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 agency 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), as issued by the Food and Drug Administration. 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). Regulations at 21 CFR Part 1210 have been promulgated establishing these provisions.

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)
Form FDA 1997 -	Score Card for Sanitary Inspection of Milk Plants (21 CFR 1210.14)

We therefore request extension of OMB approval for the information collection provisions found in 21 CFR Subchapter L; Part 1210 – *Regulations Under Certain Other Acts Administered by the Food and Drug Administration – Regulations Under the Federal Import Milk Act* and the associated forms, as discussed in this supporting statement.

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 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 will assist small firms with these requirements thus minimizing the burden. We aid small businesses in complying with our requirements through our Regional Small Business Representatives and through our scientific and administrative staffs. We also provide a Small Business Guide on our 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 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), FDA published a 60 day notice for public comment in the Federal Register of April 2, 2018 (83 FR 13992). No comments were received. Please note, however, nominal calculation nuances as discussed in *Question 12*, below.

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

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

12a. Annualized Hour Burden Estimate

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

Table 1.--Estimated Annual Reporting Burden[1]

21 CFR Section	Form FDA No.	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	2	200	400	1.5	600
1210.12	1995/Physical examination of cows	1	1	1	0.5	0.5
1210.13	1994/Tuberculin test	1	1	1	0.5	0.5
1210.14	1997/Sanitary inspections of plants	2	1	2	2.0	4.0
1210.20	1993/Application for permit	2	1	2	0.5	1.0
1210.23	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	Number of Recordkeepers	Number of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	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.

In our Federal Register of April 2, 2018 (83 FR 13992), the reporting burden reflects 607.0 hours, as burden associated with sections 1210.12 and 1210.13 were not rounded up to 1 hour. FDA notes that these figures are rounded up as they appear at reginfo.gov and thus the reporting burden reflects 609 hours. Similarly, the recordkeeping burden in our notice is not rounded, thus at reginfo.gov the burden is reflected as one hour.

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 three years. We estimate 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 we have not received any Forms FDA 1994 and 1995 in the last three years, the agency estimates no more than one will be submitted annually. We estimate the reporting burden for each to be 0.5 hours per response for a total burden reporting burden (rounded) of 1 hour each.

We estimate that two respondents will submit one Form FDA 1997 report annually, for a total of two responses. We estimate the reporting burden to be 2.0 hours per response, for a total burden of 4 hours. We estimate that two respondents will submit one Form FDA 1993 report annually. We estimate the reporting burden to be 0.5 hours per response, for a total burden of 1 hour. We estimate that two respondents each will submit one Form FDA 1815 report annually. We estimate the reporting burden to be 0.5 hours per response, for a total burden of 1 hour.

With regard to records maintenance, we estimate that 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, rounded up to 1 hour.

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 completion and submission of the required forms to be approximately $60,364. 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 2018, which makes the annual wage cost for completion and submission approximately $30,182 (609 hours x $49.56 per hour). To account for overhead, this cost is increased by 100 percent, making the total estimated burden hour cost to the respondent $60,364.

Activity	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Completion and submission of required forms	609	$99.12 ($49.56 x 2)	$60,364

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/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 that the 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 rate of $49.56 per hour, the GS- 13/Step-3 rate for the Washington-Baltimore locality pay area for the year 2018 (160 hours x $49.56 per hour = $7,929.60). 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 $49.56 per hour, the GS-13/Step-3 rate for the Washington-Baltimore locality pay area for the year 2018 (16 hours x $49.56 per hour = $792.96). Thus, the total cost is $8,722.56 ($7,929.60 + $792.96). To account for overhead, this cost is increased by 100 percent, making the total estimated annual cost to the Federal Government $17,445.12, rounded to $17,445.

15. Explanation for Program Changes or Adjustments

We retain the currently approved burden for the information collection.

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 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.