

that is provided to the government of Chile and posted on FDA's Internet site, which identifies U.S. dairy product 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 a pending warning letter. The term "dairy products," for purposes of this list, is not intended to cover the raw agricultural commodity raw milk. Application for inclusion on the list is voluntary. However, Chile has advised that dairy products from firms not on this list could be delayed or prevented by Chilean authorities from entering commerce in Chile. The revised guidance explains what information

firms should submit to FDA in order to be considered for inclusion on the list and what criteria FDA intends to use to determine eligibility for placement on the list. The document also explains how FDA intends to update the list and how FDA intends to communicate any new information to Chile. Finally, the revised guidance notes that FDA considers the information on this list, which is provided voluntarily with the understanding that it will be posted on FDA's Internet site and communicated to, and possibly further disseminated by, Chile, to be information that is not protected from disclosure under 5 U.S.C. 552(b)(4). Under this guidance, FDA recommends that U.S. firms that want to be placed on the list send the following information to FDA: Name

and address of the firm and the manufacturing plant; name, telephone number, and e-mail address (if available) of the contact person; a list of products presently shipped and expected to be shipped in the next 3 years; identities of agencies that inspect the plant and the date of last inspection; plant number and copy of last inspection notice; and, if other than an FDA inspection, copy of last inspection report. FDA requests that this information be updated every 2 years.

In the **Federal Register** of July 31, 2006 (71 FR 43202), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
New Written Requests To Be Placed On The List	15	1	15	1.5	22.5
Biannual Update	55	1	55	1.0	55.0
Occasional Updates	25	1	25	0.5	12.5
Total					90

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimate of the number of firms that will submit new written requests to be placed on the list, biannual updates and occasional updates is based on the FDA's experience maintaining the list over the past 3 years. The estimate of the number of hours that it will take a firm to gather the information needed to be placed on the list or update its information 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.

To date, over 110 producers have sought to be included on the list. FDA estimates that, each year, approximately 15 new firms will apply to be added to the list. FDA estimates that a firm will require 1.5 hours to read the guidance, 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. Under the revised guidance, every 2 years each producer on the list must provide updated information in order to remain on the list. FDA estimates that each year approximately half of the firms on the list, 55 firms, will resubmit the information to remain on the list. FDA estimates that a firm already on the list will require 1.0 hours to biannually update and resubmit the information to FDA, including time reviewing the

information and corresponding with FDA. In addition, FDA expects that, each year, approximately 25 firms will need to submit an occasional update and each firm will require 0.5 hours to prepare a communication to FDA reporting the change.

Dated: November 30, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2006N-0426]

#### Withdrawal of Federal Register Notice

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; withdrawal.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the withdrawal of a 60-day notice that published in the **Federal Register** of October 31, 2006 (71 FR 63765). The document published in error.

**DATES:** December 7, 2006.

**FOR FURTHER INFORMATION CONTACT:** Denver Presley, Jr., Office of the Chief

Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1472.

**SUPPLEMENTARY INFORMATION:** FDA is withdrawing a 60-day notice entitled "Medical Device User Fee and Modernization Act Small Business Qualification Certification (Form FDA 3602)," which published in the **Federal Register** of October 31, 2006 (71 FR 63765), because it is a duplicate of an earlier 60-day notice. The earlier 60-day notice published in the **Federal Register** of August 29, 2006 (71 FR 51196). The October 31 notice was published in error.

Dated: November 30, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2) notice