Medical Devices Inspection by Accredited Persons Program Under MDUFMA (OMB Control Number 0910–0510)—Extension

The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107–250) was signed into law on October 26, 2002. Section 201 of MDUFMA adds a new paragraph ''g'' to section 704 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 374), directing FDA to accredit third parties (accredited persons or APs) to conduct inspections of eligible manufacturers of class II or class III devices. This is a voluntary program; eligible manufacturers have the option of being inspected by an AP or by FDA. The new law requires FDA, within 180 days from the date of MDUFMA was signed into law, to publish in the **Federal Register** criteria to accredit or deny accreditation to persons who request to perform these inspections (section 704(g)(2) of the act).

In the **Federal Register** of April 28, 2003 (68 FR 22388), FDA published a notice announcing that a proposed collection of information has been submitted to OMB for emergency processing under the PRA. Interested persons were given until May 28, 2003, to comment on the notice. Elsewhere in the April 28, 2003, issue of the **Federal Register** (68 FR 22400), FDA published a document announcing the criteria it will use to accredit persons to inspect eligible device manufacturers and the availability of a guidance entitled ''Implementation of the Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria: Guidance for Industry, FDA Staff, and Third Parties.''

FDA received a total of three comments from a trade association, an industry association, and a consultant. These comments were not specifically related to the information collection for the submission of applications to become an accredited person. The comments addressed the implementation of the third party inspection program. FDA will take these comments into consideration in further developing its third party inspection program.

Description of Respondents: Businesses or other for profit organizations.

In the **Federal Register** of July 10, 2003 (68 FR 41160), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Item	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Request for Accreditation (First Year)	25	1	25	80	2,000
Request for Accreditation (Second Year)	10	1	10	15	150
Request for Accreditation (Third Year)	5	1	5	80	400
Total					2,550

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

FDA based these estimates on conversations with industry, trade association representatives, and internal FDA estimates. Our expectation is that 25 bodies will apply and meet the minimum standard for being accredited. Under MDUFMA, we can only accredit 15 persons during the first year. We (FDA) expect that the lowest ranking, 10 (the ones not accredited), will reapply the following year and will submit an updated application. Five new applicants may apply the third year. Once an organization is accredited, it will not be required to reapply.

Dated: September 30, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–25444 Filed 10–7–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0295]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Establishing and Maintaining a List of U.S. Dairy Product Manufacturers/Processors With Interest in Exporting to Chile

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.

DATES: Submit written comments on the collection of information by November 7, 2003.

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 written 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.

Establishing and Maintaining a List of U.S. Dairy Product Manufacturers/ Processors With Interest in Exporting to Chile (OMB Control Number 0910–0509)—Extension

Section 701(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(h)) authorizes the Secretary of Health and Human Services (the Secretary) to develop guidance documents with public participation presenting the views of the Secretary on matters under the jurisdiction of FDA.

In the **Federal Register** of May 23, 2003 (68 FR 28237), FDA announced the availability of a guidance entitled ''Establishing and Maintaining a List of U.S. Dairy Product Manufacturers/Processors With Interest in Exporting to Chile.'' The guidance provided voluntary recommendations on the process for firms that wish to export dairy products to Chile. FDA is taking this action in response to discussions with Chile that have been adjunct to the negotiations of the United States-Chile Free Trade Agreement. As a result of those discussions, Chile recognized FDA as the competent food safety authority in the United States to identify U.S. dairy product manufacturers and processors eligible to export to Chile and concluded that it will not conduct individual inspections of U.S. firms identified by FDA as eligible to export to Chile.

Therefore, FDA intends to establish and maintain a list identifying U.S. manufacturers/processors that have expressed interest to FDA in exporting dairy products to Chile, are subject to FDA jurisdiction, and are not the subject of a pending judicial enforcement action (i.e. an injunction or seizure) or an unresolved warning letter. Under this guidance, FDA recommends that U.S. firms that want to be placed on the list send information to FDA (i.e., name and address of the firm and the manufacturing plant; name, telephone number, and e-mail address (if available) of contact person; list of products presently shipped and expected to be shipped in the next 3 years; identities of agencies that inspect the plant and date of last inspection plant number and copy of last inspection notice; and, if other than an FDA inspection, copy of last inspection report. The term ''dairy products,'' for purposes of this list, is not intended to cover the raw agricultural commodity raw milk. The guidance can be found at *http://www.cfsan.fda.gov/guidance.html*.

The burden estimates presented in the following paragraphs considered the number of U.S. firms that FDA believes produce dairy products and that will be interested in exporting to Chile, which is estimated to total 75. After the first year, FDA believes that approximately eight new firms each year will be interested in exporting dairy products to Chile, and thus, being placed on the list. In the **Federal Register** of April 10, 2003 (68 FR 17655), FDA published an emergency notice requesting public comment on the information collection provisions that had been submitted to OMB for emergency processing under the PRA. Four comments were received from trade associations and private industry.

Those comments were answered in the 60-day notice.

In the **Federal Register** of July 10, 2003 (68 FR 41157), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Type of Survey	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Mail questionnaire	1,000	1	1,000	3	3,000
Phone Survey	1,000	1	1,000	.5	500
Internet or Cable Survey	3,000	1	3,000	1	3,000
Total					6,500

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

The estimate of the number of firms is based on the actual number of U.S. firms that applied to be placed on the list as a result of the **Federal Register** of May 23, 2003 (68 FR 28237), publication of the availability of a guidance entitled ''Establishing and Maintaining a List of U.S. Dairy Product Manufacturers/Processors With Interest in Exporting to Chile.'' The estimate of the number of hours that it will take a firm to gather the information needed to be placed on the list is based on FDA's experience with firms submitting similar requests. FDA believes that the information to be submitted will be readily available to the firms. We (FDA) estimate that for the first year a firm will require 1.5 hours to read the **Federal Register**, gather the information needed, and to prepare a communication to FDA that contains the information and requests that the firm be placed on the list. We estimate the recurring burden in subsequent years to be 1.5 hours for a new firm to be placed on the list and 0.5 hours for reporting changes to FDA for firms already on the list.

Dated: September 30, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Anesthetic and Life Support Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Anesthetic and Life Support Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on November 18, 2003, from 8 a.m. to 5 p.m. and on November 19, 2003, from 8 a.m. to 12 noon.

Location: Holiday Inn, The Ballrooms, 2 Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Johanna M. Clifford, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, or e-mail: *cliffordj@cder.fda.gov*, or FDA Advisory Committee Information Line: 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12529. Please call the Information Line for up-to-date information on this meeting.

Agenda: On November 18, 2003, the committee will discuss the assessment and management of risk related to QTc prolongation by Droperidol (Inapsine) Akorn, Inc., indicated for nausea and vomiting in surgical and diagnostic