

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N-0178]

DDM

DATE	10-6-05
Collection Date	10-7-05
BY	N. Hawkins

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

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**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:** Fax written comments on the collection of information by *[insert date 30 days after date of publication in the Federal Register]*.

**ADDRESSES:** OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

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

**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.

Under the regulations implementing 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. 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 in part 1210 (21 CFR 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).

In the **Federal Register** of May 31, 2005 (70 FR 30951), FDA published a 60-day notice requesting public comment on the information collection provisions.

FDA received one letter in response, which contained several comments and suggestions. These suggestions and FDA's responses follow.

The comment stated that the collection of information in forms FDA 1815, FDA 1993, FDA 1994, FDA 1995, FDA 1996, and FDA 1997 is necessary and that most of these forms provide practical information. However, the comment requested a number of changes to the forms. First, the comment suggested that

certification of tuberculosis-free status in Form FDA 1815 and Form FDA 1994 should be done in a manner consistent with the U.S. Department of Agriculture's Animal Plant Health and Inspection Service (APHIS) guidelines entitled "Bovine Tuberculosis Eradication Uniform Methods and Rules" (APHIS 91-45-011). Another comment suggested that that Form FDA 1815 and Form FDA 1995 include a requirement that the submitter certify that the dairy cows are free from brucellosis and that the certification of brucellosis-free status should be done in a manner consistent with the APHIS guidelines published in the document entitled "Brucellosis Eradication: Uniform Methods and Rules" (APHIS 91-45-013).

FDA agrees that, where possible, Federal agencies should act in a consistent manner. However, FDA declines to make the suggested changes to its forms because such changes are not necessary. The two referenced documents are published by APHIS as part of its national animal disease eradication efforts undertaken by the National Center for Animal Health Programs under the statutory authority provided by the Animal Health Protection Act (7 U.S.C. 8301-8320). These are domestic programs in the United States which are designed to address the general health status of U.S. domestic cattle. Under the statutory authority provided by FIMA, FDA regulates all foreign-produced milk and cream imported into the United States. FIMA requires certification of the general health of the animal, which certification is obtained by FDA on Form FDA 1995. Although the two statutory authorities may differ, the practices presented in the APHIS documents already are being followed by FDA. FDA considers the status of the brucellosis and tuberculosis control programs in the country offering milk

for importation into the United States and bases its acceptance decision on that status.

Another comment stated that Form FDA 1996 and Form FDA 1997 do not provide practical information and should be made consistent with Form FDA 2359a, which, the comment states, is “utilized to ensure milk sanitation standards are met at the farm level.”

FDA disagrees that Form FDA 1996, “Dairy Farm Sanitation Report,” and Form FDA 1997, “Score Card for Sanitary Inspection of Milk Plants,” do not provide practical information. The information collected on these two forms is used by the agency in determining whether the imported milk or cream offered for import meet FIMA’s requirements for sanitary inspections of dairy farms and plants (21 U.S.C. 142). FDA also disagrees that the two forms should be made consistent with Form FDA 2359a because that form is used domestically for inspection of facilities producing Grade “A” milk products. FDA does not use it for inspections of facilities producing manufacturing-grade milk domestically. Thus, it would be inappropriate for FDA to use it for inspection of foreign facilities manufacturing non-Grade “A” milk products.

The comment also opposed electronic submission of the forms and suggested that several changes should be made to the requirements of FIMA and the agency’s related Compliance Policy Guide. These comments are outside the scope of the four collection of information topics on which the notice solicits comments and, thus, will not be addressed here.

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

TABLE 1.— ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

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	4.0

TABLE 1.— ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>—Continued

Form No	21 CFR Section	No of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
FDA 1993/Application of permit	1210.20	8	1	8	0.5	4.0
FDA 1994/Tuberculin test	1210.13	1	1	1	0.5	0.5
FDA 1995/Physical examination of cows	1210.12	1	1	1	0.5	0.5
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	16.0
Totals						2,425.0

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

TABLE 2.— ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

21 CFR Section	No. of Recordkeepers	Annual Frequency per Record	Total Annual Records	Hours per Recordkeeper	Total Hours
1210.15	8	1	8	.05	0.40

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

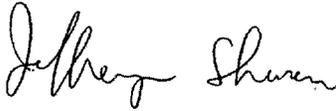
These estimates are based on the number of current permit holders and the number of inquiries that FDA has received regarding requests for applications in the past 3 years. No burden has been estimated for the tagging requirement in § 1210.22 because the information on the tag is either supplied by FDA (permit number) or is disclosed to third parties as a usual and customary part of the shipper's normal business activities (type of product, 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. Low burden has been estimated for Forms FDA 1994 and 1995 because they are not used often. 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.

**OCT 03 2005**

Dated: \_\_\_\_\_

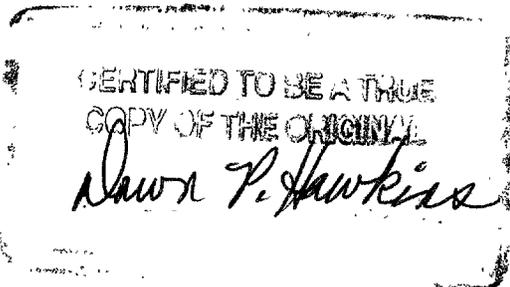
October 3, 2005.



Jeffrey Shuren,  
Assistant Commissioner for Policy.

[FR Doc. 05-????? Filed ??-??-05; 8:45 am]

**BILLING CODE 4160-01-S**



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*Dawn P. Hawkins*