

UNITED STATES FOOD & DRUG ADMINISTRATION

Establishing and Maintaining Lists of U.S. Establishments with Interest in Exporting Food Products

OMB Control No. 0910-0509

SUPPORTING STATEMENT **Part A – Justification:**

1. Circumstances Making the Collection of Information Necessary

This information collection supports agency export programs and associated guidance. The United States (U.S.) exports a large volume and variety of foods in international trade. Foreign governments often require official certification from the responsible authority of the country of origin about imported foods and establishments involved in their production, storage, or distribution. Some foreign governments establish additional requirements with which exporters are required to comply and ask for additional assurances from the responsible authority. Importing countries may require, and FDA may provide, official certification or assurances for food products in different forms, including certificates that accompany specific products or lists of establishments and products that comply with certain requirements.

To facilitate exports of food subject to importing country listing requirements, FDA has historically provided official certification in the form of country- and product-specific export lists that include establishments and their products when: (1) The establishment has expressed interest in exporting their products to these countries; (2) the establishment and the products are subject to FDA's jurisdiction; and (3) the establishment can demonstrate that it is in good regulatory standing for the products it intends to export, and the products are expected to comply with applicable FDA requirements. As we advised in the guidance document "*Establishing and Maintaining a List of U.S. Milk and Milk Product, Seafood, Infant Formula, and Formula for Young Children Manufacturers/Processors with Interest in Exporting to China*," FDA considers "good regulatory standing" as meaning that an establishment is in substantial compliance with applicable FDA requirements and is not the subject of a pending enforcement action (e.g., an injunction or seizure) or pending administrative action (e.g., a warning letter).

FDA has generally published guidance documents for these country and product-specific lists under the authority of section 701(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371(h)), which authorizes the Secretary of Health and Human Services (the Secretary) to develop guidance documents with public participation presenting the views of the Secretary on matters under the jurisdiction of FDA. The guidance documents generally explain what information establishments should submit to FDA to be considered for inclusion on the lists and what criteria FDA intends to use to determine eligibility for placement on the lists. The guidance documents also explain how FDA intends to update the lists and communicate any new information to the governments that requested the lists. Finally, the guidance documents note that the information is provided voluntarily by establishments with the understanding that it may be posted on FDA's external website and that it will be communicated to, and possibly further disseminated by, the government that requested the list; thus, FDA considers the information on the lists to be information that is not protected from disclosure under 5 U.S.C. 552(b)(4). The

guidance documents include “*Establishing and Maintaining a List of U.S. Dairy Product Manufacturers/Processors with Interest in Exporting to Chile*” and “*Establishing and Maintaining a List of U.S. Milk and Milk Product, Seafood, Infant Formula, and Formula for Young Children Manufacturers/Processors with Interest in Exporting to China*” available at <https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/guidance-documents-regulatory-information-topic-food-and-dietary-supplements>. Additional information about FDA’s Food Export Lists program is available at <https://www.fda.gov/food/exporting-food-products-united-states/food-export-lists>. FDA has also published guidance on export certification that contains useful information that applies to export lists: “*FDA Export Certification*” available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-export-certification>.

Foreign governments are increasingly relying on certification as a strategy for ensuring the safety of imported food products, and many countries have announced new requirements for lists of establishments and products certified to comply with certain food safety requirements. FDA is committed to facilitating compliance with new listing requirements for U.S. establishments that export FDA-regulated food products. We also understand that complying with multiple country- and product-specific listing requirements can be burdensome to U.S. establishments. For this reason, we plan to create a new list of establishments and products certified for export that would be offered to importing countries in lieu of country-specific lists.

Application for inclusion on all export lists will continue to be voluntary. However, some foreign governments may require inclusion on export lists as a precondition for market access or to satisfy other importing country registration or approval requirements. FDA uses the Export Listing Module (ELM), an electronic system (Form FDA 3972) to receive and process applications for inclusion on export lists for products regulated by the Center for Food Safety and Applied Nutrition (CFSAN). The ELM allows applicants to provide information about the products intended for export, the establishment that produces those products, evidence of the establishment’s compliance with applicable requirements for the products intended for export, and any additional data or information (such as third-party certifications) that foreign governments may require. We request that this information be updated every 2 years. Additional information and screenshots of the ELM are available at <https://www.fda.gov/food/exporting-food-products-united-states/food-export-lists>. If an establishment is unable to submit an application via the ELM, it may contact CFSAN and request assistance.

We therefore request extension of OMB approval of the information collection provisions pertaining to the CFSAN-regulated product export lists and associated guidance documents, as well as the ELM reporting module (Form FDA 3972), as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

We use the information submitted by establishments to determine eligibility for certification and inclusion on the export lists, which may be published on our website or the websites of foreign governments. The purpose of the lists is to help CFSAN-regulated industries meet the import requirements of foreign governments. This collection of information is intended to cover all of CFSAN's existing export lists, as well as any additional export lists established by the Center.

FDA notes section 801 of the FD&C Act (21 U.S.C. 381) also provides that FDA may assess a fee of up to \$175 if the agency issues export certification within 20 days of receipt of a complete request for such certification.

Description of Respondents: Respondents to this information collection include U.S. establishments subject to FDA/CFSAN jurisdiction that wish to be included on export lists. Respondents are from the private sector (for-profit businesses).

3. Use of Improved Information Technology and Burden Reduction

We continually seek ways to reduce the reporting burden. Our efforts include directing respondents to use the ELM for quicker submittals. If an establishment is unable to submit an application via the ELM, it may contact CFSAN and request assistance. We estimate that one-hundred percent (100%) of the respondents will use electronic means to submit information.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection. Agency regulations at 21 CFR part 1.101 provide for recordkeeping regarding the export of FDA-regulated products. Although voluntarily undertaken, the recordkeeping often depends upon respective requirements determined by the destination to where the product is exported.

5. Impact on Small Businesses or Other Small Entities

We estimate ten percent (10%) of respondents are small businesses. However, the collection gathers the minimum information that a business is required to submit to qualify to be placed on the list and we therefore believe it imposes no undue burden. In addition, we aid small businesses through our Regional Small Business Representatives and through the scientific and administrative staffs within the agency. Assistance is also 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 to be placed on the list are submitted only once. A business is requested to submit occasional updates if the previously submitted information changes. In

addition, we request that firms update their information biennially. If the information collection is not conducted, CFSAN-regulated products from firms not on this list could be delayed or prevented by foreign government authorities such as those of Chile, China, or the European Union from entering commerce in their respective countries.

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 25, 2022 (87 FR 3814), we published a 60-day notice requesting public comment on the proposed collection of information. One comment was received that generally supported export lists but offered ways to improve administration of the lists.

Comment: The comment strongly supported developing a consolidated list of U.S. dairy establishments eligible to export to any foreign market with functionality to allow establishments to select particular markets of interest. However, if FDA creates a consolidated list of all products, the comment suggested the ability to create dairy-specific subsets.

The comment also suggested merging all lists of eligible establishments that obtained U.S. Department of Agriculture's (USDA) Agricultural Marketing Service (AMS) issued sanitary certificates. Further, the comment suggests FDA collaborates with USDA sharing information with USDA dairy staff to facilitate other activities such as AMS issuance of sanitary certificates.

Lastly, the comment urged FDA to consider whether limitations on the disclosure of information would be merited in order to preserve commercially sensitive information. Although a foreign government may publish the information, the comment argued that it should not preclude FDA from denying requests directly.

Response: FDA agrees that developing a streamlined approach for addressing importing country requests for exports lists may be helpful for establishments that export FDA-regulated food products. We also understand that complying with multiple country- and product-specific listing requirements can be burdensome to U.S. establishments. For this reason, we plan to create a new list of establishments and products certified for export that would be offered to importing countries in lieu of country-specific lists. We will consider the additional functionality suggested by the comments such as the ability to sort or filter by product categories (e.g., dairy products), identify markets of interest (i.e., export destinations), and options for leveraging existing export lists.

FDA already works closely with USDA to facilitate the export of milk and milk products and we will continue to collaborate with USDA to share information to support AMS issuance of sanitary certificates for these products.

Whenever possible, FDA works with other government agencies to negotiate with importing countries to limit the information required for certification provided in the form of export lists to the minimum data elements needed to provide assurances about the safety of the exported food products. We will

continue these efforts and appreciate industry's assistance in identifying requests for commercial sensitive information. Voluntary application for inclusion on all export lists gathers the minimum information that an establishment is required to submit to qualify to be placed on the list. The requirements are preconditions for market access or to satisfy other importing country registration or approval requirements. Since application for inclusion on export lists is voluntary and this information may be further disseminated by a foreign government, FDA advises that the information is not protected from disclosure under 5 U.S.C. § 552(b)(4).

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

No assurance of confidentiality is provided. As noted in the referenced guidance documents, FDA considers the information contained in the lists, which is given voluntarily with the understanding that it will be posted on FDA's website and communicated to foreign governments, to be information that is not protected from disclosure under 5 U.S.C. § 552(b)(4).

Privacy Act

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected. The ICR collects personally identifiable information (PII) in the context of the subject individuals' professional capacity and the FDA-related work performed for their employer (e.g., point of contact at a regulated entity). The PII submitted via Form FDA 3972 is name, email address, telephone number, fax number, username, and password. We have determined that although PII is collected, the collection is not subject to the Privacy Act of 1974, and the particular notice and other requirements of the Privacy Act do not apply. Specifically, FDA does not use name or any other personal identifier to retrieve records from the information collected. Through appropriate form design, FDA has limited submission fields and minimized the PII collected to protect the privacy of the individuals.

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

11. Justification for Sensitive Questions

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

12. Estimates of Annualized Burden Hours and Costs

12a. *Annualized Hour Burden Estimate*

Table 1.--Estimated Annual Reporting Burden¹

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (hours)	Total Hours
New request	167	5	835	1	835
New request + third-party certification	85	2	170	22	3,740
Biennial update	132	4	528	0.5 (30 minutes)	264
Biennial update + third-party certification	58	2	116	22	2,552
Occasional updates	60	2	120	0.5 (30 minutes)	60
TOTAL			1,769		7,451

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

We base our estimate on the number of establishments that have submitted new written requests, biennial updates, and occasional updates. The estimate of the number of burden hours that it will take an establishment to gather the information needed to be placed on one of the lists or update its information is based on our experience with this program. We believe that the information to be submitted will be readily available to the establishments.

12b. *Annualized Cost Burden Estimate*

We estimate the annualized burden hour cost to respondents for this collection of information to be approximately \$684,151. We estimate that the new written requests, biennial updates, and occasional updates 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 2022, which is \$45.91 per hour. To account for overhead, this cost is increased by 100 percent, which is \$91.82 per hour. Thus, the annual wage cost for completion and submission of these requests and updates is approximately \$684,151 (7,451 hours x \$91.82 per hour).

Table 2.--Estimated Annual Burden Cost

Activity	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Processing of new requests, biennial updates, and occasional updates	7,451	\$91.82	\$684,151

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

While we do not currently assess fees for certification provided in the form of export lists, section 801(e)(4)(B) of the FD&C Act authorizes a fee up to \$175 for export certification. Accordingly, upon implementation of this provision, we estimate an annual cost of \$309,575, using the number of annual responses (1,769) multiplied by \$175.

14. Annualized Cost to the Federal Government

We estimate that, on average, the annualized cost to the Federal government for the review and evaluation of requests and updates submitted by respondents is approximately \$21,578. We base our estimate on the hourly rate of one full-time employee at the GS-12/Step 3 level, in the Washington-Baltimore Locality Pay Area for the year 2022, which is \$45.91 per hour. To account for overhead, this cost is increased by 100 percent, which is \$91.82 per hour. The employee spends an estimated 235 hours reviewing and evaluating the submissions. Thus, we estimate that the annual cost to the Federal Government would be approximately \$21,578 (235 hours x \$91.82/hour).

15. Explanation for Program Changes or Adjustments

We have adjusted our burden estimate downward since our last request for OMB approval. The number of respondents has declined dramatically since we transitioned to using the ELM, which also allows us to collect more precise data. These changes resulted in an overall decrease to the information collection by 3,421 responses and 14,837 hours annually.

16. Plans for Tabulation and Publication and Project Time Schedule

We currently publish the lists on our website and share the information with Chile, China, and the European Union, which may post some or all of the information on their websites.

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

Consistent with established practice, FDA will publish a *Federal Register* notice announcing OMB approval of the information collection associated with the guidance documents and will display in that notice both the OMB control number and its current expiration date. In addition, the OMB control number will be displayed on the guidance documents' cover page and include a link to <https://www.reginfo.gov/public/do/PRAMain> to identify the current expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.