agency's current thinking on these topics. 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.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance . Two copies of any 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. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: December 30, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–259 Filed 1–6–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 2002N–0276 and 2002N–0278]

Small Entity Compliance Guides on Registration of Food Facilities and Prior Notice of Imported Food; Correction.

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a document that appeared in the **Federal Register** of December 12, 2003 (68 FR 69408). This document is being republished in its entirety and will read as follows: The Food and Drug Administration (FDA) is announcing the availability of small entity compliance guides (SECGs) for the interim final rules on Registration of Food Facilities and Prior Notice of Imported Food issued under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act). Both interim final rules published in the **Federal Register** of October 10, 2003. These SECGs are intended to help small businesses better understand the registration and prior notice regulations.

DATES: Submit written or electronic comments on the SECGs at any time.

ADDRESSES: Submit written comments concerning these SECGs to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments on the SECGs to *http://www.fda.gov/dockets/ecomments*.

Submit requests for single copies of one or both SECGs to the Prior Notice help desk by telephone at 1–800–216–7331 (within the United States) or 301–575–0156 (outside the United States), by FAX: 301–210–0247, or by e-mail: furls@fda.gov. See the **SUPPLEMENTARY INFORMATION** section for electronic access to these SECGs.

FOR FURTHER INFORMATION CONTACT: Questions Concerning Registration: Nina Adler, Division of Compliance Policy (HFC–230), Office of Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0417, FAX 301–827–0482; or Judith Gushee, Center for Food Safety and Applied Nutrition (HFS–605), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD, 20740, 301–436–2417.

Questions Concerning Prior Notice: Deborah Ralston, Office of Regulatory Affairs, Office of Regional Operations (HFC–100), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–6230.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 10, 2003 (68 FR 58894 and 68 FR 58974), FDA issued two interim final rules to implement sections 305 (Registration of Food Facilities) and 307 (Prior Notice of Imported Food) of the Bioterrorism Act. The registration interim final rule requires domestic and foreign facilities that manufacture/process, pack, or hold food for human or animal consumption in the United States to register with FDA by December 12, 2003. The prior notice interim final rule requires the submission to FDA of prior notice of food, including animal feed, that is imported or offered for import into the United States beginning on December 12, 2003.

We examined the economic implications of these interim rules as required by the Regulatory Flexibility Act (5 U.S.C. 601–612) and determined that they would have a significant economic impact on a substantial number of small entities.

In compliance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Public Law 104–121), we are making available these SECGs that explain the requirements of these regulations.

FDA is issuing these SECGs as level 2 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115(c)(2)). These SECGs restate, in simplified format and language, FDA's current requirements for Registration of Food Facilities and Prior Notice of Imported Food. As guidance, these documents are not binding on either FDA or the public. FDA notes, however, that the regulations that serve as the basis for these guidance documents establish requirements for all covered activities. For this reason, FDA strongly recommends that affected parties consult the regulations at 21 CFR part 1, subparts H and I, in addition to reading these SECGs.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding these SECGs. 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 applicable docket number(s) 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.

III. Electronic Access

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

Dated: December 29, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–257 Filed 1–6–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of 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 a meeting of the Secretary's Advisory Committee on Xenotransplantation (SACX).

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: Secretary's Advisory Committee on Xenotransplantation.

Date: February 24, 2004.

Open: February 24, 2004; 8 a.m. to 5:30 p.m.

Agenda: The SACX will focus on a variety of issues relating to the science and ethics of xenotransplantation. A significant portion of the meeting will be devoted to discussion of two draft reports by the SACX. These draft reports address the state of the science in xenotransplantation and informed consent issues in xenotransplantation. Additional presentations and discussion will focus on recent advances in xenotransplantation research, including a report of a clinical study of porcine islet xenotransplantation in type 1 diabetic patients.

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

Pre-Registration: The SACX meeting is open to the public; however, seating is limited and pre-registration is encouraged. To register, please contact Capital Consulting Corporation (Terry Fisher) at 301–468–6004, extension 434. Individuals who plan to attend the meeting and who need special assistance or other reasonable accommodations should notify Ms. Fisher prior to the meeting.

Public Comment: Individuals who wish to provide public comment (oral or written) should contact the SACX Executive Director, Dr. Mary Groesch, by telephone at 301–496–0785 or e-mail at *groeschm@od.nih.gov*.

Contact Person: Mary Groesch, Ph.D., Executive Director, Secretary's Advisory Committee on Xenotransplantation, Office of Science Policy, Rockledge I, Room 750, Bethesda, MD 20892, 301–496–9838.

Information is also available on the Office's home page: *http://www4.od.nih.gov/oba/Sacx.htm*, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program, National Institutes of Health, HHS)

Dated: December 31, 2003.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04–255 Filed 1–6–04; 8:45 am]

BILLING CODE 4140–01–M

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, Immune Escape in Human Cancer: Mechanisms and Therapeutic Implications.

Date: January 19–21, 2004.

Time: 7 p.m. to 11 a.m.

Agenda: To review and evaluate grant applications.

Place: Courtyard By Marriott Shadyside/Oakland, 5308 Liberty Avenue, Pittsburgh, PA 15224.

Contact Person: Shakeel Ahmad, Ph.D., Scientific Review Administrator, Research Programs Review Branch, National Cancer Institute, Division of Extramural Activities, 6116 Executive Blvd., Bethesda, MD 20892, (301) 594–0114, *amads@mail.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.

(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: December 30, 2003.

Anna P. Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04–253 Filed 1–6–04; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research 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: Center for Inherited Disease Research Access Committee.

Date: January 8, 2004.

Time: 2 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites, Washington, DC.

Contact Person: Rudy O. Pozzatti, PhD., Scientific Review Administrator.

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.

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: December 31, 2003.

Anna P. Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04–254 Filed 1–6–04; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of 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 a meeting of the National Advisory Council on Drug Abuse.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should