

Agenda: On May 24, 2001, the committee will discuss: (1) Published interim analyses of ALLHAT (antihypertensive and lipid lowering treatment to prevent heart attack trial) sponsored by the National Heart, Lung, and Blood Institute, NIH, and (2) response to the citizen's petition of Lawrence D. Bernhardt and Arnold Liebman, regarding new drug application (NDA) 19-668, Cardura® (doxazosin), Pfizer, Inc. On May 25, 2001, the committee will discuss NDA 20-920 Natrecor® (nesiritide), Scios, Inc., for treatment of acute heart failure.

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 May 18, 2001. Oral presentations from the public will be scheduled between approximately 8:30 a.m. and 9:30 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 18, 2001, and submit a brief statement on 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: April 11, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01-10450 Filed 4-26-01; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Vaccines and Related Biological Products 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: Vaccines and Related Biological Products 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 May 16, 2001, from 8 a.m. to 6:30 p.m., and May 17, 2001, from 8 a.m. to 1:30 p.m.

Location: Holiday Inn, Grand Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

Contact: Nancy T. Cherry or Denise H. Royster, Center for Biologics Evaluations 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 12391. Please call the Information Line for up-to-date information on this meeting.

Agenda: On May 16, 2001, the committee will discuss adventitious agent testing, tumorigenicity testing, and issues related to residual cell substrate deoxyribonucleic acid (DNA) of novel and neoplastic cell substrates used to manufacture viral vaccines.

Procedure: On May 16, 2001, from 9 a.m. to 6:30 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 May 8, 2001. Oral presentations from the public will be held between approximately 2:30 p.m. and 3:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 8, 2001, 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 May 16, 2001, from 8 a.m. to 9 a.m. and on May 17, 2001, from 8 a.m. to 1:30 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (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: April 19, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01-10451 Filed 4-26-01; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D-3028]

Draft Guidance for Industry; Premarket Approval Applications for In Vitro Diagnostic Devices Pertaining to Hepatitis C Viruses (HCV); Assays Intended for Diagnosis, Prognosis, or Monitoring of HCV Infection, Hepatitis C, or Other HCV-Associated Disease; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Premarket Approval Applications for In Vitro Diagnostic Devices Pertaining to Hepatitis C Viruses (HCV): Assays Intended for Diagnosis, Prognosis, or Monitoring of HCV Infection, Hepatitis C, or Other HCV-Associated Disease; Draft Guidance for Industry and FDA." FDA is issuing this draft guidance to provide current recommendations about the design, data collection, and data analysis of studies that are important to the premarket approval application (PMA) process for in vitro diagnostic (IVD) devices pertaining to HCV. This draft guidance is not final nor is it in effect at this time.

DATES: Submit written comments on the draft guidance by July 26, 2001.

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of the draft guidance entitled "Premarket Approval Applications for In Vitro Diagnostic Devices Pertaining to Hepatitis C Viruses (HCV): Assays Intended for Diagnosis, Prognosis, or Monitoring of HCV Infection, Hepatitis C, or Other HCV-Associated Disease; Draft Guidance for Industry and FDA" to the Division of Small Manufacturers Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301-443-8818. 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. Comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for