

xenotransplantation research are critical and necessary.

The Secretary, DHHS, has established the Secretary's Advisory Committee on Xenotransplantation to provide a forum for the discussion of, and public input on, these and other relevant issues.

#### **Abridged Committee Charter**

##### *Purpose*

The DHHS has a vital role in safeguarding public health while fostering the development of promising strategies to treat tissue destruction, organ failure and other public health needs. The Secretary's Advisory Committee on Xenotransplantation considers the full range of complex scientific, medical, social, and ethical issues and the public health concerns raised by xenotransplantation, including ongoing and proposed protocols, and makes recommendations to the Secretary on policy and procedures. The recommendations of the Committee will facilitate DHHS efforts to develop an integrated approach to addressing emerging public health issues in xenotransplantation.

##### *Function*

The Secretary's Advisory Committee on Xenotransplantation shall advise the Secretary, through the Assistant Secretary for Health, on all aspects of the scientific development and clinical application of xenotransplantation. The Committee's charge includes the following activities:

- Advise the Department on the current state of knowledge regarding xenotransplantation.
- Review current and proposed xenotransplantation clinical trials. Identify and discuss the medical, scientific, ethical, legal, and/or socioeconomic issues raised by these clinical trials.
- Advise the Department on the potential for transmission of infectious diseases as a consequence of xenotransplantation.
- Recommend to the Department, as needed, changes to the PHS Guideline on Infectious Disease Issues in Xenotransplantation.
- Discuss additional scientific, medical, public health, ethical, legal and socioeconomic issues, including international policies and developments, that are relevant to xenotransplantation.

##### *Structure*

The Committee shall consist of 15 voting members, including the Chair, appointed by the Secretary or designee. Members shall be selected by the

Secretary, or designee, from authorities knowledgeable in such fields as xenotransplantation, epidemiology, virology, microbiology, infectious diseases, molecular biology, veterinary medicine, immunology, transplantation surgery, public health, applicable law, bioethics, social sciences, psychology, patient advocacy, and animal welfare. Of the appointed members, at least one shall be a current member of the Xenotransplantation Subcommittee of the Food and Drug Administration (FDA) Biologic Response Modifiers Advisory Committee and at least one shall be a current member of the Centers for Disease Control and Prevention (CDC) Hospital Infection Control Practices Advisory Committee.

In addition, the Committee shall include non-voting, *ex officio* members from relevant DHHS components, including the Office of the Secretary, CDC, FDA, Health Resources and Services Administration, National Institutes of Health and others as deemed appropriate by the Secretary or designee. As necessary, standing and ad hoc subcommittees composed of members of the parent committee may be established to perform specific functions within the Committee's jurisdiction.

Members shall be invited to serve for overlapping four year terms; terms of more than two years are contingent upon the renewal of the Committee by appropriate action prior to its termination. The Committee shall be able to call upon special consultants, assemble ad hoc working groups and convene conferences and workshops as necessary to assist in the work of the Committee. Management and support services shall be provided by the Office of Science Policy, Office of the Director, National Institutes of Health, with direction and guidance from the Assistant Secretary for Health.

##### *Meetings*

Meetings shall be held approximately three times per year at the call of the Chair with the advance approval of a Government official who shall also approve the agenda. A Government official shall be present at all meetings. Meetings shall be open to the public except as determined otherwise by the Secretary or designee; notice of all meetings shall be provided to the public. Meetings shall be conducted, and records of the proceedings kept, as required by applicable laws and Departmental regulations.

##### **Nominations**

DHHS will consider nominations of all qualified individuals. Committee

members will have expertise in such fields as xenotransplantation, epidemiology, virology, microbiology, infectious diseases, molecular biology, veterinary medicine, immunology, transplantation surgery, public health, law, bioethics, social sciences, psychology, patient advocacy, and animal welfare. Individuals may nominate themselves or other individuals, and professional associations and other organizations may nominate individuals.

DHHS has a strong interest in ensuring that women, minority groups, and physically challenged individuals are adequately represented on the Committee and, therefore, encourages nominations of qualified candidates from these groups. DHHS also encourages geographic diversity in the composition of the Committee.

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 or her curriculum vitae; and (3) the name, return address, and daytime telephone number at which the nominator can be contacted. Optimally, a nomination package would also include a statement by the nominee that he/she is willing to accept an appointment to Committee membership.

All nomination information should be provided in a single, complete package within 45 days of the publication of this notice. The nomination letter should bear an original signature; facsimile transmissions or copies cannot be accepted. All nominations for membership should be sent to Dr. Mary Groesch at the address provided above.

Dated: October 13, 1999.

**David Satcher,**

*Assistant Secretary for Health and Surgeon General.*

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Administration for Children and Families**

#### **Submission for OMB Review; Comment Request**

*Title:* Online Interstate Referral Guide (IRG).

*OMB No.:* New.

*Description:* The IRG is an essential reference maintained by the Federal Office of Child Support Enforcement (OCSE) that provides State IV-D agencies with the information needed to process interstate cases. The Online

version of the IRG will provide States with an effective and efficient way of viewing and updating State profile, address, and FIPS code information by consolidating data available through

numerous discrete sources into a single centralized, automated repository.

*Respondents:* State, Local or Tribal Governments.

*Annual Burden Estimates:*

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Online IRG .....	54	18	.3	292

*Estimated Total Annual Burden Hours:* 292.

#### Additional Information

Copies of the proposed collection may be requested by writing to the Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW, Washington, DC 20447, Attn: ACF Reports Clearance Officer.

#### 9OMB comment

OMB is required to make a decision concerning the collection of information between 30 to 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW, Washington, DC 20503, Attn: ACF Desk Officer.

Dated: October 14, 1999.

**Bob Sargis,**

*Acting Reports Clearance Officer.*

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Food and Drug Administration

[Docket No. 99N-4236]

#### Pediatric Advisory Subcommittee of the Anti-Infective Drugs Advisory Committee; Notice of Meeting; Request for Comments

**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:* Pediatric Advisory Subcommittee of the Anti-Infective Drugs Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on November 15, 1999, from 8 a.m. to 5:30 p.m., and on November 16, 1999, from 8 a.m. to 1 p.m. Interested persons and organizations may submit written comments by November 8, 1999, to the Dockets Management Branch (address below).

*Location and Addresses:* Holiday Inn, Kennedy Grand Ballroom, 8777 Georgia Ave., Silver Spring, MD.

Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

*Contact:* Jayne E. Peterson, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-6767, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12530. Please call the Information Line for up-to-date information on this meeting.

*Agenda:* The subcommittee will discuss broad pediatric issues as recommended in the final rule entitled "Regulations Requiring Manufacturers to Assess the Safety and Effectiveness of New Drugs and Biologic Products in Pediatric Patients" (63 FR 66632, December 2, 1998).

On November 15, 1999, the subcommittee will discuss ethical considerations in the conduct of pediatric clinical trials involving a drug or biologic product, specifically the role of pediatric subjects/volunteers who do not have the disease under study.

On November 16, 1999, the subcommittee will discuss whether or not there is a public health need for the pharmaceutical industry to extend their drug development program for sleep disorders into the pediatric population.

In order to prepare presentations and discussions for the meeting, the agency is requesting interested persons to submit in writing data, information, and views relevant to the agenda items. These submissions should contain the docket number 99N-4236 and be submitted to the Dockets Management Branch (address above).

*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 November 8, 1999. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 noon on November 15, 1999, and between approximately 10:30 a.m. and 11 a.m. on November 16, 1999. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 8, 1999, 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.

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

Dated: October 12, 1999.

**Linda A. Suydam,**

*Senior Associate Commissioner.*

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Food and Drug Administration

#### Dermatologic and Ophthalmic Drugs Advisory Committee; Notice of Meeting

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

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee