

Dated: July 17, 2002.

Nancy E. Cheal,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Request for Nominations for Nonvoting Representatives of Industry Interests on Public Advisory Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for nonvoting representatives of industry interests to serve on the Blood Products Advisory Committee, in the Center for Biologics Evaluation and Research (CBER). Nominations will be accepted for vacancies that will or may occur through September 30, 2003.

FDA has a special interest in ensuring that women, minority groups, individuals with disabilities, and small businesses are adequately represented on advisory committees and, therefore, encourages nominations for appropriately qualified candidates from these groups. Specifically, in this document, nominations for nonvoting representatives of industry interests are encouraged from the biologics and/or drug industry.

DATES: Nominations should be received by July 30, 2002.

ADDRESSES: All nominations and curricula vitae should be sent to Linda A. Smallwood (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT:

Linda A. Smallwood, Office of Blood Research and Review, Center for Biologics Evaluation and Research (HFM-350), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6128.

SUPPLEMENTARY INFORMATION: Section 120 of the FDA Modernization Act (FDAMA) of 1997 (21 U.S.C. 355) requires that newly formed FDA advisory committees include representatives from the biologics and/or drug manufacturing industries. This announcement is soliciting nominations for the committee listed below:

Blood Products Advisory Committee:

One vacancy occurring in September 30, 2002; clinical and administrative medicine, hematology, immunology, blood banking, surgery, internal medicine, biochemistry, engineering, statistics, biological and physical sciences, and other related scientific fields.

I. Function

Reviews and evaluates available data concerning the safety, effectiveness, and appropriate use of blood and products intended for use in the diagnosis, prevention, or treatment of human diseases.

II. Nomination Procedures

Any organization in the blood, medical device and/or biologics manufacturing industry wishing to participate in the selection of an appropriate nonvoting industry representative for the Blood Products Advisory Committee should notify the contact person of their interest in nominating one or more qualified persons. Persons who nominate themselves as representatives of industry interests for a certain advisory committee may not participate in the overall selection process.

Nominees should be familiar with firms that manufacture products regulated by the agency including biologics and/or drug manufacturers. Nomination packages should include the name of the committee and the nominee's willingness to serve on the committee. To ensure that the nomination process continues within the set timelines, submitters are strongly encouraged to include a complete curriculum vitae for each nominee with the letter of nomination. The term of office is up to 4 years.

III. Selection Procedure

A letter will be sent to each nominating organization that submitted a nomination package to FDA for a particular advisory committee. The letter will provide the complete list of all nominees. It is the responsibility of each nominating organization to consult with one another to select a single member to represent the industry interests for the advisory committee. This must be completed within 60 calendar days. If no individual is selected, the Commissioner of Food and Drugs will select a nonvoting member to represent the industry interests.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14 relating to advisory committees.

Dated: July 18, 2002.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 02-18775 Filed 7-24-02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Antiviral 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 of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Antiviral 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 August 6 and 7, 2002, from 8 a.m. to 5 p.m.

Location: Holiday Inn, Versailles Ballroom, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Tara P. Turner, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, e-mail: TurnerT@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12531. Please call the Information Line for up-to-date information on this meeting.

Agenda: On August 6, 2002, the committee will discuss new drug application (NDA) 21-449, adefovir dipivoxil tablets, Gilead Sciences, Inc., proposed for treatment of chronic hepatitis B infection (HBV). On August 7, 2002, the committee will discuss clinical trial design issues in the development of products for the treatment of chronic hepatitis B infection.

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 July 30, 2002. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. each day. Time allotted

for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 30, 2002, 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 Tara Turner at least 7 days in advance of the meeting.

FDA regrets that it was unable to publish this notice 15 days prior to the August 6 and 7, 2002, Antiviral Drugs Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Antiviral Drugs Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

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

Dated: July 18, 2002.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Food Biotechnology Subcommittee of the Food 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: Food Biotechnology Subcommittee of the Food 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 August 13, 2002, from 9 a.m. to 4:30 p.m. and August 14, 2002, from 9 a.m. to 4:30 p.m.

Location: Harvey W. Wiley Federal Bldg., 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2200.

Contact Person: Margaret E. Cole, Center for Food Safety and Applied Nutrition (HFS-006), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2397, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 10564. Please call the Information Line for up-to-date information on this meeting.

Agenda: The purpose of the meeting is to discuss science-based approaches to assessing whether new proteins in bioengineered foods are likely to cause allergic reactions in some individuals in order to assist FDA in developing a draft guidance for industry.

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 July 30, 2002. Oral presentations from the public will be scheduled between approximately 10:15 a.m. and 11:30 a.m. on August 14, 2002. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 30, 2002, 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 Margaret E. Cole 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: July 18, 2002.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Ear, Nose, and Throat Devices Panel of the Medical Devices 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). At least one portion of the meeting will be closed to the public.

Name of Committee: Ear, Nose, and Throat Devices Panel of the Medical Devices 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 August 16, 2002, from 10:30 a.m. to 4:30 p.m.

Location: Holiday Inn, Walker/Whetstone Rooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Sara M. Thornton, Center for Devices and Radiological Health (HFZ-460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2053, ext. 127, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12522. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss and make recommendations on a draft guidance entitled "Implantable Middle Ear Hearing Device; Draft Guidance for Industry and FDA." The topics for discussion will include the appropriate study population, objective measurement techniques for comparison of acoustic hearing aids and middle ear hearing devices, and subjective questionnaire development for determining postoperative effectiveness and quality of life outcome measures. The draft guidance is available to the public on the Internet at <http://www.fda.gov/cdrh/ode/guidance/1406.html>.

Background information, including the attendee list, agenda, and questions for the committee, will be available to