

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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[Docket No. 99N-0296]

Agency Information Collection Activities; Submission for OMB 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 the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by (*insert date 30 days after date of publication in the Federal Register*).

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

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: In compliance with section 3507 of the PRA (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—21 CFR Part 1210 (OMB Control Number 0910-021)—Extension

Under the regulations (part 1210 (21 CFR part 1210)) implementing the Federal Import Milk Act (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. 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. In addition, the regulations 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.

In the **Federal Register** of April 30, 1999 (64 FR 23333), the agency requested comments on the proposed collections of information. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

Form	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	4	1	4	0.5	2.0
FDA 1993/Applicant of permit	1210.20	4	4	4	0.5	2.0
FDA 1994/Tuberculin test ²	1210.13					
FDA 1995/Physical examination of cows ²	1210.12					
FDA 1996/Sanitary inspection of dairy farms	1210.11	4	200 ³	800	1.5	1200.0
FDA 1997/Sanitary inspection of plants	1210.14	4	1	4	2.0	8.0
Total						1212.0

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

²No burden has been estimated for Forms FDA 1994 and 1995 because they are not currently being used.

³Due to a clerical error, the reporting burden hours for FDA 1996/Sanitary inspection of dairy farms that appeared in a notice issued in the FEDERAL REGISTER of April 30, 1999 (64 FR 23333) were incorrect. Table 1 of this document contains the correct estimates.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

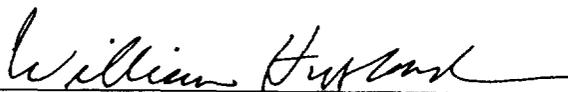
21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
1210.15	4	1	4	0.05	0.20

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

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). No burden has been estimated for Forms FDA 1994 and 1995 because they are not currently being used. 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.

Dated: July 19, 1999



William K. Hubbard
Senior Associate Commissioner for
Policy, Planning and Legislation

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