

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 BURDEN¹

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

¹There 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