

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

21 CFR Section	Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Total ..	.....	.....	.....	.....	.....	607

<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	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
1210.15 .....	2	1	2	0.05	0.10

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

The estimated number of respondents and hours per response are based on FDA's experience with the import milk permit program and the average number of import milk permit holders over the past 3 years. FDA estimates that 2 respondents will submit approximately 200 Form FDA 1996 reports annually, for a total of 600 responses. FDA estimates the reporting burden to be 1.5 hours per response, for a total burden of 607 hours.

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. Because FDA has not received any Forms FDA 1994 and 1995 in the last 3 years, the Agency estimates no more than one will be submitted annually. FDA estimates the reporting burden for each to be 0.5 hours per response for a total burden reporting burden of 0.5 hours each.

FDA estimates that two respondents will submit one Form FDA 1997 report annually, for a total of two responses. FDA estimates the reporting burden to be 2.0 hours per response, for a total burden of 4 hours. FDA estimates that two respondents will submit one Form FDA 1993 report annually, for a total of two responses. FDA estimates the reporting burden to be 0.5 hours per response, for a total burden of 1 hour. FDA estimates that two respondents will submit one Form FDA 1815 report annually, for a total of two responses. FDA estimates the reporting burden to be 0.5 hours per response, for a total burden of 1 hour.

With regard to records maintenance, FDA estimates that approximately two recordkeepers will spend 0.05 hours annually maintaining the additional

pasteurization records required by § 1210.15, for a total of 0.10 hours annually.

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 business activities.

Dated: June 22, 2012.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0755]

#### Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Implementation of the Food and Drug Administration Amendments Act of 2007

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Implementation of the Food and Drug Administration Amendments Act of 2007" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Daniel Gittleston, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5156, [Daniel.Gittleston@fda.hhs.gov](mailto:Daniel.Gittleston@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** On January 18, 2012, the Agency submitted a proposed collection of information entitled "Implementation of the Food and Drug Administration Amendments Act of 2007" to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0625. The approval expires on June 30, 2015. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: June 18, 2012.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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