

authority to the CDC. NIOSH implements this responsibility for CDC. The charter was issued on August 3, 2001, and renewed on August 3, 2003.

**Purpose:** This board is charged with (a) providing advice to the Secretary, HHS on the development of guidelines under Executive Order 13179; (b) providing advice to the Secretary, HHS on the scientific validity and quality of dose reconstruction efforts performed for this Program; and (c) upon request by the Secretary, HHS, advise the Secretary on whether there is a class of employees at any Department of Energy facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is reasonable likelihood that such radiation doses may have endangered the health of members of this class.

**Matters to be Discussed:** Agenda for this meeting will focus on comments by Members of Congress; Review of the Draft Minutes; Bethlehem Steel Technical Basis Document; Y-12 Site Profile; Y-12 SEC Petition; Board Discussion of Y-12 SEC Petition; Iowa Army Ammunition Plant (IAAP) SEC Petition; Board Discussion of IAAP SEC Petition; Mallinckrodt Site Profile; Mallinckrodt SEC Petition; Board Discussion of Mallinckrodt SEC Petition; Policy Issues related to SEC Petitions; SC&A Task III/Workbook Issues; Report on the review of the first 20 Dose Reconstructions; Report on the review of the second 18 Dose Reconstructions; SC&A Contract Issues; Board Discussion; Program Updates; and Science Issues. There will be an evening general public comment period scheduled for July 5, 2005 and one on the afternoon on July 7. Summaries of the petitions for designation of classes of employees at Mallinckrodt, IAAP, and the Y-12 Plant as members of the SEC and the NIOSH findings from evaluating the petitions that will be considered are as follows: Mallinckrodt Chemical Company, Destrehan Street Plant, St. Louis, Missouri, the entire uranium division, 1942-1957. The NIOSH SEC Petition Evaluation Report and Supplement for Mallinckrodt 1949-1957 finds sufficient scientific and technical basis to estimate radiation doses.

IAAP, Line 1, Burlington, Iowa, 1947-1974. The NIOSH SEC Petition Evaluation Report finds it is not feasible to estimate radiation doses potentially incurred by radiographers with sufficient accuracy from May 1948 to March 1949.

Y-12 Plant, Oak Ridge, Tennessee, Control Operators, January 1944 through December 1945. The NIOSH SEC Petition Evaluation Report finds it is not feasible to estimate radiation doses with sufficient accuracy for employees who worked in uranium enrichment operations or other radiological processes at the Y-12 facility from March 1943 through December 1947.

The agenda is subject to change as priorities dictate.

In the event an individual cannot attend, written comments may be submitted. Any written comments received will be provided at the meeting and should be submitted to the contact person below well in advance of the meeting.

**Contact Person for More Information:** Dr. Lewis V. Wade, Executive Secretary, NIOSH,

CDC, 4676 Columbia Parkway, Cincinnati, Ohio 45226, telephone (513) 533-6825, fax (513) 533-6826.

Due to programmatic issues that had to be resolved, the **Federal Register** notice is being published less than fifteen days before the date of the meeting.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: June 16, 2005.

**Alvin Hall,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. 05-12292 Filed 6-21-05; 8:45 am]

**BILLING CODE 4163-19-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2005D-0219]

#### Guidance for Industry: General Principles for Evaluating the Safety of Compounds Used in Food-Producing Animals; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a revised guidance for industry entitled "General Principles for Evaluating the Safety of Compounds Used in Food-Producing Animals (GFI #3)." This version of the guidance replaces the version that was made available in July 1994. This has been revised to remove outdated information on toxicological testing and to provide references to other available guidance on the topic. In addition, the document has been revised to address minor formatting issues.

**DATES:** Submit written or electronic comments on agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit written comments on the 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 guidance document.

#### FOR FURTHER INFORMATION CONTACT:

Mark M. Robinson, Center for Veterinary Medicine (HFV-150), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-5282, e-mail: [mrobinson@cvm.fda.gov](mailto:mrobinson@cvm.fda.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA published the guidance for industry entitled "General Principles for Evaluating the Safety of Compounds Used in Food-Producing Animals (GFI #3)" in July 1994. Since that time, FDA has published a number of guidance documents in its participation with International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) that provide recommendations on toxicological testing of compounds used in food-producing animals. This version of guidance #3 replaces the version that was made available in July 1994. The guidance has been updated to remove outdated information on toxicological testing and refers the reader to the relevant Center for Veterinary Medicine/VICH guidance documents. In addition, the document was revised to address minor formatting issues including correcting an error in the numbering of the guidance sections.

##### II. Significance of Guidance

This document is being revised as a level 2 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115.) The guidance represents the agency's current thinking on the subject matter. The document does not create or confer any rights for or on any person and will not operate to bind FDA or the public. Alternative methods may be used as long as they satisfy the requirements of the applicable statutes and regulations.

##### III. Comments

As with all of FDA's guidances, the public is encouraged to submit written or electronic comments pertinent to this guidance. FDA will periodically review the comments in the docket and, where appropriate, will amend the guidance. The agency will notify the public of any such amendments through a notice in the **Federal Register**.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document.

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](mailto: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.