TABLE 5.—COLLECTION OF INFORMATION REQUIRED BY CURRENT REGULATIONS AND STANDARDS—Continued

21 CFR Section	Description of Collection of Information Activity	21 CFR Section (unless otherwise stated)
3.2.5, 3.4, and 3.4.1	Herd health maintenance and surveillance to be documented, available, and in accordance with documented procedures; record standard veterinary care	211.100 and 211.122
3.2.6	Animal facility SOPs	PHS Policy[1]
3.3.3	Validate assay methods	211.160(a)
3.6.1	Procurement and processing of xenografts using documented aseptic conditions	211.100 and 211.122
3.6.2	Develop, implement, and enforce SOPs for procurement and screening processes	211.84(d) and 211.122(c)
3.6.4	Communicate to FDA animal necropsy findings pertinent to health of recipient	312.32(c)
3.7.1	PHS specimens to be linked to health records; provide to FDA justification for types of tissues, cells, and plasma, and quantities of plasma and leukocytes collected	312.23(a)(6)
4.1.1	Surveillance of xenotransplant recipient; sponsor ensures documentation of surveillance program life-long (justify >2 yrs.); investigator case histories (2 yrs. after investigation is discontinued)	312.23(a)(6)(iii)(f) and (g), and 312.62(b) and (c)
4.1.2	Sponsor to justify amount and type of reserve samples	211.122
4.1.2.2	System for prompt retrieval of PHS specimens and linkage to medical records (recipient and source animal)	312.57(a)
4.1.2.3	Notify FDA of a clinical episode potentially representing a xenogeneic infection	312.32
4.2.2.1	Document collaborations (transfer of obligation)	312.52
4.2.3.1	Develop educational materials (sponsor provides investigators with information needed to conduct investigation properly)	312.50
4.3	Sponsor to keep records of receipt, shipment, and disposition of investigative drug; investigator to keep records of case histories	312.57 and 312.62(b)

[1]The ''Public Health Service Policy on Humane Care and Use of Laboratory Animals'' (*http://www.grants.nih.gov/grants/olaw/references/phspol.htm*). (FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the *Federal Register*.)

[2]AAALAC International Rules of Accreditation (*http://www.aaalac.org*). (FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the *Federal Register*.)

[3]The NRC's ''Guide for the Care and Use of Laboratory Animals'' (1996).

Dated: July 2, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–17407 Filed 7–9–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0295]

Agency Information Collection Activities; Proposed Collection; 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 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 the procedures being implemented by FDA to assist U.S. dairy product manufacturers and processors that wish to export dairy products to Chile. In the **Federal Register** of May 21, 2003 (68 FR 27821), FDA published a notice announcing the Office of Management and Budget's (OMB) approval of this collection of information (OMB control number 0910–0509). Since this was an emergency approval that expires on

October 31, 2003, FDA is following the normal PRA clearance procedures by issuing this notice.

DATES: Submit written or electronic comments on the collection of information by September 8, 2003.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.fda.gov/dockets/ecomments*. Submit written comments 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: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from 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: (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.

Guidance for Industry and FDA: Establishing and Maintaining a List of U.S. Dairy Product Manufacturers/Processors With Interest in Exporting to Chile

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.

Two comments expressed concern that there may be a significant delay between the time a firm submits a request to FDA to be listed and the time it is actually placed on the list for export to Chile. FDA believes that it has addressed this situation in development of its guidance. The agency developed procedures for establishing and maintaining the list to minimize the time required for placement of an eligible firm within a reasonable and predictable time after making a request to FDA to be listed.

One comment expressed concern that it is unnecessary for FDA to request, for firms already on other recognized Federal Government lists, the identity of the agencies that inspect the plant and the date of last inspection; plant number and copy of the last inspection notice; and, if other than an FDA inspection, a copy of the last inspection. FDA believes that it is necessary to verify the status of all firms making application to the agency to be included on the list. This process will be greatly facilitated by the information that is being requested. By placing a firm on the list, FDA will be attesting that the firm is under the regulatory jurisdiction of FDA and is not the subject of a pending FDA judicial enforcement action or an unresolved warning letter. The lists identified by the comments, ''The Interstate Milk Shippers List for Grade 'A' Dairy Plants'' and ''The List of Dairy Plants Surveyed and Approved for USDA Grading Service,'' are product specific and may not include the products the firms intend to export to Chile. This would preclude the use of these lists for some firms.

One comment noted that FDA should make use of existing lists and inspection programs when determining if a firm should be placed on the list. FDA believes that it is necessary, for each initial listing of a firm, for the agency to create a complete and unique file corresponding to each request for placement on the list. The documentation contained in this file

would include all relevant information necessary to demonstrate satisfaction of the minimum conditions for listing of a firm, including a copy of the most current inspection report, whether that inspection was conducted by FDA or by another regulatory entity, i.e., the U.S. Department of Agriculture (USDA) or a State regulatory agency. FDA believes that a copy of the inspection report, appended to the request for placement on the list, is necessary to meet minimum documentation requirements. A firm's presence on any other list would not be sufficient to document satisfaction of the listing criteria. FDA's request to receive information on the Federal or State agency that conducted the most current inspection and, if other than FDA, a copy of the most current inspection report, will facilitate the completion of the documentation file and the review process and will expedite the overall listing procedure.

One comment encouraged FDA to establish a system for adding plants to the list that is simple and rapid, with clear administrative rules and to consider allowing application to the list through the Internet. FDA will be using the Internet to post and maintain the list. FDA is not prepared to allow application to the list through the Internet at this time. Once the list is established and in use, FDA will consider whether it is feasible to use the Internet to receive applications.

One comment expressed concern that FDA, by establishing a list of U.S. dairy product manufacturers/processors that wish to export dairy products to Chile, would do the following actions: (1) Duplicate existing procedures already in place at USDA and State Departments of Agriculture for obtaining export ''documents'' necessary for market access of U.S. dairy products into Chile; (2) cause manufacturers to have to obtain such documents from more than one Federal or State agency; and (3) otherwise complicate the procedures whereby U.S. dairy manufacturers could export their products to Chile. These comments also suggested that, in the future, FDA should defer to the USDA on ''negotiations'' pertaining to export of U.S. dairy products to other countries.

The comments indicate that some clarification of the roles and responsibilities of U.S. Government agencies is necessary. While FDA participates in many cooperative activities with U.S. States and with USDA in the area of food safety, FDA is the principal Federal agency within the U.S. Government responsible for the human health aspects of dairy product safety. As such, FDA is the appropriate U.S. agency to participate in discussions with foreign governments on matters relevant to the public (human) health aspects of U.S. dairy products. As stated in the April 10, 2003, **Federal Register** document, Chilean authorities have recognized FDA as the competent food safety (public health) authority in the United States to identify U.S. dairy product manufacturers eligible to export to Chile. In this context, Chilean authorities will rely on FDA to list these firms and to notify Chile regularly of all U.S. dairy firms that have met the criteria to be listed. On the basis of a regularly updated list identifying firms that have applied to FDA to be listed, that are under FDA jurisdiction, and that are not the subject of a pending judicial FDA enforcement action or unresolved FDA warning letter, Chilean authorities will consider U.S. dairy products entering Chile to have satisfied public (human) health requirements. Contrary to the suggestion in the comment, no consignment-specific ''document'' issued by FDA must accompany any individual consignment of these dairy products.

USDA's Animal and Plant Health Inspection Service (APHIS) is responsible for dairy product safety with respect to animal health. Many countries, including Chile, mandate that each exported consignment of U.S. dairy products be accompanied by a certificate issued by APHIS attesting to satisfaction of certain animal health requirements. With regard to the present situation, Chilean authorities will still require the consignment-specific certificate demonstrating satisfaction of certain animal health provisions. The establishment of the proposed list of U.S. dairy product manufacturers and processors by FDA will not affect the requirement for the consignment-specific APHIS certificate.

Negotiations with Chile which led to the proposal for, and decision to move forward with, the list were conducted by a U.S. Government team comprised of, among others, both FDA and several USDA agencies, including APHIS and Agricultural Marketing Service.

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

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

No. of Respondents	Annual Frequency per Response	Total Annual Records	Hours per Response	Total Hours
75[2]	1	75	1.5	112.5
8[3]	1	8	1.5	12
8[4]	1	8	0.5	4
Total				129

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] First year burden.
[3] Recurring burden.
[4] Recurring burden in reporting changes, including time reviewing collection of information and corresponding to FDA.

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 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: July 2, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–17408 Filed 7–9–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0117]

Agency Information Collection Activities; Proposed Collection; Comment Request; Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002

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 the publication of the criteria FDA intends to use to accredit third parties to conduct inspections of eligible manufacturers of class II or class III medical devices.

DATES: Submit written or electronic comments on the collection of information by September 8, 2003.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.fda.gov/dockets/ecomments*. 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: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 26, 2003 (68 FR 38065), FDA published a notice announcing the Office of Management and Budget's (OMB) approval of this collection of information (OMB control number 0910–0510). Since this was an emergency approval that expires on September 30, 2003, FDA is following the normal PRA clearance procedures by issuing this notice. Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from 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: (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.

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 that 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.

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