candidates with training in inborn errors of metabolism, biochemical and/or molecular genetics, population genetics, epidemiology and related statistical training. Additionally, individuals with experience in genetic counseling, medical ethics as well as ancillary fields of study will be considered. The term of office is up to 4 years.

The Panel will also include technically qualified members who are identified with consumer interests and representatives of industry interests.

Nomination Procedures

Any interested person may nominate one or more qualified persons for membership on the Panel. Self-nominations are also accepted. Nominations shall include a complete curriculum vitae of each nominee, current business address and telephone number, and shall state that the nominee is aware of the nomination, is willing to serve as a member, and appears to have no conflict of interest that would preclude Panel membership. FDA will ask the potential candidates to provide detailed information concerning such matters as financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflict of interest.

Criteria for Consumer-Nominated Members

Selection of members representing consumer interests is conducted through procedures that include use of a consortium of consumer organizations which has the responsibility for screening, interviewing and recommending candidates for the agency's selection. Candidates from this group, like all other candidates for membership on the Panel, should possess appropriate qualifications to understand and contribute to the Panel's work.

Industry Representatives

Regarding nominations for members representing industry interests, a letter will be sent to each person or organization that has made a nomination and to other organizations that have expressed an interest in participating in the selection process together with a complete list of all such organizations and the nominees. The letter will state that it is the responsibility of each nominator or organization that has expressed an interest in participating in the selection process to consult with the others to provide a consensus slate of possible members representing industry interests within 60 days. In the event that a slate of nominees has not been provided within 60 days, the agency will select an industry representative for each such vacancy from the entire list of industry nominees to avoid delay or disruption of the work of the Panel. The agency is particularly interested in nominees that possess the essential scientific credentials needed to participate fully and knowledgeably in the Panel's deliberations. In addition to this expertise, the agency believes that it would be an advantage to the Panel's work if the individual had special insight and direct experience into specific industrywide issues, practices, and concerns that might not otherwise be available to others not similarly situated.

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: September 17, 1999.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 99–24980 Filed 9–24–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0969]

Antimicrobial Resistance in Food-Producing Animals; Notice of General Public Meeting and Public Workshops; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) will sponsor a general public meeting and two public workshops to discuss important issues related to antimicrobial resistance (AR) in food-producing animals. The agency is seeking public comment on the general public meeting in its further planning of the two public workshops.

DATES: The general public meeting and the public workshops are scheduled as follows:

1. ''General Public Meeting,'' Monday, October 4, 1999, 1 p.m. to 5 p.m.
2. ''The Risk Assessment and the Establishment of Resistance Thresholds Workshop,'' Thursday and Friday, December 9 and 10, 1999, 9 a.m. to 5 p.m.
3. ''Preapproval Studies in AR,'' Tuesday and Wednesday, February 22 and 23, 2000, 9 a.m. to 5 p.m.

ADDRESSES: The general public meeting and the public workshops will be held at the DoubleTree Hotel, 1750 Rockville Pike, Rockville, MD, 301–468–1100.

FOR FURTHER INFORMATION CONTACT:

For general information regarding the general public meeting and public workshops: Lynda W. Cowatch, Center for Veterinary Medicine (CVM) (HFV–150), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–5281, e-mail: lcowatch@cvm.fda.gov.

For information regarding technical inquiries: Sharon R. Thompson or Aleta M. Sindelar at 301–594–1798, FAX 301–594–1830.

Registration: The general public meeting and the public workshops are free, however, registration is required. Limited space is available and early registration is encouraged. Registration forms are available on CVM's home page at ''http://www.fda.gov/cvm/fda/mappqs/arregis1.doc''. If you need special accommodations for a disability, please contact the DoubleTree Hotel at least 7 days in advance.

SUPPLEMENTARY INFORMATION: The agency believes it is essential to provide opportunities for public input regarding the following:

I. The General Public Meeting

The general public meeting is intended to provide an opportunity for stakeholders to give input to FDA on the appropriate issues, experts, and agenda items to be included in two subsequent scientific workshops related to AR. In general terms, the first scientific public workshop on December 9 and 10, 1999, is intended to focus on issues related to risk assessment and the establishment of resistance thresholds in food-producing animals. The second scientific public workshop on February 22 and 23, 2000, is intended to discuss the design of preapproval studies in food-producing animals to model the rate and extent of resistance development. FDA will consider comments received at the general public meeting in its further planning of the two scientific public workshops. We also encourage the submission of written comments at any time, but no later than 30 days after the date of publication of this notice to ensure time for full consideration in planning the December meeting. Comments should be identified with the docket number found in brackets in the heading of this document and submitted to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

II. The Risk Assessment and the Establishment of Resistance Thresholds Workshop

The risk assessment and the establishment of resistance thresholds workshop is intended to allow a public discussion of FDA's risk assessment model to evaluate the risk to human health from resistant foodborne pathogens associated with the use of antimicrobials in food-producing animals. The meeting will also discuss FDA's current thinking on the use of this model to establish resistance and monitoring thresholds in food-producing animals. The agency seeks scientific input from experts at the meeting on these issues as well as suggestions for alternative approaches.

III. The Preapproval Studies in AR

The preapproval studies in AR public workshop is intended to allow a public discussion of FDA's current thinking on the appropriate design of preapproval studies in food-producing animals to model the rate and extent of resistance development. The agency will seek suggestions for alternative approaches.

Supportive documents for discussion, including the ''Framework Document,'' can be found on CVM's Internet home page at http://www.fda.gov/cvm. Information including meeting agendas and relevant background information will be posted on the CVM home page in anticipation of each meeting and workshop.

Dated: September 22, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 99–25083 Filed 9–22–99; 4:28 pm]

BILLING CODE 4160–01–F

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 November 1, 1999, from 8:30 a.m. to 5 p.m.

Location: Holiday Inn, The Ballrooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Rhonda W. Stover or John B. Schupp, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, 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: The committee will discuss new drug application (NDA) 20–993, adefovir dipivoxil (Gilead Sciences Inc.), for the treatment of human immunodeficiency virus 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 October 25, 1999. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 25, 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: September 17, 1999.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 99–24982 Filed 9–24–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0834]

Draft Guidance for Industry on Noncontraceptive Estrogen Class Labeling; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Labeling Guidance for Noncontraceptive Estrogen Drug Products—Prescribing Information for Healthcare Providers and Patient Labeling.'' The draft guidance is intended to serve as a template for sponsors of estrogen class drug products to ensure that such products contain uniform health care provider and patient labeling information. FDA published a notice of availability of an earlier version of this draft guidance in the **Federal Register** of October 15, 1998 (63 FR 55399). The agency received numerous comments. As a result, the original draft guidance was revised substantially and is being issued in draft for a second time.

DATES: Written comments on the draft guidance document may be submitted by November 26, 1999. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of the draft guidance for industry can be obtained on the Internet at http://www.fda.gov/cder/guidance/index.htm. Submit written requests for single copies of ''Labeling Guidance for Noncontraceptive Estrogen Drug Products—Prescribing Information for Healthcare Providers and Patient Labeling'' to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Lana L. Pauls, Reproductive and Urologic Drug Products, Center for Drug Evaluation and Research (HFD–580), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4260.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''Labeling Guidance for Noncontraceptive Estrogen Drug Products—Prescribing Information for Healthcare Providers and Patient Labeling.'' The draft guidance is intended to serve as a template for sponsors of estrogen class drug products to ensure that such products contain uniform health care provider and patient labeling information. Once finalized, this draft guidance will replace the ''Labeling Guidance for Estrogen Drug Products, Physician Labeling'' and ''Labeling Guidance for Estrogen Drug Products, Patient Package