

Establishing and Maintaining Lists of U.S. Milk Product Manufacturers/Processors with Interest in Exporting

OMB Control Number 0910-0509
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JUSTIFICATION MEMORANDUM FOR 83-C CHANGE REQUEST

June 6, 2016

Request

The Food and Drug Administration (FDA) is submitting this nonmaterial/non-substantive change request (83-C) for changes to an OMB approved information collection under OMB No. 0910-0509, “Establishing and Maintaining Lists of U.S. Milk Product Manufacturers/processors with Interest in Exporting.” We are requesting this change to allow the U.S. milk product firms to use an electronic system, in addition to the current paper-based system, to voluntarily submit milk product information to FDA so the information may be included on an established list of U.S. milk product firms who wish to export their products. The information to be submitted via the electronic system is the same as the currently approved paper-based system.

Background

The United States exports a large volume and variety of foods in international trade. For certain food products, foreign governments may require assurances from the responsible authority of the country of origin of an imported food that the producer of the food is in compliance with applicable country of origin regulatory requirements. With regard to U.S. milk products, FDA is the competent U.S. food safety authority to provide this information to foreign governments. This ICR supports an agency program by which respondents may voluntarily request to be included on an established list of U.S. milk product firms who wish to export their products. As currently approved, this collection accepts the submission of paper-based documentation to FDA’s Center for Food Safety and Applied Nutrition (CFSAN) from U.S. milk firms wishing to be added to the export list, and lack of inclusion on the list may result in these firms’ products being detained or refused entry into the foreign country’s port of entry. Processing of paper-based information is time-consuming due to its volume and non-standardized format. The use of an electronic system to receive information is expected to standardize information, eventually leading to reduced burden for respondents and faster processing and response times for FDA.

Consequences of Non-Approval

Without this approval, international trade would be negatively impacted if U.S. milk product firms are unable to be quickly included on the export list. In 2016, the United States completed the Trans-Pacific Partnership (TPP) Free Trade Agreement, which includes Chile and provides enhanced market access for U.S. products into TPP countries (<https://ustr.gov/tpp/>). The U.S. is also currently negotiating with the European Union (28 countries) in the TransAtlantic Trade and Investment Partnership (TTIP), where agriculture and food products are major sectors in the negotiations (<https://ustr.gov/ttip/>). We expect the TPP and TTIP will increase market access for U.S. FDA-regulated milk products and will result in an increased number of voluntary requests to be processed and an increased demand to be included on the

export list. Providing U.S. milk product firms an electronic system is necessary to allow FDA to meet this anticipated increased demand. Automation of the current paper-based information collection is expected to lead to increased U.S. milk product exports to Chile, China, the 28 European Union countries, and other foreign entities.

Public Comment

Upon approval of this request to revise this information collection, FDA plans to begin regular renewal procedures for this collection so the public will have adequate opportunity to comment on the new electronic system.

Burden

FDA bases its estimate of the number of respondents that have submitted new written requests, biennial updates, and occasional updates over the past 10 years through the existing paper-based process. The estimate of the number of burden hours it will take a respondent to gather the information needed to be placed on the list is based on FDA's experience with respondents submitting similar requests via a paper-based process. However, with the electronic system, the estimated number of hours needed for a respondent to complete or update their application electronically to the export list should decrease substantially.

With the current paper-only registration system, FDA estimated that it would take 90 minutes (1.5 hours) to submit a new request for inclusion on the export list, 60 minutes (1 hour) for the biennial, and 30 minutes (0.5 hour) to occasionally update information. With the electronic system, FDA estimates that it will take an average of 60 minutes (1 hour) to submit a new request for inclusion on the list, an average of 30 minutes (0.5 hour) for the biennial, and an average of 15 minutes (0.25 hour) to occasionally update information in this system. FDA believes that the option to submit via the electronic system will reduce the number of paper-based submissions and lower the amount of paper-based burden estimates. An electronic system is expected to enhance the ability of firms to more efficiently request inclusion on export lists. Because of the ratification of the TPP and the expected ratification of the TTIP international trade treaties, FDA expects a significant increase in the number of respondents for this collection of information, which can be more easily processed by an electronic system. FDA's expectations are for the percentage of respondents who respond to this collection electronically to rise to over 90 percent, but FDA will continue to allow paper submissions for those respondents who may not have access to FDA's electronic system.

As users become more comfortable with the electronic system, FDA expects that the overall burden will decrease because of increased efficiency and ease of use for this collection of information.