Based on the submissions received, FDA identified three other tiers of FCNs that represent escalating levels of burden required to collect information (denoted as Categories C, D, and E in the third, fourth, and fifth rows of table 1 of this document). FDA estimated the median number of hours necessary for collecting information for each type of notification within each of the three tiers based on input from industry sources. FDA estimates that five respondents will submit two Category C submissions annually, for a total of 10 responses. FDA estimates the reporting burden to be 120 hours per response, for a total burden of 1,200 hours. FDA estimates that 33 respondents will submit 2 Category D submissions annually, for a total of 66 responses. FDA estimates the reporting burden to be 150 hours per response, for a total burden of 9,900 hours. FDA estimates that 30 respondents will submit 1 Category E submission annually, for a total of 30 responses.

FDA estimates the reporting burden to be 150 hours per response, for a total burden of 4,500 hours.

FDA estimates that two respondents will submit one indirect food additive petition under § 171.1, for a total of two responses. FDA estimates the reporting burden to be 10,995 hours per response, for a total burden of 21,990 hours.

FDA estimates that 10 respondents will utilize the recommendations in the guidance document entitled ''Use of Recycled Plastics in Food Packaging: Chemistry Considerations,'' to develop the additional information for one such submission annually, for a total of 10 responses. FDA estimates the reporting burden to be 25 hours per response, for a total burden of 250 hours.

Dated: November 25, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–28694 Filed 12–3–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0607]

Agency Information Collection Activities; Proposed Collection; Comment Request; Reclassification Petitions for Medical Devices

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 reclassification petitions for medical devices.

DATES: Submit written or electronic comments on the collection of information by February 2, 2009.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (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: Denver Presley, Jr.,Office Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3793.

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, including each proposed extension of an existing 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 these topics: (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.

Reclassification Petitions for Medical Devices—21 CFR Section 860.123 (OMB Control Number 0910–0138)—Extension

FDA has responsibility under sections 513(e) and (f), 514(b), 515(b), and 520(l) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(e) and (f), 360d(b), 360e(b), and 360j(l)) and part 860 (21 CFR part 860), subpart C, to collect data and information contained in reclassification petitions. The reclassification provisions of the act allow any person to petition for reclassification of a device from any one of the three classes, i.e., I, II, and III, to another class. The reclassification content regulation (§ 860.123) requires the submission of sufficient, valid scientific evidence demonstrating that the proposed reclassification will provide a reasonable assurance of safety and effectiveness of the device type for its indications for use. Thus, the reclassification provisions of the act serve primarily as a vehicle for manufacturers to seek reclassification from a higher to a lower class, thereby reducing the regulatory requirements applicable to a particular device type or to seek reclassification from a lower to a higher class, thereby increasing the regulatory requirements. The reclassification petitions requesting classification from class III to class II or class I, if approved, provides an alternative route to the market in lieu of premarket approval for class III devices or from class I or II to one or the other class, which may increase requirements.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
860.123	6	1	6	500	3,000

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

Based on the last 3 years, and actual reclassification petitions received, FDA anticipates that six petitions will be submitted each year. The time required to prepare and submit a reclassification petition, including the time needed to assemble supporting data, averages 500 hours per petition. This average is based upon estimates by FDA administrative and technical staff that are familiar with the requirements for submission of a reclassification petition, have consulted and advised manufacturers on these requirements, and have reviewed the documentation submitted.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Dated: November 25, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–28695 Filed 12–3–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0453]

Agency Information Collection Activities; Submission for Office of Management and Budget 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 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 January 5, 2009.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0212. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3794.

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—(OMB Control Number 0910–0212—Extension)

Under 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 (21 U.S.C. 141). 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 (21 U.S.C. 142).

FDA's regulations in part 1210 (21 CFR part 1210) implement the provisions of FIMA. Sections 1210.11 and 1210.14 require reports on the sanitary conditions of, respectively, dairy farms and plants producing milk and/or cream to be shipped to the United States. Section 1210.12 requires reports on the physical examination of herds, while § 1210.13 requires the reporting of tuberculin testing of the herds. In addition, the regulations in 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). Section 1210.20 requires that an application for a permit to ship or transport milk or cream into the United States be made by the actual shipper. Section 1210.23 allows permits to be granted based on certificates from accredited officials.

In the **Federal Register** of August 25, 2008 (73 FR 50031), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
1210.11	FDA 1996/Sanitary inspection of dairy farms	8	200	1,600	1.5	2,400
1210.12	FDA 1995/Physical examination of cows	1	1	1	0.5	0.5