AR–22 Research Integrity

Executive Order 12372 does not apply to this program.

J. Where To Obtain Additional Information

This and other CDC announcements, the necessary applications, and associated forms can be found on the CDC Web site, Internet address: *http://www.cdc.gov.* Click on ''Funding'' then ''Grants and Cooperative Agreements''.

For general questions about this announcement, contact: Technical Information Management, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341–4146. Telephone: 770–488–2700.

For business management and budget assistance, contact: Wanda Allison, Grants Management Specialist, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, Atlanta, GA 30341–4146, Telephone: 770–488–2645, E-mail address: *wba3@cdc.gov.*

For business management and budget assistance in the territories, contact: Angelia Hill, Grants Management Specialist, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, Atlanta, GA 30341–4146, Telephone: 770–488–2785, E-mail address: *aph8@cdc.gov.*

For program technical assistance, contact: Judy Stevens, Ph.D., Technical Adviser, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention, 4770 Buford Highway NE, MS K–63, Atlanta, GA 30341–3724, Telephone: 770–488–4649, E-mail address: *JAS2@cdc.gov.*

Dated: May 1, 2003.

Sandra R. Manning,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 03–12395 Filed 5–16–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Notice for June 2003 Advisory Committee Meeting

AGENCY: Administration on Children, Youth and Families, ACF, DHHS.

ACTION: Notice of meeting; Advisory Committee on Head Start Research and Evaluation.

SUMMARY: The 1998 Head Start Reauthorization (42 U.S.C. 9844(g); section 649(g)(1) of the Head Start Act, as amended) called on the Secretary of Health and Human Services to form an independent panel of experts (*i.e.,* an Advisory Committee) to offer advice concerning research designs that would provide a national analysis of the impact of Head Start Programs. The June 16 and 17 meeting provides an opportunity for the Advisory Committee to receive an update on the design and implementation plans for the study.

DATES: June 16, 2003, 9 a.m.–5 p.m. June 17, 2003, 9 a.m.–4 p.m.

Place: Loews L'Enfant Plaza Hotel, 480 L'Enfant Plaza, Washington, DC 20024. Telephone 202–484–1000. Fax: 202–646–4456.

SUPPLEMENTARY INFORMATION: This meeting is open to the public and is barrier free. Meeting records will also be open to the public and will be kept at the Switzer Building located at 330 C Street, SW., Washington, DC 20447. The Head Start Bureau also intends to make material related to this meeting available on the Head Start Web site (*http://www.acf.hhs.gov/programs/hsb/research/hsreac/index.htm*). An interpreter for the deaf and hearing impaired will be available upon advance request by calling Xtria at 703–821–3090 (ext. 265).

FOR FURTHER INFORMATION CONTACT: Michael L. Lopez, Ph.D. at 202–205–8212 for substantive information. ACF Office of Public Affairs at 202–401–9215 for press inquiries. Xtria at 703–821–3090 (ext. 265) for logistical information.

Dated: May 13, 2003.

Frank Fuentes,

Deputy Commissioner, Administration on Children, Youth and Families.

[FR Doc. 03–12462 Filed 5–16–03; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Biological Response Modifiers 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: Biological Response Modifiers 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 June 9, 2003, from 1 p.m. to approximately 3:30 p.m.

Location: National Institutes of Health, Bldg. 29A, rm. 1A09, 29 Lincoln Dr., Bethesda, MD. This meeting will be held by a telephone conference call. Members of the public attending the meeting may participate during the open session of the meeting at the specified location.

Contact Person: Gail Dapolito or Rosanna L. Harvey, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12389. Please call the Information Line for up-to-date information on this meeting.

Agenda: On June 9, 2003, the committee will receive an update on individual research programs in the Division of Cellular and Gene Therapies.

Procedure: On June 9, 2003, from 1 p.m. to approximately 3 p.m., the meeting is open to the public. 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 June 2, 2003. Oral presentations from the public will be scheduled between approximately 2 p.m. and 3 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before June 2, 2003, 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.

Closed Committee Deliberations: On June 9, 2003, from approximately 3 p.m. to 3:30 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The committee will discuss a review of individual research programs in the Center for Biologics Evaluation and Research.

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 Gail Dapolito 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: May 8, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03–12367 Filed 5–16–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03D–0167]

Draft Guidance for Industry on Dispute Resolution Procedures for Science-based Decisions on Products Regulated by the Center for Veterinary Medicine; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance for industry (#79) entitled ''Dispute Resolution Procedures for Science-Based Decisions on Products Regulated by the Center for Veterinary Medicine (CVM).'' This draft guidance document describes dispute resolution procedures by which sponsors, applicants, or manufacturers of FDA regulated products for animals may request review of science-based decisions. This draft guidance does not address procedures for handling issues associated with FDA's new initiative to enhance pharmaceutical good manufacturing practices (GMP's).

DATES: Submit written or electronic comments on this draft guidance by August 4, 2003 to ensure their adequate consideration in preparation of the final document. General comments on agency guidance documents are welcome at any time.

Written comments on the information collection requirements must be received by July 18, 2003.

ADDRESSES: Submit written requests for single copies of the draft guidance document to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit written comments on the draft guidance document to the Dockets Management Branch (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 should be identified with the full title of the draft guidance document and the docket number found in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section of this document for electronic access to the draft guidance document.

Submit written comments on the collection of information requirements to the Dockets Management Branch (address above). Comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Marcia Larkins, Center for Veterinary Medicine (HFV–7), Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, 301–827–4535, e-mail: mlarkins@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: FDA regulations, § 10.75 (21 CFR 10.75), provide a mechanism for any interested person to obtain internal review of any agency decision by raising the matter through the established agency channels of supervision or review for that matter.

On November 21, 1997, the President signed into law the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105–115). Section 404 of FDAMA creates new section 562 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360bbb–1). Section 562 of the act provides that, if a procedure under which an applicant, sponsor, or manufacturer (applicant) could request a review of a scientific controversy related to human drugs, animal drugs, human biologics, or devices did not already exist, either as a provision in the act or a regulation issued under the act, FDA must, by regulation, establish a procedure under which such an applicant may request a review of the controversy, including review by an appropriate scientific advisory panel or advisory committee.

In the **Federal Register** of November 18, 1998 (63 FR 63978), FDA amended § 10.75 to state explicitly that an applicant of a drug (including human drugs, animal drugs, and human biologics) or device may request review of a scientific controversy by an appropriate scientific advisory panel or an advisory committee. In the preamble to the final rule, FDA stated that implementation of this provision would be undertaken by the individual FDA centers and would be described in guidance documents. This draft guidance describes CVM's dispute resolution procedures under section 562 of the act.

CVM Appeals Procedure Guide 1240.3130 (Guide 1240.3130) of the CVM Program Policy and Procedures Manual (P & P Manual) describes CVM's current appeals procedure. Because this guidance predates FDAMA, CVM is revising its procedures. Draft Guidance #79, when finalized, will supercede Guide 1240.3130, and, at that time, CVM will eliminate the guide from the P & P Manual.

This draft guidance document describes CVM's procedures for handling requests for internal review of scientific controversies relating to agency decisions affecting animal drugs or other products regulated by CVM. Incorporated in this document is the dispute resolution procedure set forth in section 404 of FDAMA. While CVM seeks comments on all aspects of this draft guidance, CVM is particularly interested in the definition of a scientific controversy, standards for granting and denying a request for the review of a scientific controversy by an advisory committee, and the time frames for conducting the review.

II. Significance of Guidance

This Level 1 draft guidance is being issued consistent with FDA's Good Guidance Practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on dispute resolution and the procedures regarding requests for review of scientific controversies relating to decisions affecting animal drugs or other products regulated by CVM. The document does not create or confer any rights for or on any person and will not operate to bind FDA or the public. Alternative methods may be used as long as they satisfy the requirements of the applicable statutes and regulations. If an applicant wants to discuss an alternative approach, they should contact the FDA staff responsible for implementing the guidance. If the applicant cannot identify the appropriate FDA staff, call 301–827–4535.

III. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3 and includes agency requests or