Food and Cosmetic Export Certificate Application Process

OMB Control No. 0910-NEW

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Federal Food, Drug, and Cosmetic Act (the FD&C Act or the act) provides that FDA shall, upon request, issue certificates for FDA-regulated products that either meet applicable requirements and may be legally marketed in the United States, or may be legally exported under the FD&C Act although they may not be legally marketed in the United States. While the act does not require FDA to issue certificates for food, including animal feeds, food and feed additives, and dietary supplements, or cosmetics, foreign governments may require certificates for these types of products and the agency intends to provide this service as resources permit. A Certificate of Free Sale is a certificate (not pertaining to a particular production lot or export consignment) that indicates that the particular product is marketed in the United States or eligible for export, and that the particular manufacturer has no unresolved enforcement actions pending before or taken by FDA. FDA's Center for Food Safety and Applied Nutrition (CFSAN) issues such certificates for food, food additives, seafood, dietary supplements, and cosmetics.

FDA is requesting approval for export certificates for food and cosmetics submitted on paper Forms FDA 3613d and FDA 3613e and, electronically, via the CFSAN Certificate Application Process. Previously these forms were approved under OMB control number 0910-0498, however the agency is seeking to obtain separate approval for these forms as they are administered by a distinct agency component.

2. Purpose and Use of the Information Collection

Interested persons may request a certificate by using the electronic CFSAN Certificate Application Process, which is part of FDA Unified Registration and Listing System, or by submitting a paper Form FDA 3613d for cosmetic products or a paper Form FDA 3613e for food products. Information requested on the forms allows the agency to determine whether the requested certificate may be issued.

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.

3. Use of Improved Information Technology and Burden Reduction

The agency estimates 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.

4. Efforts to Identify Duplication and Use of Similar Information

FDA knows of no similar data gathered or maintained by any Federal agency or other source.

5. Impact on Small Businesses or Other Small Entities

We estimate that approximately ten percent (10%) of the respondents are small businesses. However, because the collection gathers the minimum information that a business is required to submit to request a certificate, there is no way to reduce the burden on small businesses. We aid small businesses through the agency's Regional Small Business Representatives and through the scientific and administrative staffs within the agency. We have provided a Small Business Guide on the agency's website at http://www.fda.gov/oc/industry/.

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 entering 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 the Federal Register of January 9, 2015 (80 FR 1422), FDA published a 60-day notice requesting public comment on the proposed collection of information. Four comments were received in response to the notice. The comments generally supported the necessity and practical utility of the information collected during the export certificate application process for food, however no comments were received regarding the export certificate application process for cosmetics. Our responses to the comments are incorporated below.

One comment had concerns about our request for the manufacturer's (and exporter's, if different from manufacturer) state license or registration number on Form FDA 3613(e), stating that doing so could allow third parties unnecessary and/or unauthorized access to confidential commercial information. We appreciate this comment and note that we do not place the firm's state license or registration numbers on the certificates we issue. In addition, confidential commercial information is protected from disclosure under FOIA under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)), and under our regulations at 21 CFR part 20. At the same time, the state license or registration number is necessary for our review of the application. We verify the license or registration and investigate inspection data on the listed products.

One comment suggested ways we might modify the electronic submission system, including expanding the number of characters that may be entered per data field; developing corporate identification numbers and passwords, permitting a product label to be submitted electronically through the CFSAN Certificate Application Process; and, permitting a submitter to pay the application fees electronically within the CFSAN Certificate Application Process. Similarly, another comment discussed possible changes to the content of the Export Certificates or the Certificates of Free Sale that we issue for food, including incorporating pagination to indicate the number of sequential pages that would be part of the certificate; adding statements that the product is fit for human consumption, may be freely sold or exported in the United States, and, is produced in a manner consistent with good manufacturing practice; and providing the applicant the ability to request the type of certificate referenced on the header of the document and to request additional services, such as a notarized certificate document or expedited processing. While we are not able to accommodate the suggested modifications at this time, we will consider them as we contemplate future revisions to the relevant forms and solicit additional comments at that time through a notice published in the Federal Register.

Finally, one comment was received that did not respond to any of the four information collection topics solicited and was therefore addressed by the agency.

9. Explanation of Any Payment or Gift to Respondents

FDA does not provide any payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

Trade secret or confidential commercial information is safeguarded by Section 301(j) of the FD&C Act and would be 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 Costs

12 a. Annualized Hour Burden Estimate

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.

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

Table 1.--Estimated Annual Reporting Burden[1]						
Category	Form No.[2]	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Avg. Burden per Response	Total Hours
Cosmetics	Form FDA 3613d	600	1	600	1.5	900
Conventional Food (Including Seafood)	Form FDA 3613e	398	1	398	1.5	597
Dietary Supplements, Food for Special Dietary Use, Infant Formula, & Medical Foods	Form FDA 3613e	2,129	1	2,129	1.5	3,194
Food Additives and Food Contact Substances	Form FDA 3613e	167	1	167	1.5	251
Total						4,942

[1] There are no operating and maintenance costs associated with this collection of information.
[2] Form FDA 3613d and Form FDA 3613e may be submitted electronically via the Certificate Application Process.

For the purpose of this information collection request, we are basing our estimate of the average burden per response in column 6 of Table 1 on the estimates previously submitted under OMB Control No. 0910-0498. Our estimate of the average burden per response in column 6 of Table 1 varies according to the product category for which the certificate is requested. We base our estimates of the total annual responses in column 5 of Table 1 on our experience with certificate applications received in the past 2 fiscal years. Some respondents send in requests as often as three or four times a month while others may submit only periodic requests.

We expect that most if not all firms requesting export certificates in the next three years will choose to take advantage of the option of electronic submission via the CFSAN Certificate Application Process. Thus, our burden estimates in Table 1 are based on the expectation of one hundred percent (100%) participation in the electronic submission process. The opportunity to provide the information in electronic format could reduce the agency's previous estimates for the time to prepare each submission. However, as a conservative approach for the purpose of this analysis, we are assuming that the opportunity to submit the information in electronic format will have no effect on the average time to prepare a submission.

12 a. Annualized Cost Burden Estimate

FDA estimates the annualized burden hour cost to respondents for this collection of information to be approximately $385,871. FDA estimates that 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 2015, which is $39.04 per hour. To account for overhead, this cost is increased by 100 percent, which is $78.08 per hour. Thus, the annual wage cost for completion and submission of these requests and updates is approximately $385,871 (4,942 hours x $78.08 per hour).

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

Section 801(e)(4)(B) authorizes FDA to charge firms for export certificates. CFSAN charges $10 per certificate. Assuming FDA receives payment for the annual number of requests estimated in Table 1, Column 5 (3,294), fees would total $32,940 (3,294 requests x $10 per request).

14. Annualized Cost to the Federal Government

Reviewing and responding to requests for export certificates involves the expenditure of by technicians, consumer safety officers and managers. These positions range from GS-4 to GS-15 and contractors. FDA estimates the annual cost of wages to be $1,309,362 and the annual cost of supplies to be $172,000, for a total of $1,481,362.

15. Explanation for Program Changes or Adjustments

This is a new collection.

16. Plans for Tabulation and Publication and Project Time Schedule

These information collection requirements will not be published, tabulated, or manipulated.

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

No approval is requested.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.