

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N-0112]

DMB

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Certifier D. Hawkins

Agency Information Collection Activities; Proposed Collection; 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 an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on reporting and recordkeeping requirements in implementing the Federal Import Milk Act (FIMA).

DATES: Submit written or electronic comments on the collection of information by *[insert date 60 days after day of publication in the Federal Register]*.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm>. Submit written comments on the collection of information to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520) Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Regulations Under the Federal Import Milk Act (21 CFR Part 1210) (OMB Control No. 0910–0212)—Extension

FIMA (21 U.S.C. 141–149) provides that milk or cream may be imported into the United States only by the holder of a valid import milk permit. 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. The regulations in 21 CFR 1210.15 require that dairy farmers and plants maintain pasteurization records. The regulations in 21 CFR 1210.22 require 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.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

FDA Form No.	21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours*
FDA 1815/Permits granted on certificates	1210.23	8	1	8	0.5	4
FDA 1993/Application of permit	1210.20	8	1	8	0.5	4
FDA 1994/Tuberculin test	1210.13	1	1	1	1	1
FDA 1995/Physical examination of cows	1210.12	1	1	1	1	1
FDA 1996/Sanitary inspection of dairy farms	1210.11	8	200	1,600	1.5	2,400
FDA 1997/Sanitary inspections of plants	1210.14	8	1	8	2.0	16
Total						2,426

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
1210.15	8	1	8	.05	.4

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

These estimates are based on the number of current permit holders and the number of inquiries that FDA has received regarding requests for applications in the next 3 years.

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 and 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. 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.

Dated: 4/5/02
April 5, 2002.

Margaret M. Dotzel
Margaret M. Dotzel,
Associate Commissioner for Policy.

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Dawn T. Hawkins