Regulations Under The Federal Import Milk Act

0910-0212

SUPPORTING STATEMENT

Terms of Clearance: None.

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 United States 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 United States 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 United States 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 United States 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 United States (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.

Description of Respondents: The likely respondents include foreign dairy farms and plants engaged in transporting milk and/or cream into the United States. Respondents are from the private sector (for-profit businesses).

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 regulations is acceptable. The agency estimates that about twenty-five percent (25%) of the reports will be submitted electronically in the next three years.

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

FDA estimates that fifty percent (50%) of respondents are small businesses. 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. FDA aids small businesses in complying with its requirements through the agency's Regional Small Business Representatives and through the scientific and administrative staffs within the agency. FDA has provided a Small Business Guide on the agency's website at http://www.fda.gov/oc/industry/.

6. Consequences of Collecting the Information Less Frequently

Data collection occurs occasionally. 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

There are no special circumstances associated with this collection of information.

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 April 20, 2012 (77 FR 23732). FDA received one letter in response to the notice. The letter contained one relevant comment while additional comments were outside the scope of the four collection of information topics on which the notice solicits comments and will not be discussed in this document.

(Comment) One comment suggested that "huge bureaucratic expenses created by the usa [sic] for 2 forms" for taxpayers.

(Response) While FDA appreciates the comment, the commenter did not specify which two forms might create an undue expense for taxpayers. Each form relating to this information collection request is necessary for the proper performance of FDA's functions. FDA has examined each form related to this information collection request to assure its efficiency.

9. Explanation of Any Payment or Gift to Respondents

FDA does not provide any payments 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 that are of a personally sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

Description of Respondents: The likely respondents include foreign dairy farms and plants engaged in transporting milk and/or cream into the United States. Respondents are from the private sector (for-profit businesses).

12a. Annualized Hour Burden Estimate

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

Table 1 – Estimated Annual Reporting Burden[1]						
21 CFR Section	Form No.	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
1210.11	FDA 1996/Sanitary inspection of dairy farms	2	200	400	1.5	600
1210.12	FDA 1995/Physical examination of cows	1	1	1	0.5	0.5
1210.13	FDA 1994/Tuberculin test	1	1	1	0.5	0.5
1210.14	FDA 1997/Sanitary inspections of plants	2	1	2	2.0	4.0
1210.20	FDA 1993/Application for permit	2	1	2	0.5	1.0
1210.23	FDA 1815/Permits granted on certificates	2	1	2	0.5	1.0
Total						607.0

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

Table 2 – Estimated Annual Recordkeeping Burden[1]					
21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Response	Total Hours
1210.15	2	1	2	0.05	0.10

[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 two respondents will submit approximately 200 Form FDA 1996 reports annually, for a total of 400 responses. FDA estimates the reporting burden to be 1.5 hours per response, for a total burden of 600 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 two respondents will submit one Form FDA 1997 report annually, for a total of two responses. FDA estimates the reporting burden to be 2.0 hours per response, for a total burden of 4 hours. FDA estimates that two respondents will submit one Form FDA 1993 report annually, for a total of two responses. FDA estimates the reporting burden to be 0.5 hours per response, for a total burden of 1 hour. FDA estimates that two respondents will submit one Form FDA 1815 report annually, for a total of two responses. FDA estimates the reporting burden to be 0.5 hours per response, for a total burden of 1 hour.

With regard to records maintenance, FDA estimates that approximately two recordkeepers will spend 0.05 hours annually maintaining the additional pasteurization records required by § 1210.15, for a total of 0.10 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.

12b. Annualized Cost Burden Estimate

FDA estimates the annualized burden hour cost to a respondent for completion and submission of the required forms to be approximately $55,249. FDA estimates a respondent's average wage to be that of a Federal government employee at the GS-13/Step-3 rate for the Washington-Baltimore locality pay area for the year 2012, which makes the annual wage cost for completion and submission approximately $27,624.57 (607 hours x $45.51 per hour). To account for overhead, this cost is increased by 100 percent, making the total estimated burden hour cost to the respondent $55,249.14, rounded to $55,249.

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

There are no capital, start-up, operating, or 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 $45.51 per hour, the GS-13/Step-3 rate for the Washington-Baltimore locality pay area for the year 2012 (160 hours x $45.51 per hour = $7,281.60). 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 $45.51 per hour, the GS-13/Step-3 rate for the Washington-Baltimore locality pay area for the year 2012 (16 hours x $45.51 per hour = $728.16). Thus, the total cost is $8,009.76 ($7,281.60 + $728.16). To account for overhead, this cost is increased by 100 percent, making the total estimated annual cost to the Federal Government $16,019.52, rounded to $16,020.

15. Explanation for Program Changes or Adjustments

This is an extension request in which both the total annual number of responses and the total annual hour burden are being decreased. The total annual number of responses decreased from 1,634 to 410 responses (a decrease of 1,224 responses) and the total annual hour burden has decreased from

2,425.40 to 607.10 hours (a decrease of 1,818.30 hours). The decrease was due to the decrease in the number of firms importing milk and/or cream into the United States. Thus, we are characterizing the decreases as adjustments.

TABLE 3—Summary of Change in Responses and Hour Burden		
IC Number	Change in Responses	Change in Hour Burden
IC#1	-1,200	-1,800.0
IC#2	0	-0.5
IC#3	0	-0.5
IC#4	-6	-12.0
IC#5	-6	-3.0
IC#6	-6	-3.0
IC#7	-6	-0.3
Total Change	-1,224	-1,819.3

For IC#1, we estimate that the respondents have decreased from 8 to 2, causing the annual number of responses to decrease from 1,600 to 400 (a decrease of 1,200 responses) and the annual hour burden to decrease from 2,400 to 600 (a decrease of 1,800 hours). We are characterizing the decrease as an adjustment because it is based on the decrease in the number of reports received by FDA, caused by the decrease in the number of firms importing milk and/or cream into the United States.

For IC#2 and IC#3, the burden estimates for the subject ICR was inadvertently overreported in ICRAS/ROCIS in 2009. IC#2 and IC#3 for 2012 decrease the annual hour burden for each from 1 to 0.5 (a decrease of 0.5 hour for each). This error has been corrected in this ICR; the previously overreported response burden appears as IC#2 and IC#3 in ICRAS/ROCIS.

For IC#4, we estimate that the respondents have decreased from 8 to 2, causing the annual number of responses to decrease from 8 to 2 (a decrease of 6 responses) and the annual hour burden to decrease from 16 to 4 (a decrease of 12 hours). We also are characterizing this decrease as an adjustment because it is based on the decrease in the number of reports received by FDA.

For IC#5, we estimate that the respondents have decreased from 8 to 2, causing the annual number of responses to decrease from 8 to 2 (a decrease of 6 responses) and the annual hour burden to decrease from 4 to 1 (a decrease of 3 hours). We also are characterizing this decrease as an adjustment because it is based on the decrease in the number of reports received by FDA.

For IC#6, we estimate that the respondents have decreased from 8 to 2, causing the annual number of responses to decrease from 8 to 2 (a decrease of 6 responses) and the annual hour burden to decrease from 4 to 1 (a decrease of 3 hours). We also are characterizing this decrease as an adjustment because it is based on the decrease in the number of reports received by FDA.

For IC#7, we estimate that the recordkeepers have decreased from 8 to 2, causing the annual number of records to decrease from 8 to 2 (a decrease of 6 records) and the annual hour burden to decrease from 0.40 to 0.10 (a decrease of 0.30 hour). We also are characterizing this decrease as an adjustment because it is based on the decrease in the number of records maintained by firms.

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

There are no exceptions to the certification.