

the accomplishment of the various identified objectives of the cooperative agreement. Measures of effectiveness must relate to the performance goals stated in the "Purpose" section of this announcement. Measures must be objective and quantitative, and must measure the intended outcome. These measures of effectiveness must be submitted with the application and will be an element of evaluation.

Your application will be evaluated against the following criteria:

1. Methods (30 points)
  - a. Is a plan for educating organizational members regarding the NVDRS included?
  - b. Does the applicant describe methods for developing standards for representing concepts and data elements among its members?
2. Goal(s) and Objectives (20 points)
  - a. Are objectives that are measurable, specific, time phased and achievable provided?
3. Background and Need (15 points)
  - a. Does the applicant describe its role regarding access to ME/coroners and the need for a NVDRS?
4. Collaboration (15 points)
  - a. Does the applicant document a process for developing a working relationship between medical examiners and coroners?
5. Management (10 points)
  - a. Does the applicant provide details regarding staff responsible for activities related to the objectives?
  - b. Does the applicant provide an organizational chart of the organization?
6. Evaluation (10 points)
  - a. Is a plan for evaluating and reporting results of proposed activities included?
7. Budget (not scored)
8. Performance Measures (not scored)
  - a. Are measures of effectiveness included and do they address those areas identified under the "Purpose" section above?

#### *V.2. Review and Selection Process*

An objective review panel will evaluate your application according to the criteria listed above.

#### *V.3. Anticipated Announcement and Award Dates*

September 1, 2004.

### **VI. Award Administration Information**

#### *VI.1. Award Notices*

Successful applications will receive a Notice of Grant Award (NGA) from the CDC Procurement and Grants Office. The NGA shall be the only binding, authorizing document between the recipient and CDC. The NGA will be signed by an authorized Grants

Management Officer, and mailed to the recipient fiscal officer identified in the application.

Unsuccessful applicants will receive notification of the results of the application review by mail.

#### *VI.2. Administrative and National Policy Requirements*

45 CFR Part 74 or 92

For more information on the Code of Federal Regulations, see the National Archives and Records Administration at the following Internet address: <http://www.access.gpo.gov/nara/cfr/cfr-table-search.html>.

The following additional requirements apply to this project:

- AR-8 Public Health System Reporting Requirements
- AR-9 Paperwork Reduction Act Requirements
- AR-10 Smoke-Free Workplace Requirements
- AR-11 Healthy People 2010
- AR-12 Lobbying Restrictions
- AR-13 Prohibition on Use of CDC Funds for Certain Gun Control Activities
- AR-14 Accounting System Requirements
- AR-15 Proof of Non-Profit Status
- AR-20 Conference Support
- AR-21 Small, Minority, and Women-Owned Business

Additional information on these requirements can be found on the CDC Web site at the following Internet address: <http://www.cdc.gov/od/pgo/funding/ARs.htm>.

#### *VI.3. Reporting Requirements*

You must provide CDC with an original, plus two hard copies of the following reports:

1. Interim progress report, no less than 90 days before the end of the budget period. The progress report will serve as your non-competing continuation application, and must contain the following elements:
    - a. Current Budget Period Activities Objectives.
    - b. Current Budget Period Financial Progress.
    - c. New Budget Period Program Proposed Activity Objectives.
    - d. Detailed Line-Item Budget and Justification.
    - e. Additional Requested Information.
    - f. Measures of Effectiveness.
  2. Financial status report, no more than 90 days after the end of the budget period.
  3. Final financial and performance reports, no more than 90 days after the end of the project period.
- This report must be mailed to the Grants Management or Contract

Specialist listed in the "Agency Contacts" section of this announcement.

### **VII. Agency Contacts**

For general questions about this announcement, contact: Technical Information Management Section, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770-488-2700.

For program technical assistance, contact: Leroy Frazier, Jr., Project Officer, Division of Violence Prevention, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention, 4770 Buford Hwy, NE., MS K60, Atlanta, GA 30341, Telephone: 770-488-1507, E-mail: [Lfrazier1@cdc.gov](mailto:Lfrazier1@cdc.gov).

For budget assistance, contact: Nancy Pillar, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770-488-2721, E-mail: [nfp6@cdc.gov](mailto:nfp6@cdc.gov).

Dated: May 7, 2004.

**William P. Nichols,**  
*Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention.*

[FR Doc. 04-10857 Filed 5-12-04; 8:45 am]

**BILLING CODE 4163-18-P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

[Docket No. 1999N-1852]

#### **Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Draft Guidance for Industry: Reports on the Status of Postmarketing Studies—Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Guidance for Industry: Reports on the Status of Postmarketing Studies—Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Karen Nelson, Office of Management Programs (HFA-250), Food and Drug

Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

**SUPPLEMENTARY INFORMATION:** In the *Federal Register* of April 4, 2001 (66 FR 17912), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0528. The approval expires on March 31, 2007. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: April 23, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 04-10833 Filed 5-12-04; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Request for Nominations for Voting and Nonvoting Consumer Representative Members on Public Advisory Committees and Panels

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is requesting nominations for voting and nonvoting consumer representatives to serve on its advisory committees and panels in the Center for Biologics Evaluation and Research (CBER), Center for Drug Evaluation and Research (CDER), and Center for Devices and Radiological Health (CDRH). Nominations will be accepted for current vacancies and for those that will or may occur through December 31, 2004.

FDA has a special interest in ensuring that women, minority groups, and individuals with disabilities are adequately represented on advisory committees and, therefore, encourages nominations of qualified candidates from these groups.

**DATES:** Scheduled vacancies occur on various dates throughout the year. As a result, no cutoff date is established for the receipt of nominations.

**ADDRESSES:** All nominations should be sent to the contact person listed in the

**FOR FURTHER INFORMATION CONTACT** section of this document.

**FOR FURTHER INFORMATION CONTACT:** Michael Ortwerth, Advisory Committee Oversight and Management Staff (HF-4), FDA Office of the Commissioner, 5600 Fishers Lane, Rockville, MD 20857, e-mail: [Michael.Ortwerth@fda.gov](mailto:Michael.Ortwerth@fda.gov).

**SUPPLEMENTARY INFORMATION:** FDA is requesting nominations for voting and nonvoting consumer representatives of the following advisory committees and panels for vacancies:

#### CBER

1. Blood Products Advisory Committee

#### CDRH

1. Neurological Devices Panel of the Medical Devices Advisory Committee

#### CDER

1. Anti-Infective Drugs Advisory Committee
2. Arthritis Advisory Committee
3. Peripheral and Central Nervous System Drugs Advisory Committee
4. Pulmonary-Allergy Drugs Advisory Committee

#### I. Criteria for Members

Persons nominated for membership on the committees as a consumer representative must meet the following criteria: (1) Demonstrate ties to consumer and community-based organizations, (2) be able to analyze technical data, (3) understand research design, (4) discuss benefits and risks, and (5) evaluate the safety and efficacy of products under review. The consumer representative must be able to represent the consumer perspective on issues and actions before the advisory committee; serve as a liaison between the committee and interested consumers, associations, coalitions, and consumer organizations; and facilitate dialogue with the advisory committees on scientific issues that affect consumers.

#### II. Selection Procedures

Selection of members representing consumer interests is conducted through procedures that include use of organizations representing the public interest and consumer advocacy groups. The organizations have the responsibility of recommending candidates of the agency's selection.

#### III. Nomination Procedures

All nominations must include a cover letter, a curriculum vitae or resume

(which should include nominee's office address, telephone number, and e-mail address), and a list of consumer or community-based organizations for which the candidate can demonstrate active participation.

Any interested person or organization may nominate one or more qualified persons for membership on one or more of the advisory committees to represent consumer interests. Self-nominations are also accepted. FDA will ask the potential candidates to provide detailed information concerning such matters as financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflict of interest. The nomination should specify the committee(s) of interest. The term of office is up to 4 years, depending on the appointment date.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: May 5, 2004.

**Peter J. Pitts,**

*Associate Commissioner for External Relations.*

[FR Doc. 04-10831 Filed 5-12-04; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Advisory Committee; Renewals

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the renewal of certain FDA advisory committees by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the charters of the committees listed in the following table for an additional 2 years beyond charter expiration date. The new charters will be in effect until the dates of expiration listed in the following table. This notice is issued under the Federal Advisory Committee Act of October 6, 1972 (Public Law 92-463 (5 U.S.C. app. 2)).

**DATES:** Authority for these committees will expire on the dates indicated in the following table unless the Commissioner formally determines that renewal is in the public interest.