DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date July 10, 2007

From Acting Chief, Paperwork Reduction and Records Management Branch, HFA-250

Subject Request for OMB Approval of "Rapid Response Survey for Milk Pasteurization Time and Temperature Data Collection" Reference OMB No: 0910-0500

To Chief, Human Resources and Housing Branch
Office of Information and Regulatory Affairs, OMB
Through: Reports Clearance Officer, HHS _____

Pursuant to the Terms of Clearance for information to be collected under the generic approval for Rapid Response Surveys (0910-0500, expires 11/30/2007), the Food and Drug Administration (FDA) is requesting that OMB conduct a 10-day review prior to data collection.

Justification:

Grade "A" milk processors must comply with their State's Grade "A" Milk Program, each of which is based on the United States Public Health Service (USPHS)/FDA Model Ordinance commonly known as the Pasteurized Milk Ordinance (see http://www.cfsan.fda.gov/~ear/pmo03toc.html). During quarterly inspections and validations, the State regulatory agency inspectors verify and document that the required minimum pasteurization time and temperatures are in compliance. FDA believes that most Grade "A" milk producers pasteurize at holding times and temperatures above the current minimum stated in the Pasteurized Milk Ordinance. However, FDA believes that there is a need to collect and assess the actual pasteurization holding time and temperature processes used. FDA requests OMB approval of the Rapid Response Survey titled, "Milk Pasteurization Time and Temperature Data Collection."

FDA will communicate the survey to the States through the instrument attached as Attachment A, which is comprised of a cover letter of instructions, a signature page and the survey instrument. Response to the survey is voluntary. The data will be collected by the State Grade "A" Milk Program Regulatory Inspectors during the routine quarterly inspections, the routine biannual pasteurization equipment validations or from records of the most recent pasteurization equipment validations. The information to be collected will include the actual pasteurization holding times, pasteurization

temperatures, pounds of fluid milk produced in specific timeframes, and plant identification for each fluid milk product (for final consumer packaging) for each milk plant. The information will be used to support FDA's public health mission of oversight of Grade "A" milk and milk products.

No other part of the agency is collecting milk pasteurization holding times, temperatures and production data. Without this timely data collection, FDA would not be able to collect and assess the actual pasteurization holding time and temperature processes used. It is important to the public health to obtain this information rapidly so FDA may assess the actual pasteurization holding time and temperature processes used.

The effect that pasteurization holding times and temperatures have on the inactivation of certain biological agents has been studied and characterized. These data were shared with a number of stakeholders including industry, states and other federal agencies. FDA and Congressional and White House representatives agree that a second data collection is necessary to determine the level of acceptance and implementation within industry.

This collection of information does not employ statistical methods. Data collection will be performed by State regulatory personnel working directly with milk processing facilities listed on FDA's Interstate Milk Shipper's (IMS) Listing, to collect the necessary data from as many of the IMS listed firms as possible. Currently, there are approximately 330 firms on the IMS Listing. The response rate on the first data collection conducted in 2005 was greater than 90 percent (90%). FDA estimates that this follow up collection will achieve, or exceed that response rate. In an effort to maximize the response rate, FDA/CFSAN's Food Defense Oversight Team will schedule conference calls with FDA Regional Milk Specialists and regulatory personnel from each State. FDA plans to conduct these conference calls in September 2007. Once OMB approval is given, FDA expects to begin the data collection on or about October 1, 2007.

All data will be collected with an assurance that the respondents' data submissions will remain confidential. The cover letter containing the instructions for the data collection and the signature page provides the assurance that, "data may only be viewed by FDA/CFSAN unless additional release privileges are requested from you." In addition, FDA has included the statement "not for public distribution" on the survey instrument. The information submitted is 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 by part 20 of the agency's regulations (21 CFR part 20). In addition, pursuant to the Critical Infrastructure Act of 2002 (CII Act) (6 U.S.C. 1, et seq.), the Protected Critical Infrastructure Information (PCII) Program of the Department of Homeland Security has determined that the information to be collected falls into the category that can be protected under that Act. FDA has completed the steps necessary to permit respondents to use the PCII Program for their submissions. If the respondents' submissions meet the qualifications for protection under the CII Act, the information will be protected from disclosure under FOIA.

FDA estimates that the total one time burden for this survey concerning milk pasteurization holding times, temperatures and production data will be 347 hours. Each of the 51 respondents (the 50 States plus Puerto Rico) will inspect an average of 13 plants. The data collection is estimated to take an average of 30 minutes per plant to complete. Thus, the hour burden associated with the data collection is estimated to be 331.5 hours (51 x 13 x .5 = 331.5 hours). In addition, each time information is forwarded a special signature page is used. Use of the signature page is estimated to take an average of 18 minutes per State. Thus, the hour burden associated with the signature page is estimated to be 15.3 hours (51 x .3 = 15.3 hours). The total one-time burden is 347 hours (331.5 + 15.3 = 346.8).

The agency has no plans for publication of information from this information collection. It is not FDA policy to pay or provide gifts to Rapid Response Survey respondents. The information collection involves no questions of a sensitive nature.

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