Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research, by the Commissioner, approval of the applications listed in the table in this document, and all amendments and supplements thereto, is hereby withdrawn, effective April 4, 2005.

Dated: January 31, 2005.

Steven Galson,

Acting Director, Center for Drug Evaluation and Research.

[FR Doc. 05–4158 Filed 3–3–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0554]

Revised Compliance Policy Guide Regarding Prior Notice of Imported Food 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 draft revisions to Compliance Policy Guide (CPG) Sec. 110.310 entitled ''Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.'' The CPG provides written guidance to FDA and Customs and Border Protection (CBP) staff on enforcement of section 307 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) and the agency's implementing regulations, which require prior notice for food imported or offered for import into the United States. The CPG has been revised to provide additional guidance to FDA and CBP staff regarding specific situations covering routine shipments of food that are transported through the United States, arriving from and exiting to the same country, and regarding the Harmonized Tariff Schedule (HTS) code that is part of the planned shipment information.

DATES: The draft revisions to the CPG are found in section C, items 7 and 8. Submit written or electronic comments concerning the draft revisions to the CPG by April 4, 2005. You may submit written or electronic comments on the other sections of the CPG at any time.

ADDRESSES: Submit written requests for single copies of the revised 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, 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: Domenic Veneziano, Office of Regulatory Affairs (HFC–100), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 703–621–7809.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft revision to CPG Sec. 110.310 entitled ''Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.'' This revised guidance is issued with CBP concurrence and explains to FDA and CBP staff the new FDA and CBP policies on enforcement of section 307 of the Bioterrorism Act and its implementing regulations, which require prior notice to FDA of all food imported or offered for import into the United States (21 CFR part 1.276 through 1.285).

FDA is considering taking these steps while the prior notice final rule is under development to provide additional flexibility in filing prior notice when, due to the geography, the only practical transportation route available for the shipment is through the United States and when there is a prior notice violation because the prior notice does not include the 6-digit HTS code for the article of food.

FDA is issuing the revisions to the CPG as level 1 draft guidance consistent with FDA's good guidance practices regulation § 10.115 (21 CFR 10.115). The draft revisions to the CPG represent the agency's current thinking on its enforcement policy concerning prior notice. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. The draft revisions to the CPG are found in section C, items 7 and 8.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the revised CPG. Submit a single copy of electronic copies or two 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 CPG and 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

An electronic version of the revised CPG is available on the Internet at *http://www.fda.gov/ora* under ''Compliance References.''

Dated: February 24, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–4218 Filed 3–3–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Organ Transplantation; Request for Nominations for Voting Members

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) is requesting nominations to fill up to 13 vacancies on the Advisory Committee on Organ Transplantation (ACOT). The ACOT was established by the Amended Final Rule of the Organ Procurement and Transplantation Network (OPTN) (42 CFR Part 121) and, in accordance with Pub. L. 92–463, was chartered on September 1, 2000.

DATES: The agency must receive nominations on or before April 4, 2005.

ADDRESSES: All nominations should be submitted to the Executive Director, Advisory Committee on Organ Transplantation, Healthcare Systems Bureau, HRSA, Parklawn Building, Room 12C–06, 5600 Fishers Lane, Rockville, Maryland 20857. Federal Express, Airborne, UPS, etc., mail delivery should be addressed to Executive Director, Advisory Committee on Organ Transplantation, Healthcare Systems Bureau, HRSA, at the above address.

FOR FURTHER INFORMATION CONTACT: Thomas E. Balbier, Jr., Executive Director, Advisory Committee on Organ Transplantation, at (301) 443–1896 or e-mail *Thom.Balbier@hrsa.hhs.gov* or Sherry Whipple, Public Health Analyst, Division of Transplantation, at (301) 443–2764 or e-mail *Sherry.Whipple@hrsa.hhs.gov.*

SUPPLEMENTARY INFORMATION: As provided by 42 CFR 121.12 (64 FR 56661), the Secretary established the Advisory Committee on Organ Transplantation. The Committee is governed by the Federal Advisory Committee Act (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

The ACOT advises the Secretary, acting through the Administrator, HRSA, on all aspects of organ procurement, allocation, and transplantation, and on other such matters that the Secretary determines. One of its principal functions shall be to advise the Secretary on ways to maximize Federal efforts to increase living and deceased organ donation nationally. Matters that may be reviewed by the ACOT include the following:

- Proposed enforceable OPTN policies submitted for Secretarial approval;
- Organ allocation policies of the OPTN;
- The OPTN's system of collecting, disseminating and ensuring the validity, accuracy, timeliness and usefulness of data;
- The current state of knowledge regarding transplantation; and
- Additional medical, public health, ethical, legal, coverage and financing issues and socioeconomic issues relevant to transplantation.

The ACOT consists of up to 25 members, including the Chair. Members and Chair shall be selected by the Secretary from individuals knowledgeable in such fields as organ donation, health care public policy, transplantation medicine and surgery, critical care medicine and other medical specialties involved in the identification and referral of donors, non-physician transplant professions, nursing, epidemiology, immunology, law and bioethics, behavioral sciences, economics and statistics, as well as representatives of transplant candidates, transplant recipients, organ donors, and family members. To the extent practicable, Committee members should represent the minority, gender and geographic diversity of transplant candidates, transplant recipients, organ donors and family members served by the OPTN. In addition, the Director, Centers for Disease Control and Prevention; the Administrator, Centers for Medicare and Medicaid Services; the Commissioner, Food and Drug Administration; and the Director, National Institutes of Health (or the designees of such officials) serve as non-voting ex officio members.

Specifically, HRSA is requesting nominations for up to 13 voting members of the ACOT representing: Thoracic transplant surgery, thoracic transplant medicine (physicians), liver transplant surgery, pediatrics, ethics, organ procurement organizations, transplant candidates/recipients, and transplant/donor family members. Nominees will be invited to serve a 4-year term beginning approximately July 27, 2005, and ending July 26, 2009.

HHS will consider nominations of all qualified individuals with a view to ensuring that the Advisory Committee includes the areas of subject matter expertise noted above. Individuals may nominate themselves or other individuals, and professional associations and organizations may nominate one or more qualified persons for membership on the ACOT. Nominations shall state that the nominee is willing to serve as a member of the ACOT and appears to have no conflict of interest that would preclude the ACOT membership. Potential candidates will be asked to provide detailed information concerning financial interests, consultancies, research grants, and/or contracts that might be affected by recommendations of the Committee to permit evaluation of possible sources of conflicts of interest.

A nomination package should include the following information for each nominee: (1) A letter of nomination stating the name, affiliation, and contact information for the nominee, the basis for the nomination (*i.e.*, what specific attributes recommend him/her for service in this capacity), and the nominee's field(s) of expertise; (2) a biographical sketch of the nominee and a copy of his/her curriculum vitae; and (3) the name, return address, and daytime telephone number at which the nominator can be contacted.

The Department of Health and Human Services has special interest in assuring that women, minority groups, and the physically disabled are adequately represented on advisory committees; and therefore, extends particular encouragement to nominations for appropriately qualified female, minority, or disabled candidates.

Dated: February 24, 2005.

Elizabeth M. Duke,

Administrator.

[FR Doc. 05–4223 Filed 3–3–05; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Meeting; Interagency Autism Coordinating Committee

The National Institutes of Health (NIH) hereby announces a meeting of the Interagency Autism Coordinating Committee to be held on May 16, 2005, on the NIH campus in Bethesda, Maryland.

The Children's Health Act of 2000 (Pub. L. 106–310), Title I, Section 104, mandated the establishment of an Interagency Autism Coordinating Committee (IACC) to coordinate autism research and other efforts within the Department of Health and Human Services (HHS). In April 2001, the HHS Secretary delegated the authority to establish the IACC to the NIH. Within the NIH, the National Institute of Mental Health (NIMH) is the designated lead for this activity.

The IACC meeting will be open to the public, 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: Interagency Autism Coordinating Committee.

Date: May 16, 2005.

Time: 9 a.m.–4:30 p.m.

Agenda: Discussion of autism activities across Federal agencies.

Place: National Institutes of Health, 31 Center Drive, Building 31, Conference Room 10 (6th floor), Bethesda, Maryland 20892.

Contact Person: Ann Wagner, PhD, Division of Services and Intervention Research, NIMH, NIH, 6001 Executive Boulevard, Room 7142, MSC 9633, Bethesda, Maryland 20892, E-mail: *awagner@mail.nih.gov,* Phone: 301–443–4283.

Any member of the public interested in presenting oral comments to the Committee may notify Dr. Wagner, as listed above, at least 5 days in advance of the meeting. Interested individuals and representatives of organizations may submit a letter of intent, a brief description of the organization represented, and a short description of the oral presentation. Presentations may be limited to 5 minutes; we request both printed and electronic copies for the record. In addition, any interested person may file written comments with the Committee by forwarding his or her statement to Dr.