*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

information on electronic access to the guidance.

**FOR FURTHER INFORMATION CONTACT:** Doria DuBois, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2096.

**SUPPLEMENTARY INFORMATION:**

## I. Background

On February 12, 1998, FDA called a meeting of the Microbiology Devices Advisory Panel to obtain recommendations from the panel regarding scientific information necessary for premarket approval of tests for hepatitis viruses. Following the panel meeting and subsequent discussions between FDA and industry, FDA developed and published a draft guidance (See 64 FR 54902, October 8, 1999). FDA accepted public comments regarding the draft guidance until January 6, 2000. This second draft guidance incorporates those comments and replaces the October 8, 1999, draft guidance document.

## II. Significance of Guidance

This draft guidance document represents the agency's current thinking on assays for detecting evidence of infection with HCV. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statutes and regulations.

The agency has adopted good guidance practices (GGPs) and published the final rule, which set forth the agency's regulations for the development, issuance, and use of guidance documents (65 FR 56468, September 19, 2000). This draft guidance document is issued as a level 1 guidance in accordance with the GGP regulations.

## III. Electronic Access

In order to receive ''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'' via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number (1353) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. The CDRH home page may be accessed at http://www.fda.gov/cdrh. ''Premarket Approval Applications for In Vitro Diagnostic Devices Pertaining Hepatitis C Viruses (HCV): Assays Intended for Diagnosis, Prognosis, or Monitoring of HCV Infection or HCV-Associated Disease; Draft Guidance for Industry and FDA,'' will be available at http://www.fda.gov/cdrh/ode/guidance/1353.pdf. Updated on a regular basis, the CDRH home page also includes the civil money penalty guidance documents package, device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information.

## IV. Comments

Interested persons may submit to Dockets Management Branch (address above) written comments regarding this draft guidance by July 26, 2001. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 18, 2001.

**Linda S. Kahan,**

*Deputy Director for Regulations Policy, Center for Devices and Radiological Health.*

[FR Doc. 01–10528 Filed 4–26–01; 8:45 am]

**BILLING CODE 4160–01–S**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1891.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

**Proposed Project: Evaluation of the Health Care for the Homeless Respite Pilot Initiative—New**

The Bureau of Primary Health Care (BPHC), Health Resources Services Administration (HRSA), proposes to conduct an evaluation of the Health Care for the Homeless (HCH) Respite Pilot Initiative. Data will be collected from the ten HCH grantees participating in the Pilot Initiative. The evaluation will be developed and conducted by the National Health Care for the Homeless Council through a cooperative agreement with the BPHC. The focus of the evaluation will be on assessing the effect of respite services on the health of homeless people as well as looking at any differences in outcomes based on client or program characteristics. The evaluation will be conducted throughout the three-year period of the Pilot Initiative.

The estimated response burden is as follows: