Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Copies of the guidance document entitled ''General Principles for Evaluating the Safety of Compounds Used in Food-Producing Animals (#3)'' may be obtained on the Internet from the CVM home page at *http://www.fda.gov/cvm*.

Dated: June 13, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–12323 Filed 6–21–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0180]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or agency) is announcing the availability of a revised guidance document entitled ''Guidance for Industry and FDA: Establishing and Maintaining a List of U.S. Dairy Product Manufacturers/Processors With Interest in Exporting to Chile.'' The guidance explains that FDA has established a list that is provided to the government of Chile and posted on FDA's Internet site, which identifies U.S. dairy product manufacturers 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 (e.g., injunction or seizure) or a pending warning letter. 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 document describes the recommended process for U.S. manufacturers to follow to be included on the list and explains FDA's request, on Chile's behalf, that this information be updated every 2 years.

DATES: This revised guidance is final upon the date of publication. Submit written or electronic comments on the revised guidance document at any time.

ADDRESSES: Submit written requests for single copies of the revised guidance document to the Office of Plant and Dairy Foods and Beverages, Division of Dairy and Egg Safety (HFS–306), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Include a self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance document may be sent.

Submit written comments on the revised guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revised guidance document.

FOR FURTHER INFORMATION CONTACT: Esther Z. Lazar, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1485, or e-mail: *elazar@cfsan.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

As a direct result of discussions that have been adjunct to the United States-Chile Free Trade Agreement, Chile has recognized FDA as the competent U.S. food safety authority and has accepted the U.S. regulatory system for dairy inspections. Chile has concluded that it will not require individual inspections of U.S. firms by Chile as a prerequisite for trade, but will accept firms identified by FDA as eligible to export to Chile. Therefore, FDA has established a list, which is provided to the government of Chile and posted on FDA's Internet site, identifying U.S. dairy product manufacturers/processors that have expressed to FDA their interest 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.

II. Discussion

The revised guidance document states that FDA has established 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 a pending warning letter. Inclusion of U.S. dairy product manufacturers/processors on this list is voluntary. However, Chile has advised that dairy products from firms not on this list could be refused entry at the Chilean port of entry. 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).

This is a revision of the guidance that FDA issued in May 2003 (68 FR 28237, May 23, 2003). This revised guidance adds to the information that FDA intends to post on its Web site and share with Chile, and it explains the actions that FDA intends to take to update the list every 2 years.

FDA is issuing this revised guidance as a level 1 guidance consistent with FDA's good guidance practices regulation § 10.115 (21 CFR 10.115). Consistent with FDA's good guidance practices regulation, the agency will accept comment, but is implementing the revised guidance document immediately in accordance with § 10.115(g)(2), because the agency has determined that prior public participation is not feasible or appropriate. This revised guidance represents the agency's current thinking on how FDA intends to comply with Chile's request for a list of U.S. manufacturers or processors that are eligible to export dairy products to Chile. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

This revised final guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in this guidance was approved under OMB control number 0910–0509. The approval expires on December 31, 2006. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this revised guidance at any time. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The revised guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Persons with access to the Internet may obtain the revised guidance document at *http://www.cfsan.fda.gov/guidance.html*.

Dated: June 13, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–12234 Filed 6–21–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Heritable Disorders and Genetic Diseases in Newborns and Children; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

Name: Advisory Committee on Heritable Disorders and Genetic Diseases in Newborns and Children (ACHDGDNC).

Dates and Times: July 21, 2005, 9 a.m. to 5 p.m., and July 22, 2005, 9 a.m. to 3 p.m.

Place: Ronald Reagan Building and International Trade Center, Rotunda Room, 1300 Pennsylvania Avenue, NW., Washington, DC 20004.

Status: The meeting will be open to the public with attendance limited to space availability.

Purpose: The Advisory Committee provides advice and recommendations concerning the grants and projects authorized under the Heritable Disorders Program and technical information to develop policies and priorities for this program that will enhance the ability of the State and local health agencies to provide for newborn and child screening, counseling and health care services for newborns and children having or at risk for heritable disorders. Specifically, the Advisory Committee shall advise and guide the Secretary regarding the most appropriate application of universal newborn screening tests, technologies, policies, guidelines, and programs for effectively reducing morbidity and mortality in newborns and children having or at risk for heritable disorders.

Agenda: Presentations and discussions will include: an update on the American College of Medical Genetics report; the role of evidence and other factors in decisionmaking; the status of newborn screening in States; the newborn screening policy of the American College of Obstetrics and Gynecology; and reports from the Subcommittees on Education and Training, Treatment and Follow-up, and Laboratory Standards and Procedures.

Proposed agenda items are subject to change as priorities indicate.

Public Comments: Time will be provided each day for public comment. Written comments should be submitted no later than July 14, 2005. Individuals who wish to provide public comment or who plan to attend the meeting and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the ACHDGDNC Executive Secretary, Michele A. Lloyd-Puryear, M.D., Ph.D., Maternal and Child Health Bureau, Health Resources and Services Administration, Room 18A–19, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–1080.

For Further Information Contact: Anyone interested in obtaining a roster of members or other relevant information should write or contact Jill Shuger, Maternal and Child Health Bureau, Health Resources and Services Administration, Room 18A–19, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–1080. Information on the Advisory Committee is available at *http://mchb.hrsa.gov/programs/genetics/committee.*

Dated: June 16, 2005.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 05–12233 Filed 6–21–05; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institutes on Aging; Notice of Closed Meetings

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

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would institute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Aging Special Emphasis Panel HRS.

Date: June 29–30, 2005.

Time: 6:15 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, Bethesda, MD 20814.

Contact Person: Alfonso R. Latoni, PhD, Health Scientist Administrator, Scientific Review Office, National Institute on Aging, National Institutes of Health, 7201 Wisconsin Avenue, Room 2C212, Bethesda, MD 20892, 301–402–7707, *latonia@nia.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute on Aging Special Emphasis Panel; Alzheimer Trials.

Date: July 8, 2005.

Time: 2 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Gateway Building, 7201 Wisconsin Ave, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Ramesh Vemuri, PhD, Health Scientist Administrator, Scientific Review Office, National Institute on Aging, National Institutes of Health, Room 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301–402–7700, *rv23r@nih.gov.*

Name of Committee: National Institute on Aging Special Emphasis Panel; Long Term Care.

Care: July 10–11, 2005.

Time: 6 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Jon Rolf, PhD, Health Scientist Administrator, Scientific Review