SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 26, 2024, FDA published a notice announcing a request for comments entitled ''FDA Information Technology Strategy and Customer Experience Strategy; Request for Comments.''

Interested persons were originally given until July 31, 2024, to comment on the document. The Agency has elected to extend the comment period so that all interested parties are able to consider the request for input more thoroughly. FDA is extending the comment period for 30 days, until August 30, 2024. The Agency believes that this 30-day extension allows adequate time for interested persons to submit comments.

Dated: July 17, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–16089 Filed 7–22–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–0972]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Regulations Under the Federal Import Milk Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by August 22, 2024.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0212. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Regulations Under the Federal Import Milk Act (FIMA)—21 CFR Part 1210

OMB Control Number 0910–0212—Extension

This information collection supports FDA regulations. Under 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).

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

The information collected 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: 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).

In the **Federal Register** of March 21, 2024 (89 FR 20221), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1] [2]

21 CFR section	Form FDA number/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 minutes)	1
1210.13	1994/Tuberculin test	1	1	1	0.5 (30 minutes)	1

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1] [2]—Continued

21 CFR section	Form FDA number/ description	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
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 minutes)	1
1210.23	1815/Permits granted on certificates.	1	1	1	0.5 (30 minutes)	1
Total	.....	.....	.....	.....	.....	306

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1] [2]

21 CFR section/activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
1210.15/Pasteurization records	1	1	1	0.05 (3 minutes)	1

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 OMB under the PRA. 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.

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.

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

[2] Numbers have been rounded.

Dated: July 17, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–16101 Filed 7–22–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–2581]

Postapproval Manufacturing Changes to Biosimilar and Interchangeable Biosimilar Products: Questions and Answers; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Postapproval Manufacturing Changes to Biosimilar and Interchangeable Biosimilar Products: Questions and Answers.'' This draft guidance provides answers to commonly asked questions from applicants and other interested parties regarding postapproval manufacturing changes made to biosimilar and interchangeable biosimilar products licensed under the Public Health Service Act (PHS Act).

DATES: Submit either electronic or written comments on the draft guidance by September 23, 2024 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows: