REGULATIONS UNDER THE FEDERAL IMPORT MILK ACT

OMB No. 0910-0212

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

Under the Federal Import Milk Act (FIMA) (21 U.S.C. 141–149), milk or cream may be imported into the United States only by the holder of a valid import milk permit (21 U.S.C. 141). Before such permit is issued: (1) All cows from which import milk or cream is produced must be physically examined and found healthy; (2) if the milk or cream is imported raw, all such cows must pass a tuberculin test; (3) the dairy farm and each plant in which the milk or cream is processed or handled must be inspected and found to meet certain sanitary requirements; (4) bacterial counts of the milk at the time of importation must not exceed specified limits; and (5) the temperature of the milk or cream at time of importation must not exceed 50° F (21 U.S.C. 142). FDA's regulations in part 1210 (21 CFR part 1210) implement the provisions of FIMA.

We request OMB approval of the following reporting and recordkeeping requirements contained in the following citations which are needed to assure the conformance with FIMA:

21 CFR 1210.11 - Reporting - Sanitary Inspection of Dairy Farms

Requires reports on the sanitary conditions of dairy farms producing milk and/or cream to be shipped to the U.S. to determine the sanitary conditions of the facility, equipment and processing/milking procedures.

21 CFR 1210.12 - Reporting - Physical Examination of Cows

Requires reports on physical examination of herds producing milk/cream to be shipped into the U.S. to aid in determining whether or not such herds are in a healthy condition.

21 CFR 1210.13 - Reporting - Tuberculin Tests of Cattle

Requires the reporting of tuberculin testing of all herds producing milk/cream to be shipped into the U.S. to aid in determining whether or not the herds are free of tuberculosis.

21 CFR 1210.14 - Reporting - Sanitary Inspection of Plants

Requires the reporting on the sanitary conditions of plants handling milk/cream to be shipped into the U.S. to determine the sanitary condition of such plants and of their facility, equipment and procedures.

21 CFR 1210.20 - Reporting - Application for Permit

Requires that an application for a permit to ship or transport milk or cream into the United States be made by the actual shipper on forms prescribed by the Secretary.

21 CFR 1210.22 - Disclosure - Form of Tag

Requires that each container of milk or cream shipped or transported into the United States be tagged with the permit number, type of product, and shipper's name and address. **(Language approval only.)**

21 CFR 1210.23 - Reporting - Permits Granted on Certificates

Permits a statement signed by an accredited official saying that copies of reports attached are based on the necessary inspections and examination performed under the supervision of that official.

21 CFR 1210.15 - Recordkeeping - Pasteurization, Equipment/Methods

Requires pasteurization of milk products at proper time and temperature using proper equipment. Requires recordkeeping to include pasteurization/processing charts properly recorded, initialed, numbered, and dated by authorized official and requires retention of the charts for two years.

We are also requesting OMB approval for the following forms which are used in collecting the information:

Form FDA 1815 -	Certificate/Transmittal for an Application (21 CFR 1210.23)
Form FDA 1993 -	Application for Permit to Ship or Transport Milk and /or Cream into the U.S. (21 CFR 1210.20)
Form FDA 1994 -	Report of Tuberculin Tests of Cattle (21 CFR 1210.13)
Form FDA 1995 -	Report of Physical Examination of Cows (21 CFR 1210.12)
Form FDA 1996 -	Dairy Farm Sanitary Report (21 CFR 1210.11)
Form FDA 1997 -	Score Card for Sanitary Inspection of Milk Plants (21 CFR 1210.14)

2. Purpose and Use of the Information Collection

The information is used by the Food and Drug Administration (FDA) to determine whether a permit to import milk and/or cream into the United States should be granted.

3. Use of Improved Information Technology and Burden Reduction

The major portion of the annual burden for this information collection is associated with Form FDA 1996, Dairy Farm Sanitary Report. This form is completed by a sanitarian on-site in rural areas. Under these circumstances, electronic data entry would most likely increase the burden rather than reduce the burden. However, industry is increasingly turning to the use of automatic production facilities. Any use of improved technology appropriate to satisfy FDA regulation is acceptable.

4. Efforts to Identify Duplication and Use of Similar Information

The information collected in fulfilling the statutory requirements for applying for a permit to import under FIMA is unique to the dairy herds which are the source of the milk and the plants in which the product is pasteurized. Because FDA is the only Federal agency with the authority to issue permits to import milk under FIMA, there is no likelihood of duplication by other Federal agencies.

5. Impact on Small Businesses or Other Small Entities

Small firms may also apply for a permit. The forms to be completed are simple, consisting of check boxes and short narrative responses. FDA will assist small firms with these requirements thus minimizing the burden.

6. Consequences of Collecting the Information Less Frequently

Under FIMA and our implementing regulations, submission of the required information and approval of the information after review by FDA is a condition precedent to the issuance of a permit. Therefore, if the information is not submitted, FDA cannot issue a permit to the importing party, and the milk and/or cream offered for import would be denied entry into the United States.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

None of the requirements are inconsistent with the guidelines in 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the Federal Register of August 25, 2008 (73 FR 50031). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

This information collection does not provide for payment or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

The information and data collected do not concern any method or processing which is entitled to protection as a trade secret nor is it concerned with matters that are commonly considered private or sensitive in nature. No assurance of confidentiality is given.

11. Justification for Sensitive Questions

This information collection does not involve any questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

FDA estimates the burden of this collection of information as follows:

21 CFR Section	Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
1210.11	FDA 1996/Sanitary inspection of dairy farms	8	200	1,600	1.5	2,400
1210.12	FDA 1995/Physical examination of cows	1	1	1	0.5	1
1210.13	FDA 1994/Tuberculin test	1	1	1	0.5	1
1210.14	FDA 1997/Sanitary inspections of plants	8	1	8	2.0	16.0
1210.20	FDA 1993/Application for permit	8	1	8	0.5	4.0
1210.23	FDA 1815/Permits granted on certificates	8	1	8	0.5	4.0
Total						2,426.0

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

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
1210.15	8	1	8	0.05	0.40

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

The estimated number of respondents and hours per response are based on FDA's experience with the import milk permit program and the average number of import milk permit holders over the past three years. FDA estimates that eight respondents will submit approximately 200 Form FDA 1996 reports annually, for a total of 1,600 responses. FDA estimates the reporting burden to be 1.5 hours per response, for a total burden of 2,400 hours.

The Secretary of Health and Human Services has the discretion to allow Form FDA 1815, a duly certified statement signed by an accredited official of a foreign government, to be submitted in lieu of Forms FDA 1994 and 1995. To date, Form FDA 1815 has been submitted in lieu of these forms. Because FDA has not received any Forms FDA 1994 and 1995 in the last three years, the agency estimates no more than one will be submitted annually. FDA estimates the reporting burden for each to be 0.5 hours per response for a total burden reporting burden of 0.5 hours each.

FDA estimates that eight respondents will submit one Form FDA 1997 report annually, for a total of eight responses. FDA estimates the reporting burden to be 2.0 hours per response, for a total burden of 16 hours. FDA estimates that eight respondents will submit one Form FDA 1993 report annually, for a total of eight responses. FDA estimates the reporting burden to be 0.5 hours per response, for a total burden of 4 hours. FDA estimates that eight respondents will submit one Form FDA 1815 report annually, for a total of eight responses. FDA estimates the reporting burden to be 0.5 hours per response, for a total burden of 4 hours.

With regard to records maintenance, FDA estimates that approximately eight recordkeepers will spend 0.05 hours annually maintaining the additional pasteurization records required by § 1210.15, for a total of 0.40 hours annually.

No burden has been estimated for the tagging requirement in § 1210.22 because the information on the tag is either supplied by FDA (permit number) or is disclosed to third parties as a usual and customary part of the shipper's normal business activities (type of product, shipper's name and address). Under 5 CFR 1320.3(c)(2), the public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public is not a collection of information. Under 5 CFR 1320.3(b)(2)), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities.

Estimated Annualized Cost for the Burden Hours

FDA estimates the annualized burden hour cost to a respondent for completion and submission of the required forms to be approximately $162,136. FDA estimates a respondent's average wage to be that of a Federal government employee at the GS-12/Step-1 rate for the Washington-Baltimore locality pay area for the year 2008, which makes the annual wage cost for completion and submission approximately $81,067.75 (2,425 hours x $33.43 per hour). To account for overhead, this cost is increased by 100 percent, making the total estimated burden hour cost to the respondent $162,135.50, rounded to $162,136.

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no capital costs or operating and maintenance costs associated with this collection. Many of the requirements of FDA's regulations are also regulatory requirements of the country in which the firm is located. By complying with their own country's regulations they also comply with many of ours, mitigating the cost burden. This particularly applies to tuberculosis testing and physical examination of herds, which are required by the government of New Zealand.

14. Annualized Cost to Federal Government

FDA estimates that the staffing burden to review and respond to the current level of applications for a permit to import milk and/or cream to this country is 160 hours at rate of $33.43/hour, the GS-12/Step-1 rate for the Washington-Baltimore locality pay area for the year 2008 (160 hours x $33.43 /hour = $5,349). Additional reviews at the Division, office/center and Associate Commissioner levels are estimated by program specialists to take an additional 16 hours at an aggregate rate of $39.75/hour, the GS-13/Step-1 rate for the Washington-Baltimore locality pay area for the year 2008 (16 hours x $39.75/hour = $636). Thus, the total cost is $5,985 ($5,349 + $636). To account for overhead, this cost is increased by 100 percent, making the total estimated annual cost to the Federal Government $11,970.

15. Explanation for Program Changes or Adjustments

The one burden hour increase is due to rounding in ICRAS. The increase of eight respondents is also due to ICRAS. The system calculated these eight recordkeepers in the total number of

respondents. These increases are system-related and do not reflect a revision in the agency estimate nor any program changes.

16. Plans for Tabulation and Publication and Project Time Schedule

The information obtained from this data collection will not be published.

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

No approval is requested.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

N/A