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