

Dated: December 15, 2003.

**William K. Hubbard,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. 03-31385 Filed 12-18-03; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Advisory Committee on Special Studies Relating to the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants (Ranch Hand 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). The meeting will be open to the public.

*Name of Committee:* Advisory Committee on Special Studies Relating to the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants (Ranch Hand Advisory Committee).

*General Function of the Committee:* To advise the Secretary and the Assistant Secretary for Health concerning its oversight of the conduct of the Ranch Hand Study by the U.S. Air Force and provide scientific oversight of the Department of Veterans Affairs Army Chemical Corps Vietnam Veterans Health Study, and other studies in which the Secretary or the Assistant Secretary for Health believes involvement by the committee is desirable.

*Date and Time:* The meeting will be held on January 21, 2004, 8 a.m. to 3:30 p.m.

*Location:* Food and Drug Administration, 5630 Fishers Lane, rm. 1066, Rockville, MD 20857.

*Contact Person:* Leonard Schechtman, National Center for Toxicological Research (HFT-10), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-6696, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512560. Please call the Information Line for up-to-date information on this meeting.

*Agenda:* The U.S. Air Force will provide a program management update and present information on the following topics: Syndrome X; cancer and hepatitis in the comparison group

vs. years in Southeast Asia; prostate cancer; adipose tissue study results; and memory loss and end of study transition.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by January 9, 2004. Oral presentations from the public will be scheduled between approximately 1:30 p.m. to 2:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before January 6, 2004, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Leonard Schechtman at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: December 15, 2003.

**William K. Hubbard,**

*Associate Commissioner for Policy and Planning.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2002D-0525]

#### Guidance for Industry and FDA Staff; Premarket Notification Submissions for Chemical Indicators; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Premarket Notification [510(k)] Submissions for Chemical Indicators." The document provides guidance for industry and other interested parties regarding the submission of chemical

indicators such as process indicators, chemical integrators, and air removal indicators used in test packs.

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

**ADDRESSES:** Submit written requests for single copies on a 3.5" diskette of the guidance document entitled "Premarket Notification [510(k)] Submissions for Chemical Indicators" to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301-443-8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this 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>. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Chiu Lin, Center for Devices and Radiological Health (HFZ-480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8913, ext. 143.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

This guidance is for chemical indicators intended for use in health care facilities. Chemical indicators are Class II devices identified in 21 CFR 880.2800. The chemical indicators discussed in the guidance document include process indicators, chemical integrators, and air removal indicators used in test packs such as the Bowie Dick Test Pack.

In the **Federal Register** of January 27, 2003 (68 FR 3887), FDA invited interested persons to comment by April 28, 2003, on the draft guidance entitled "Chemical Indicators Premarket Notification [510(k)] Submissions; Draft Guidance for Industry and FDA." FDA received one comment. FDA considered the comment and revised the guidance document for clarity.

##### **II. Significance of Guidance**

This guidance is being issued consistent with FDA's good guidance practices (GGPs) regulation (21 CFR 10.115). The guidance represents the agency's current thinking on chemical

indicators used in health care facilities. 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 statute and regulations.

### III. Paperwork Reduction Act of 1995

This 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 (the PRA) (44 USC 3501–3520). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E, OMB control number 0910–0120). The labeling provisions addressed in the guidance have been approved by OMB under OMB control number 0910–0485.

### IV. Electronic Access

To receive a copy of “Premarket Notification [510(k)] Submissions for Chemical Indicators” by fax machine, call the Center for Devices and Radiological Health (CDRH) Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1420) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers’ addresses), small manufacturer’s assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at <http://www.fda.gov/cdrh>. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available on the Division of Dockets Management Internet site at <http://www.fda.gov/ohrms/dockets>.

### V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding the guidance at any time. Submit a single copy of electronic comments to <http://www.fda.gov/dockets/ecomments>, or submit two paper copies of any mailed comments, except that individuals may submit one 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.

Dated: December 4, 2003.

**Linda S. Kahan,**

*Deputy Director, Center for Devices and Radiological Health.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2003D–0562]

#### Compliance Policy Guide Sec.110.300—“Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002;” Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a compliance policy guide (CPG) Sec. 110.300 entitled “Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.” The CPG provides written guidance to FDA’s staff on enforcement of section 305 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) and the agency’s implementing regulation, which require, beginning on December 12, 2003, registration with FDA for all domestic and foreign facilities that manufacture/process, pack, or hold food for human or animal consumption in the United States.

**DATES:** This guidance is final upon the date of publication. However, you may submit written or electronic comments at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance to the

Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance may be sent.

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:

*Food for human consumption:* Judith Gushee, Division of Enforcement, Office of Compliance, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 301–436–2417.

*Food for animal consumption:* Isabel Pocurull, Division of Animal Feeds, Office of Surveillance and Compliance, Center for Veterinary Medicine, Food and Drug Administration, 301–827–0175.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of CPG Sec.110.300 entitled “Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.” This guidance outlines for FDA staff the agency’s policy on enforcement of section 305 of the Bioterrorism Act and its implementing regulation (68 FR 58894, October 10, 2003; to be codified at 21 CFR part 1, subpart H). The Bioterrorism Act and subpart H require that, beginning on December 12, 2003, all domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States be registered with FDA.

FDA is issuing this document as level 1 guidance consistent with FDA’s good guidance practices regulation § 10.115 (21 CFR 10.115). The CPG Sec. 110.300 is being implemented immediately without prior public comment, under § 10.115(g)(2), because the agency has determined that prior public participation is not feasible. As noted, under section 305 of the Bioterrorism Act, the requirement that food facilities be registered is effective December 12, 2003, making it urgent that the agency explain how it intends to enforce this requirement.