

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