U.S. Food and Drug Administration
Food and Cosmetic Export Certificate Applications Process

OMB Control Number 0910-0793

SUPPORTING STATEMENT **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

The Federal Food, Drug, and Cosmetic Act (the FD&C Act) provides that the Food and Drug Administration (FDA, us or we) 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 FD&C 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 Certificates of Free Sale for food, food additives, seafood, dietary supplements, and cosmetics.

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.

CFSAN issues export certificates for food and cosmetic products. Interested persons may request a certificate via an electronic system, a component of the FDA Unified Registration and Listing System (FURLS), or by contacting CFSAN for assistance. To facilitate the application process, FDA has eliminated paper-based forms. For food products, FDA has 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 (FEI) number, or Data Universal Numbering System (DUNS) 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.

We therefore request approval for the information collection supporting FDA's Food and Cosmetic Export Certificate program and included in associated electronic Forms FDA 3613d, FDA 3613e, FDA 3613g, 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 is part of FURLS. 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

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). 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 3613k are available for comment online at https://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Exporting/default.htm.

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 by CFSAN. We are otherwise unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

FDA estimates 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

Regional Small Business Representatives and through the scientific and administrative staffs within the agency. We also 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 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), FDA published a 60-day notice requesting public comment in the Federal Register of January 2, 2018 (83 FR 133). FDA received two comments regarding the information collection.

Comments and Responses

<Comment 1 :> One comment noted that it was vital to properly document cosmetics that may be exported.

<Response 1: > FDA export certificates are voluntary for exporters of cosmetics, so the CAP does not include a record of all cosmetics that may be exported. However, FDA does maintain a record of all active FDA-issued cosmetic export certificates.

<Comment 2: > Another comment agreed with FDA's statements that some countries may require manufacturers of FDA-regulated products to provide certificates for products that they wish to export those countries, as countries often seek official assurance that products exported to their countries can be marketed in the United States, or meet specific U.S. requirements. FDA's export certificates or certificates of free sale generally indicate the particular product is marketed in the United States or eligible for export, and has no unresolved enforcement actions pending before or taken by the FDA. The comment noted that the request for official federal assurance is increasingly necessary for dietary supplement products, and most dietary supplement manufacturers currently use FDA's electronic export certificate/certificate of free sale CAP.

While the comment indicated agreement with the information collected for these certificates, it stated that there should always be the option to review and edit auto-populated fields, as the information could change. The comment also agreed that the proposed collection of information is necessary for the proper performance of FDA's functions and the information

will have practical utility. It also urged FDA to improve the performance and practical utility through a more complex and revised Export Certificate/Certificate of Free Sale process.

<Response 2: > FDA appreciates the support from these comments, and notes that we are continually working to improve the export certificate/certificate of free sale experience. We agree that some countries do require certification that products they import are safe, and our certificate process is one way to assure that the product could be marketed in the United States, meet specific U.S. requirements, or be intended solely for export to another country. FDA will take into consideration the comment's request to modify auto-populated fields and appreciates that the comment recognizes that the information collected for these certificates does have practical utility and is necessary for assuring
that exported products from the Unites States meet specific standards of safety.

<Comment 3: > Subsequent to publication of our 30 day notice (83 FR 22984) we received additional comment. The comment appeared to communicate some uncertainty regarding the scope of the information collection. Specifically that, "[*i]f the FDA certification program described in the Federal Register notice is limited to transitioning an existing certificate program from paper to electronic applications, USDEC has no concerns*," while conversely that, "[*i]f the intention of the FDA notice is to develop a new certification program for animal-derived products using form FDA 3613G, or other foods using form FDA 3613k, we urge that the scope of the FDA certification program be limited to certifying foods that are not already under existing FDA, USDA or other government certification programs*." To clarify, our decision to transition from paper-based forms to electronic submissions is intended to improve the efficiency of the program. As communicated in our notice, while we have expanded the electronic options for providing facility and product information through proposed Forms FDA 3613g and 3613l, we have not otherwise altered the information collection. If a respondent is unable to submit information electronically, CFSAN will provide assistance.

The comment also suggested that "*FDA consider the benefits to its mandate of 'ensuring that the nation's food supply is safe, sanitary, wholesome, and honestly labeled' that could be achieved by outsourcing additional export-related functions …*" and questioned whether other government agencies might be able to issue certificates more expediently and at a lower cost. Regarding the first suggestion, the agency always considers how best to allocate limited resources as appropriate and will continue to do so. Regarding the second suggestion, we take note that the commenter acknowledges, "[u]*nder the current structure in place with respect to FDA's role in export issues, we do understand that there may be a need for FDA to provide certificates for products that are not eligible for USDA's existing dairy certificates.* Accordingly, we will continue to respond to requests for export certificates promptly, consistent with section 801(e)(4) of the FD&C Act, and, in a manner similar to other FDA components, charge fees that are reflective of the costs.

Internal Agency Discussion Regarding Export Certificate Fees

In January, 2011, section 801(e)(4)(A) of the FD&C Act was amended by the FDA Food Safety and Modernization Act (FSMA) (Pub. L. 111-353) authorizing FDA to charge firms export certification fees for food and animal feed for export certificates issued pursuant to that section. Section 801(e)(4)(B) further authorizes FDA to charge firms up to $175 for export certificates issued pursuant to that section of the FD&C Act.

FDA has updated the export certificates for food as part of this information collection of information to account for the January, 2011 FSMA amendment authorizing export certification fees for food and animal feed. CFSAN does not currently charge a fee for export certificates for food products. Section 801(e)(4) of the FD&C Act provides that persons exporting certain FDA-regulated products may request FDA to certify that the products meet the requirements of sections 801(e) or other requirements of the FD&C Act. FDA is authorized to charge firms up to $175 for export certificates that certify the certificate meets the requirements of section 801(e), and FDA may implement this fee in the future for food products.

We so advised respondents in our 30-day notice, which published in the Federal Register of May 17, 2018 (83 FR 22984).

9. Explanation of Any Payment or Gift to Respondents

No payments or gifts are provided 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 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

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

Table 1. --Estimated Annual Reporting Burden[1]						
Type of Respondent	Form No.	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
Cosmetics	Form FDA 3613d	270	3	810	0.5	405
Food	Forms FDA 3613e, 3613g, 3613k	881	5	4,405	0.5	2,203
Total						2,608

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

Our estimate of the average burden per response in column 6 assumes that the use of the electronic system will substantially reduce the time to prepare an application for a certificate from 1.5 to 0.5 hours. Our estimate of the total annual responses in column 5 is based on our experience with certificate applications received in the past 3 fiscal years. We also note that some respondents send in requests as often as three or four times a month while others may submit only periodic requests.

We expect that all firms requesting export certificates in the next three years will choose to submit via the electronic system. 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 reduces the agency's previous estimates for the time to prepare each submission.

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 via the electronic system. 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 for this analysis. We base our estimates of the total annual responses on our experience with certificate applications received in the past 3 fiscal years.

If a firm is unable to submit their information via the electronic system, they may contact CFSAN to 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.

12b. Annualized Cost Burden Estimate

FDA estimates the annualized burden hour cost to respondents for this collection of information to be approximately $217,403 (rounded from $217,402.88). 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 2018, which is $41.68 per hour. To account for overhead, this cost is increased by 100 percent, which is $83.36 per hour. Thus, the annual wage cost for completion and submission of these requests and updates is approximately $217,403 (2,608 hours x $83.36 per hour).

Table 2 – Cost of Collection to Respondents			
Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Manufacturers/Processors seeking an export certificate	2,608	$83.36	$217,403

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

While we do not currently charge for export certificates classified as Certificates of Free Sale, section 801(e)(4)(B) of the FD&C Act authorizes a fee up to $175 for export certificates. Accordingly, upon implementation of this provision, we estimate an annual cost of $770,875, using the number of annual export certificates for food (4,405) multiplied by $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. FDA estimates 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

The information collection reflects both adjustment and revision. Specifically, the number of annual responses has increased by 1,921 responses (from 3,294 to 5,215 responses), while the number of annual burden hours has decreased by 2,334 hours (from 4,942 to 2,608 hours). We attribute this to the implementation of electronic forms and the elimination of paper-based forms, as discussed more fully under *Question 12*.

Also, for food products, we have expanded the electronic options for providing facility and product information through proposed Forms FDA 3613g and 3613l. Respondents can then identify facilities based on a food facility registration number, FDA Establishment Identification (FEI) number, or Data Universal Numbering System (DUNS) 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.

We have also consolidated two individual ICs for dietary supplements and food additives, respectively, into the more broad category of food.

Finally, we have revised this supporting statement to include our response to a comment that was received after submission to OMB. This can be found on page 4 under *Question 8* above.

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

FDA is 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.