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). At least one portion of the meeting will be closed 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 October 4, 1999, 8 a.m. to 5 p.m., and on October 5, 1999, 8 a.m. to 12 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: On October 4, 1999, presentations and committee discussions will address issues related to the potential applicability of information from non-U.S. studies of prevention of perinatal human immunodeficiency virus transmission to U.S. clinical settings.

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 September 27, 1999. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on October 4, 1999. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 27, 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.

Closed Committee Deliberations: On October 4, 1999, from 2 p.m to 5 p.m., and on October 5, 1999, from 8 a.m. to 12 m., the meeting will be closed to permit discussion and review of trade secret and/or confidential commercial information relevant to pending investigational new drug applications and drug development plans (5 U.S.C. 552b(c)(4)).

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

Dated: September 2, 1999.

Linda A. Suydam,

Senior Associate Commissioner.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Food and Drug Administration/Industry Exchange Workshop on Medical Device Quality Systems Inspection Technique; Public Workshops

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of workshops.

SUMMARY: The Food and Drug Administration (FDA), Office of the Commissioner, Office of Regulatory Affairs, Center for Devices and Radiological Health, and the Regional Small Business Assistance Offices in cooperation with the American Society for Quality, Association of Food and Drug Officials, BioFlorida, Inc., Health Industry Manufacturers Association, Medical Alley, New England Biomedical Discussion Group, Organization of Regulatory and Clinical Associates, Pharmaceutical Quality Institute, and the Regulatory Affairs Professionals Society is announcing a series of workshops on the FDA Quality System Inspection Technique (QSIT). Topics for discussion include: Development of QSIT, Compliance Program and Warning Letter (Pilot), Management Controls, Corrective and Preventative Action, Design Controls, Production and Process Controls, and Industry Perspective of QSIT. Through the workshops, FDA seeks to increase the medical device community's understanding of QSIT, and ensure that the device industry takes appropriate actions to establish effective quality systems, thus preventing regulatory problems when inspections occur.

Date and Time: See Table 1 in the **SUPPLEMENTARY INFORMATION** section of this document.

Location: See Table 1 in the **SUPPLEMENTARY INFORMATION** section of this document.

Registration: Send registration information as listed in the **SUPPLEMENTARY INFORMATION** section of this document, along with the correct payment amount, to the registrar for the site you wish to attend. Fees cover refreshments, organization and site costs, and materials. Space is limited, therefore interested parties are encouraged to register early. If you need special accommodations due to a disability, please inform the registrar for your site at least 7 days in advance of the workshop.

Contact: Herman B. Janiger, Northeast Regional Office (HFRNE–17), Food and Drug Administration, 850 Third Ave., Brooklyn, NY 11232, 718–340–7000, ext. 5528.

SUPPLEMENTARY INFORMATION: In the fall of 1999, FDA field offices will begin using the QSIT nationwide as the primary tool for medical device good manufacturing practice/quality system inspections. QSIT was developed using a collaborative effort with stakeholders and tested in three districts. The following workshops are scheduled to increase the medical community's understanding of QSIT: