

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DMS

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Certifier G. Presley

[Docket Nos. 02N-0102 and 02N-0112]

**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; correction.

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. This document also corrects some inadvertent typographical errors that published in the **Federal Register** of June 28, 2002 (67 FR 43633).

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: Stuart Shapiro, 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 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) Part 1210 (21 CFR Part 1210) (OMB Control Number 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 § 1210.15 require that dairy farmers and plants maintain pasteurization records. The regulations in § 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 for 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 inspection of plants	1210.14	8	1	8	2	16
Totals						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 Recordkeepers	Total Annual Records	Hours per Recordkeeper	Total Hours
1210.15	8	1	8	0.5	.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.

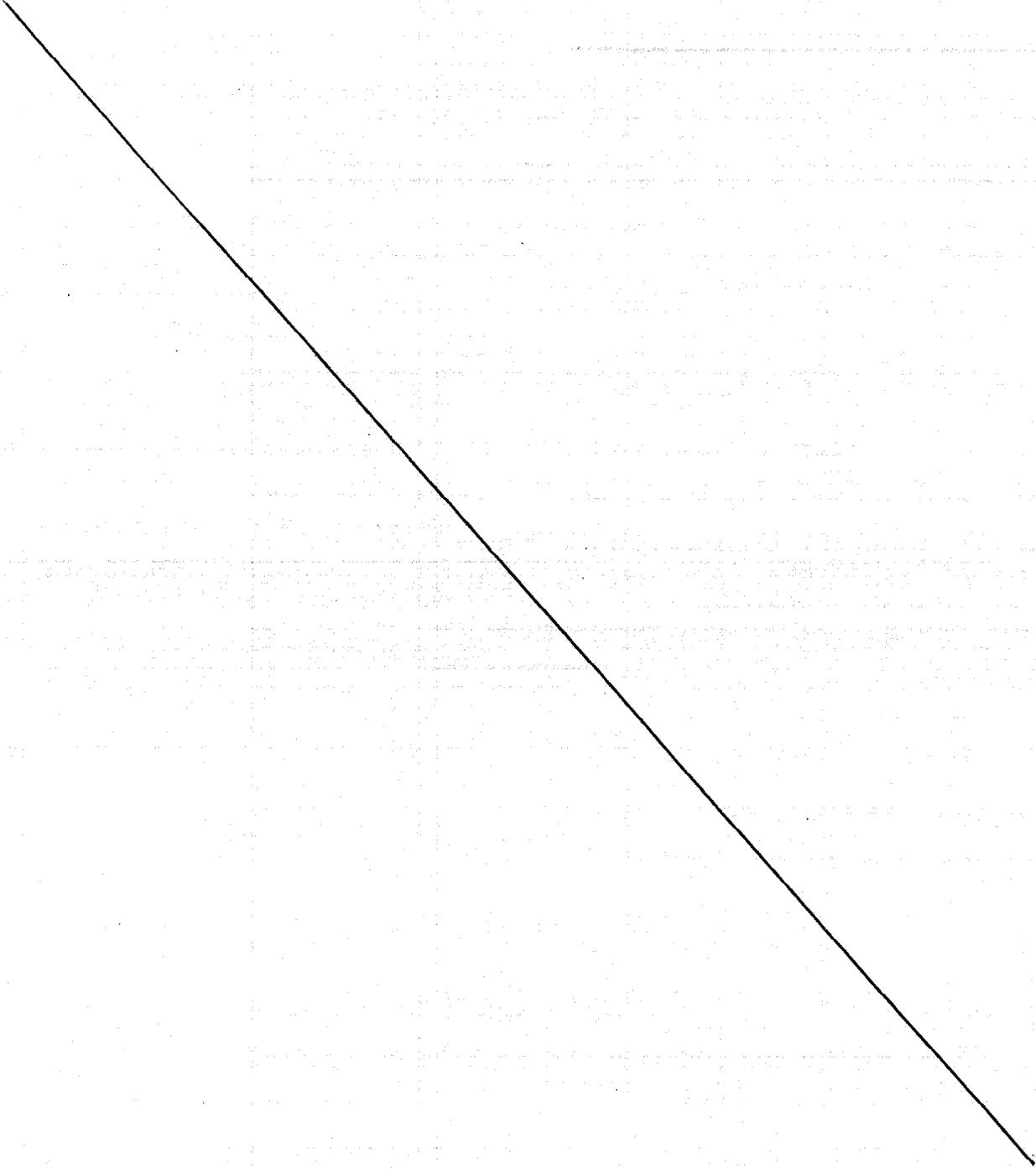
No burden has been estimated for the tagging requirement in § 1210.22 because the information on the tag is either supplied by FDA (permit number) or is disclosed to third parties as a usual and customary part of the shipper's normal business activities (type of product and shipper's name and address). 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.

In FR Doc. 02–16343, appearing on page 43633 in the **Federal Register** of Friday, June 28, 2002, for Docket No. 02N–0102 the following corrections are made.

1. On page 43633, in the third column, the title “Agency Information Collection Activities; Submission for OMB Review; Comment Request; Medical Devices; Notification of a Health Claim or Nutrient Content Claim Based on

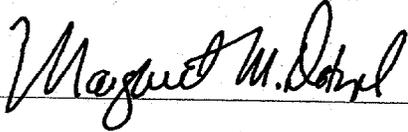
an Authoritative Statement of a Scientific Body” is corrected to read “Agency Information Collection Activities; Comment Request; Notification of a Health Claim Based on an Authoritative Statement of a Scientific Body”.

2. On page 43634, in the first and second columns, the title “Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based



on an Authoritative Statement of a Scientific Body” is corrected to read
“Guidance for Industry: Notification of a Health Claim Based on an
Authoritative Statement of a Scientific Body.”.

Dated: 7-10-02
July 10, 2002.



Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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