

Chronic Disease Prevention and Health Promotion (NCCDPHP), 4770 Buford Highway, NE, MS K-47 Atlanta, Georgia 30341, Telephone: (770) 488-8055, E-Mail Address: mmalone@cdc.gov.

Technical assistance for the Jackson State University, Office of Research and Development to establish an epidemiological research institute will be provided by: Mags Malone, Division of Adult and Community Health, National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), 4770 Buford Highway, NE, MS K-47, Atlanta, Georgia 30341, Telephone: (770) 488-8055, E-Mail Address: mmalone@cdc.gov.

Technical assistance for the Baltimore City Health Department, Maryland, to establish a Center for Chronic Diseases will be provided by: Catherine A. Hutsell, M.P.H., Division of Adult and Community Health, National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), 4770 Buford Highway, NE, MS K-30, Atlanta, Georgia 30341, Telephone: (770) 488-5438, E-Mail Address: chutsell@cdc.gov.

Technical assistance for the University of Texas, Dallas, for the

Southwestern Medical Center, National Multiple Sclerosis Training center will be provided by: David Thurman, Division of Adult and Community Health, National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), 4770 Buford Highway, NE, MS K-45, Atlanta, Georgia 30341, Telephone: (770) 488-6090, E-Mail Address: dthurman@cdc.gov.

Dated: April 23, 2001.

**John L. Williams,**

*Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).*

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**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

#### Proposed Information Collection Activity; Comment Request

Proposed Projects:

#### ANNUAL BURDEN ESTIMATES

| Instrument                                | Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|-------------------------------------------|-----------------------|------------------------------------|-----------------------------------|--------------------|
| ADD02 .....                               | 55                    | 2                                  | 9                                 | 990                |
| Estimated total annual burden hours ..... |                       |                                    |                                   | 990                |

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, S.W., Washington, D.C. 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection.

*The Department specifically requests comments 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) 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. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: April 24, 2001.

**Bob Sargis,**

*Reports Clearance Officer.*

[FR Doc. 01-10504 Filed 4-26-01; 8:45 am]

**BILLING CODE 4184-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Cardiovascular and Renal 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

Title: Financial Status Reporting (SF-269) with Supplemental ADD-02 for State Councils on Dev. Disabilities

**OMB No. 0980-0212**

*Description:* For the program of the State Council on Developmental Disabilities, funds are awarded to State Agencies contingent on fiscal requirements in Subtitle B of the Developmental Disabilities Assistance and Bill of Rights Act. The SF-269, mandated in the revised OMB Circular A-102, provides no accounting breakouts necessary for proper stewardship. The proposed supplement will allow compliance monitoring and proactive compliance maintenance and technical assistance.

*Respondents:* State and Tribal Governments.

of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Cardiovascular and Renal 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 May 24, 2001, from 8:30 a.m. to 5 p.m., and on May 25, 2001, from at 9 a.m. to 3:30 p.m.

*Location:* National Institutes of Health (NIH), 9000 Rockville Pike, Bldg. 10, Clinical Center, Jack Masur Auditorium, Bethesda, MD.

*Contact:* Joan C. Standaert, Center for Drug Evaluation and Research (HFD-110), Food and Drug Administration, Woodmont II Bldg., 1451 Rockville Pike, Rockville, MD, 20752, 419-259-6211, or John M. Treacy, 301-827-7001, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington DC area), code 12533. Please call the Information Line for up-to-date information on this meeting.

*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