United States Food and Drug Administration
Establishing and Maintaining Lists of U.S. Milk Product Manufacturers/Processors with Interest in Exporting

OMB Control Number 0910-0509
Expiration Date: November 30, 2020

JUSTIFICATION MEMORANDUM FOR NON-SUBSTANTIVE CHANGE REQUEST

The Food and Drug Administration (FDA) is requesting a change to the information collection OMB control no. 0910-0509, "*Establishing and Maintaining Lists of U.S. Milk Product Manufacturers/processors with Interest in Exporting*." We are revising the Dairy Listing Module of our electronic reporting system (Form FDA 3972), to include data elements from other approved information collections: OMB control nos. 0910-0320 and 0910-0839 ("*Request for Information from U.S. Processors that Export to the European Community*" and "*Establishing and Maintaining Lists of U.S. Manufacturers/Processors with Interest in Exporting CFSAN-Regulated Products to China*," respectively). There are no changes to the information being collected, however, the latter collections utilize paper-based submissions where this change allows for electronic submission. Upon implementation of the electronic data elements, we intend to discontinue or otherwise modify the latter collections accordingly.

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. The electronic system approved under 0910-0509, entitled "the Dairy Listing Module" or DLM, collects only submissions for milk product firm lists. Allowing the system to collect submissions for firms covered under 0910-0320 and 0910-0839 will afford these firms the efficiencies of submitting information electronically. As currently approved, these collections accept the submission of paper-based documentation to FDA from U.S. firms wishing to be added to the respective export list. 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 will standardize information, eventually leading to reduced burden for respondents and faster processing and response times for FDA. 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.