United States Food and Drug Administration

Regulations Under the Federal Import Milk Act

OMB Control No. 0910-0212

SUPPORTING STATEMENT

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, us or we) regulations. 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 by FDA: (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).

Our regulations in part 1210 (21 CFR part 1210) implement the provisions of FIMA. Sections 1210.11 and 1210.14 require reports on the sanitary conditions of, respectively, dairy farms and plants producing milk and/or cream to be shipped to the United States. Section 1210.12 requires reports on the physical examination of herds, while § 1210.13 requires the reporting of tuberculin testing of the herds. In addition, the regulations in part 1210 require that dairy farmers and plants maintain pasteurization records (§ 1210.15) and that each container of milk or cream imported into the United States bear a tag with the product type, permit number, and shipper's name and address (§ 1210.22). Section 1210.20 requires that an application for a permit to ship or transport milk or cream into the United States be made by the actual shipper. Section 1210.23 allows permits to be granted based on certificates from accredited officials.

To assist respondents with the regulatory requirements we have developed the following forms:

- 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); and
- Form FDA 1997: *Score Card for Sanitary Inspection of Milk Plants* (21 CFR 1210.14).

We therefore request extension of OMB approval of the information collection provisions found in 21 CFR part 1210 and the associated forms as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

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

Description of Respondents: The 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 our regulations is acceptable. We estimate that about fifty percent (50%) of the reports will be submitted electronically in the next three years.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection. 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, duplication by other Federal agencies is unlikely.

5. Impact on Small Businesses or Other Small Entities

We estimate that fifty percent (50%) of respondents are small businesses; however, we estimate no undue burden on small entities. Small firms may also apply for a permit. The forms to be completed are simplified to the extent possible, consisting of check boxes and short narrative responses. We assist small firms with these requirements thus minimizing the burden. We aid small businesses in dealing with the requirements of the Federal Food, Drug, and Cosmetic Act through the agency's Regional Small Business Representatives and through the scientific and administrative staffs within the agency. Additional assistance is available for small businesses via the agency's website at https://www.fda.gov/industry/small-business-assistance.

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 our review is a condition precedent to the issuance of a permit. Therefore, if the information is not submitted, we 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), we published a 60-day notice for public comment in the *Federal Register* of March 21, 2024 (89 FR 20221). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

We do not provide any payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected.

This ICR collects personally identifiable information (PII). PII is collected in the context of the subject individuals' professional capacity and the FDA-related work they perform for their employer (e.g., point of contact at a regulated entity).

- The PII submitted via Form FDA 1815, "Certificate/Transmittal for an Application" is name.
- PII submitted via Form FDA 1993, "Application for Permit to Ship or Transport Milk and/or Cream into the United States" is name and business address.
- PII submitted via Form FDA 1994, "Report of Tuberculin Tests of Cattle" is name and business/work address.
- Likewise, PII submitted via Form FDA 1995, "Report of Physical Examination of Cows" is also name and business/work address.
- PII submitted via Form FDA 1996, "Dairy Farm Sanitation Report," as well Form FDA 1997, "Score Card for Sanitary Inspection of Milk Plants" is name and business/work address.

These forms also allow submission of potentially identifying work-related information including job title and credentials.

FDA further determined that although PII is collected, the collection is not subject to the Privacy Act of 1974, and the particular notice and other requirements of the Act do not apply. Specifically, FDA (including vendors or service providers acting on behalf of FDA) does not use name or any other personal identifier to retrieve records from the information collected. Through appropriate form design, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information. The data will be kept private to the extent allowed by law.

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 Cost

12a. Annualized Hour Burden Estimate

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1,2]						
21 CFR Section	Form FDA No./Description	Number of Respondents	Number of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
1210.11	1996/Sanitary inspection of dairy farms	1	200	200	1.5	300
1210.12	1995/Physical examination of cows	1	1	1	0.5 (30 min.)	1
1210.13	1994/Tuberculin test	1	1	1	0.5 (30 min.)	1
1210.14	1997/Sanitary inspections of plants	1	1	1	2.0	2
1210.20	1993/Application for permit	1	1	1	0.5 (30 min.)	1
1210.23	1815/Permits granted on certificates	1	1	1	0.5 (30 min.)	1
Total						306

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Numbers have been rounded.

Table 2.--Estimated Annual Recordkeeping Burden[1,2]					
21 CFR Section	Number of Recordkeepers	Number of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
1210.15	1	1	1	0.05 (3 min.)	1

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Numbers have been rounded.

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. In the past, Form FDA 1815 has been submitted in lieu of these forms. Because we have not received any Forms FDA 1994 or 1995 in the last 3 years, we assume no more than one will be submitted annually.

No burden has been estimated for the tagging requirement in § 1210.22 because the information on the tag is either supplied by us (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 subject to review by the Office of Management and Budget under the Paperwork Reduction Act. 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 business activities.

12b. Annualized Cost Burden Estimate

We estimate the annualized burden hour cost to a respondent for submission of the required forms and maintaining records to be approximately $41,647.62. We estimate a respondent's average wage to be that of a Federal government employee at the GS-13/Step-7 rate for the Washington-Baltimore locality pay area for the year 2024 ($67.83), which makes the annual wage cost for completion and submission approximately $20,823.81 (307 hours x $67.83 per hour). To account for overhead, this cost is increased by 100 percent, making the total estimated burden hour cost to the respondent $41,647.62.

Table 3.--Annual Cost Burden Estimate

Activity	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Completion and submission of required forms	306	$135.66 ($67.83 x 2)	$41,511.96
Recordkeeping	1	$135.66 ($67.83 x 2)	$135.66
Total			41,647.62

13. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or Capital Costs

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, respondents also comply with many of ours, mitigating cost burden. This applies particularly to tuberculosis testing and physical examination of herds, which are required by the government of New Zealand.

14. Annualized Cost to the Federal Government

We estimate staffing allocation 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 a rate of $67.83 per hour, the GS-13/Step-7 rate for the Washington-Baltimore locality pay area for the year 2024 (160 hours x $67.83 = $10,852.80). 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 $67.83 per hour (16 hours x $67.83 = $1,085.28). Thus, the cost is $11,938.08 ($10,852.80 + $1,085.28). To account for overhead, this cost is increased by 100 percent, making the total estimated annual cost to the Federal government $23,876.16.

15. Explanation for Program Changes or Adjustments

Based on a review of the information collection since our last OMB approval, we have retained our burden estimate. The estimated number of respondents and hours per response are based on our experience with the import milk permit program and the average number of import milk permit holders over the past 3 years. However, we have not received any responses in the last 3 years; therefore, we estimate that one or fewer to be submitted annually. Although we have not received any responses in the last 3 years, we believe these information collection provisions should be extended to provide for the potential future need for a milk importer.

16. Plans for Tabulation and Publication and Project Time Schedule

The information collected will not be published or tabulated.

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

No approval is requested for FDA to not display the expiration date of OMB approval.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.