

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

**OMB Control Number 0910-0509**  
**Expiration Date: September 30, 2017**

## **JUSTIFICATION MEMORANDUM FOR 83-C CHANGE REQUEST**

**May 20, 2016**

### **Request**

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

### **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 producers who wish to export their products. As currently approved, respondents wishing to be added to the export list submit paper-based documentation to FDA. Lack of inclusion on the list may result in respondent’s products being detained or refused entry into the foreign country’s port of entry. The use of an electronic system to receive information is expected to standardize information, which will lead 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 producers are unable to quickly be included on the list to export their products. In 2016, the U.S. completed the TransPacific Partnership (TPP) Free Trade Agreement and provides enhanced market access for U.S. products into TPP countries. 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. 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 requests to be processed and an increased demand for inclusion on the export list. Providing U.S. milk product producers an electronic system is necessary to allow FDA to meet this anticipated increased demand. Automation of the current paper-based information collection system is expected to lead to increased U.S. milk product exports to Chile, China, the 28 European Union countries, and other foreign entities.