by fax machine, call the 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 (1222) 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 home page 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.*

IV. 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 (44 USC 3501–3520) (the PRA). 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 No. 0910–0120). The labeling provisions addressed in the guidance have been approved by OMB under the PRA under OMB control number 0910–0485.

V. Comments

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 to *http://www.fda.gov/dockets/ecomments* or two paper copies of any written 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.

Dated: October 17, 2003.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 03–27393 Filed 10–30–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0476]

Guidance for Industry on Product Recalls, Including Removals and Corrections; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document for industry entitled ''Product Recalls, Including Removals and Corrections.'' This document provides members of industry regulated by FDA with guidance for handling all aspects of product recalls, including removals and corrections. The guidance applies to the recalls of all FDA-regulated products.

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

ADDRESSES: Submit written requests for single copies of ''Product Recalls, Including Removals and Corrections'' to the Food and Drug Administration, Office of Enforcement, Division of Compliance Management and Operations (HFC–210), 1350 Piccard Dr., Rockville, MD 20850. Requests should be identified with the docket number found in brackets in the heading of this document. For documents without a docket number, include the title of the guidance document. Send one self-addressed adhesive label to assist that office in processing your requests. You may fax your request to 301–827–0342. 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.* Comments may be submitted at any time. *See* the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Willie R. Bryant, Jr., Senior Recall Officer, Division of Compliance Management and Operations (HFC–210), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–827–0391.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance document that provides the agency's recommendations to members of FDA-regulated industry for the handling of product recalls. This document sets forth the agency's existing practices in recommending procedures for addressing all aspects of product recalls, including removals and corrections. The cooperation of manufacturers and distributors in expediting recall activities is vital. The recalling firm's notification of the local FDA District Recall Coordinator and submission of recall information outlined in the guidance allows FDA the opportunity to review, comment, offer assistance, and monitor the recall process.

II. Significance of Guidance

This is a level 2 guidance issued consistent with FDA's good guidance practices regulation (§ 10.115 (21 CFR 10.115)). The agency is implementing this guidance document immediately in accordance with § 10.115(g)(4)(i)(B) and inviting public comment in accordance with § 10.115(g)(4)(i)(C). This guidance represents the agency's current thinking on product recalls, including removals and corrections. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons interested in obtaining an electronic copy of the guidance may do so using the Internet. ORA maintains an entry on the Internet for easy access to information, including recent publications, consumer information references, compliance and inspection references, and recall information (model recall letters and press releases) that may be downloaded to a personal computer with Internet access. The ORA home page may be accessed at *http://www.fda.gov/ora/.* A search capability for all ORA guidance documents is available at *http://www.fda.gov/cdrh/guidance.html.* Guidance documents are also available at *http://www.fda.gov/ohrms/dockets.*

IV. Paperwork Reduction Act

The information collection requirements in this guidance have been approved under 21 CFR part 7, Office of Management and Budget (OMB) control number 0910–0249, which expires on October 31, 2004.

V. Comments

Two copies of mailed comments are to be submitted, 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. For documents without a docket number, include the title of the guidance document. The guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

VI. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/ora* or *http://www.fda.gov/ohrms/dockets/default*.

Dated: October 22, 2003.

John R. Marzilli,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 03–27387 Filed 10–30–03; 8:45 am]

BILLING CODE 4160–01–S

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 is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 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 constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel Innovative Technologies for the Molecular Analysis of Cancer.

Date: November 12–13, 2003.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Gaithersburg Hilton, 620 Perry Parkway, Gaithersburg, MD 20877.

Contact Person: Sherwood Githens, PhD, Scientific Review Administrator, Special Review and Logistics Branch, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, Room 8068, Bethesda, MD 20892, (301) 435–1822.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: October 24, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–27399 Filed 10–30–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye 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 is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 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 constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Eye Institute Special Emphasis Panel; P30, R24, and K08 Review Meeting.

Date: December 3, 2003.

Time: 8:30 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Select Bethesda, 8120 Wisconsin Ave, Bethesda, MD 20814.

Contact Person: Samuel Rawlings, PhD, Chief, Scientific Review Branch, Division of Extramural Research, National Eye Institute, Bethesda, MD 20892, 301–451–2020.

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: October 24, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–27404 Filed 10–30–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; Notice of Closed Meeting

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 meeting.

The meeting will be closed to the public in accordance with the provisions set forth in section 552b(c)(4) and 552b(c)(6), Title 5 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 constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Deafness and Other Communications Disorders Special Emphasis Panel—Childhood Speech-Sound Acquisition.

Date: December 5, 2003.

Time: 1 p.m. to 3:30 p.m.

Agenda: To review an evaluate grant applications.

Place: National Institutes of Health, 6120 Executive Blvd., Rockville, MD 20852. (Telephone Conference Call).

Contact Person: Ali A. Azadegan, DVM, PhD, Scientific Review Administrator, Scientific Review Branch Division of Extramural Activities, NIDCD, NIH, EPS–400C, 6120 Exeutive blvd, MSC 7180, Bethesda, MD 20892–7180, (301) 496–8683, *azadegan@nih.gov.*

Catalogue of Federal Domestic Assistance Program Nos. 93.173, Biological Research Related to Deafness and Communicative Disorders, National Institutes of Health, HHS)

Dated: October 24, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–27400 Filed 10–30–03; 8:45 am]

BILLING CODE 4140–01–M