues to provide this service as resources permit. Notifications and records required for food and cosmetic products exported under sections 801 or 802 of the FD&C Act (21 U.S.C. 381 and 382), or section 351 of the Public Health Service Act (42 U.S.C. 262), are found in 21 CFR part 1.101 of our regulations.

CFSAN issues export certificates for human food and cosmetic products. Interested persons may request a certificate electronically via the CFSAN Export Certification Application and Tracking System (CFSAN eCATS) or Certificate Application Process (CAP), components of the FDA Industry Systems, or by contacting CFSAN for assistance. Health certificates are the exception and are requested via email. To facilitate the application process, we have eliminated paper-based forms. For food products, respondents are able to identify facilities using their Food Facility Registration or FDA Establishment Identifier (FEI) 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.

All information is entered using electronic Forms FDA 3613d, 3613e, and 3613k and used to evaluate certificate requests. CFSAN eCATS is Form FDA 3613k and CAP is Form FDA 3613e (https://www.fda.gov/food/food-export-certificates/online-applications-export-certificates-food). Form FDA 3613d is used to request export certificates for cosmetics (https://www.fda.gov/cosmetics/cosmetics-exporters/online-applications-export-certificates-cosmetics). Download the instructions to view representations of these forms. All "forms" are electronic and part of the CFSAN eCATS or CAP portal accessed via https://www.access.fda.gov.

We therefore request extension of OMB approval for the information collection supporting FDA's Food and Cosmetic Export Certificate program and the associated electronic Forms FDA 3613d, FDA 3613e, and FDA 3613k.

2. Purpose and Use of the Information Collection

We use the information provided in the applicable forms to determine whether certificates may be issued. Interested persons may request a certificate by using FDA's electronic system, which includes CFSAN eCATS and CAP.

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

3. Use of Improved Information Technology and Burden Reduction

We estimate that one hundred percent (100%) of firms will use information technology (electronic means) to assist them in requesting export certificates in the next three years. 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).

4. Efforts to Identify Duplication and Use of Similar Information

While burden associated with information collection activities for export certificates issued for other FDA-regulated products is approved under OMB control no. 0910-0498; and burden associated with information collection activities for the export of tobacco products is approved under OMB control no. 0910-0482; this collection specifically supports export certificates issued for human food and cosmetic products by CFSAN. We are otherwise unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

We estimate that approximately ten percent (10%) of the respondents are small businesses. However, we do not believe the information collection imposes undue burden on any small entities. Rather, we gather what we believe is the minimum information necessary to issue requested certificates. In addition, we assist small businesses through the agency's Regional Small Business Representatives and through the scientific and administrative staffs within the agency. Assistance is available for small businesses via the agency's website at https://www.fda.gov/industry/small-business-assistance.

6. Consequences of Collecting the Information Less Frequently

Data collection occurs occasionally. The data in new requests for certificates are submitted only once. If the information collection is not conducted, U.S. exporters could be delayed or prevented by the government authorities of a foreign country from participating in commerce in that country.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances associated with this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), we published a 60-day notice requesting public comment on the proposed collection of information in the *Federal Register* of March 16, 2021 (86 FR 14452). We received one comment, which generally supported FDA's cosmetic export certificate program. The comment also recommended a way to improve the cosmetic export certificate program by providing a certificate which would allow exporters to use an exemption from requirements in China for animal testing for certain imported cosmetic products. We will review and consider suggestions from the public to enhance the utility of the cosmetic export certificate program.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected. Although this ICR collects personally identifiable information (PII) or other data of a personal nature, it is collected in the context of the subject individuals' professional capacity and the FDA-related work they perform for their employer (e.g., point of contact at a regulated entity). The PII submitted via Form FDA 3613d, *Office of Cosmetics and Colors "Certificate" Export Application*, is name, work email address, work telephone numbers, and work fax telephone number for the primary contact at a business. Form FDA 3613e, *Food Export Certificate Application*, is name, work email address, work telephone numbers, and work fax telephone number for the primary contact at a business. Form FDA 3613k, *Certificate Application Process for Certification issued Pursuant to Section 801*, is name, work email address, work telephone numbers, and work fax telephone number for the primary contact at a business.

We have determined that although PII is collected, it is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Privacy Act do not apply. Specifically, the contractor or FDA do not use name or any other personal identifier to routinely retrieve records from the information collected.

Trade secret or confidential commercial information is safeguarded by Section 301(j) of the FD&C Act and protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)), and under our regulations at 21 CFR part 20.

11. Justification for Sensitive Questions

This collection of information does not contain questions that are of a personally sensitive nature.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

We estimate the burden of this collection 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	113	3	339	0.5 (30 min.)	170
Food	FDA 3613e, 3613k	468	9	4,212	0.5 (30 min.)	2,106
Total						2,276

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

Based on a review of the information collection since our last OMB approval, we have reduced our estimate. Because we have had fewer requests for export certificates, we have lowered the number of respondents. We base our estimates on our experience with certificate applications received in the past 3 fiscal years.

12b. Annualized Cost Burden Estimate

We estimate the annualized burden hour cost to respondents for this collection of information to be $202,883. We assume new requests for certificates will be prepared by an employee making an average wage similar that of a Federal government employee at the GS-12/Step-3 rate for the Washington-Baltimore Locality Pay Area for the year 2021, which is $44.57 per hour. To account for overhead, this cost is increased by 100 percent, which is $89.14 per hour. Thus, the annual wage cost for completion and submission of these requests and updates is approximately $202,883 (2,276 hours x $89.14 per hour).

Table 2.--Annual Cost Burden Estimate			
Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Manufacturers/Processors seeking an export certificate	2,276	$89.14	$202,883

13. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or Capital Costs

The FD&C Act authorizes a fee up to $175 for export certificates and therefore respondents to the information collection may incur annual average costs of $737,100. We calculated this figure by multiplying the number of annual export certificates for food (4,212) by a factor of $175.

14. Annualized Cost to the Federal Government

Reviewing and responding to requests for export certificates involves the expenditure of resources by technicians, consumer safety officers and managers. These positions range from GS-4 to GS-15 and contractors. We estimate the annual personnel costs to be $1,250,000 and the annual information technology costs to be $300,000, for a total of $1,550,000.

15. Explanation for Program Changes or Adjustments

We have adjusted our estimate based on fewer submission received in the past 3 fiscal years. This results in a reduction of 664 responses and 332 hours annually, with a corresponding reduction in costs of $6,640.

16. Plans for Tabulation and Publication and Project Time Schedule

This information collected will not be published or tabulated.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

We are not seeking approval not to display the OMB expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.