

families. The data also will have significant implications for policy and program development for child well-being programs nationwide.

The purpose of this request is to obtain OMB approval for an extension of the original three year request which was approved on March 31, 2009. Forty-three of the original 53 grantees were awarded for a five-year grant period, thus necessitating an extension of the original request in order to continue data collection for the remainder of the grant period. The first submission of RPG grantee data to the RPG data collection system occurred in December, 2008, and every six months thereafter. Data collection will be conducted for the fifth year of the grant period, ending September 30, 2012, with data submission by January 2013. Data collection may be extended for one year

until January 2014 should grantees request and be granted no-cost extensions.

To minimize grantee data collection and reporting burden, many of the data elements are already being collected by counties and States in order to report Federally-mandated data for the Adoption and Foster Care Analysis and Reporting System (AFCARS), the Treatment Episode Data Set (TEDS) and the National Outcome Measures (NOMs); in addition, all States voluntarily submit data for the Federal National Child Abuse and Neglect Data System (NCANDS). Therefore, most child welfare data elements included in the RPG performance measures can be found in a State's automated case management system, which is often a Federally-funded Statewide Automated Child Welfare Information System

(SACWIS). TEDS admission and discharge data are collected by State substance abuse agencies according to their own information systems for monitoring substance abuse treatment admissions and transmitted monthly or quarterly to the SAMHSA contractor.

As a result of prior Federal government reporting requirements, States are already collecting several data elements needed by the RPGs. The RPG lead agency or their state or local partners are able to download information from these existing State child welfare and substance abuse treatment data systems to obtain data to monitor their RPG program outcomes, thereby reducing the amount of primary data collection needed.

Respondents: RPG Grantees.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
State, local, and Tribal Government	26	2	175.50	9,126
Private Sector	17	2	175.50	5,967
Estimated Total Annual Burden Hours				15,093

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 Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, *Attn:* ACF Reports Clearance Officer. *E-mail address:* infocollection@acf.hhs.gov. 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.

Robert Sargis,
Reports Clearance Officer.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0002]

Request for Notification From Industry Organizations Interested in Participating in the Selection Process for a Nonvoting Industry Representative and Request for Nominations for a Nonvoting Industry Representative on an FDA Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting that any industry organizations interested in participating in the selection of a

nonvoting industry representative to serve on its Cellular, Tissue, and Gene Therapies Advisory Committee notify FDA in writing. FDA is also requesting nominations for nonvoting industry representatives to serve its Cellular, Tissue, and Gene Therapies Advisory Committee. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative. Nomination will be accepted for current vacancies effective with this notice.

DATES: Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests must send a letter stating that interest to FDA by August 5, 2011, for vacancies listed in the notice. Concurrently, nomination material for prospective candidates should be sent to FDA by August 5, 2011.

ADDRESSES: All letters of interest and nominations should be submitted in writing to Gail Dapolito (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Gail Dapolito, Center for Biologics Evaluation and Research (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-

1448, 301-827-1289; Fax: 301-827-0294; E-mail: gail.dapolito@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Cellular, Tissue, and Gene Therapies Advisory Committee

The Agency requests nominations for a nonvoting industry representative on the Cellular, Tissue, and Gene Therapies Advisory Committee. The Cellular, Tissue, and Gene Therapies Advisory Committee advises the Commissioner of Food and Drugs (the Commissioner) or designee in discharging responsibilities as they relate to the regulation of cellular and gene therapy products.

This committee has 13 voting members. Members are asked to provide their expert scientific and technical advice to FDA to help make sound decisions on the safety, effectiveness, appropriate use, and labeling of cellular and gene therapy products.

II. Selection Procedure

Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests should send a letter stating that interest to the FDA contact (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see **DATES**). Within the subsequent 30 days, FDA will send a letter to each organization that has expressed an interest, attaching a complete list of all such organizations; and a list of all nominees along with their current resumes. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select a candidate, within 60 days after the receipt of the FDA letter, to serve as the nonvoting member to represent industry interests for the Cellular, Tissue, and Gene Therapies Advisory Committee. The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within 60 days, the Commissioner will select the nonvoting member to represent industry interests.

III. Application Procedure

Individuals may self nominate and/or an organization may nominate one or more individuals to serve as a nonvoting industry representative. A current curriculum vitae and the name of the committee of interest should be sent to the FDA contact person (see **FOR FURTHER INFORMATION CONTACT**) within the 30 days (see **DATES**). FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the committee. (Persons who nominate

themselves as nonvoting industry representatives will not participate in the selection process).

FDA has a special interest in ensuring that women, minority groups, individuals with physical disabilities, and small businesses are adequately represented on its advisory committees, and therefore, encourages nominations for appropriately qualified candidates from these groups. Specifically, in this document, nominations for nonvoting representatives of industry interests are encouraged from the cellular and gene therapy products biotech industry.

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

Dated: June 29, 2011.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0002]

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 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 September 8, 2011, from 8 a.m. to 5 p.m.

Location: The Marriott Inn and Conference Center, University of Maryland University College (UMUC), The Ballroom, 3501 University Blvd. East, Adelphi, MD 20783-7998. The conference center's telephone number is 301-985-7300.

Contact Person: Kristina Toliver, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX: 301-847-8533, e-mail: CRDAC@fda.hhs.gov, or FDA Advisory

Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On September 8, 2011, the committee will discuss new drug application (NDA) 202439, rivaroxaban tablets, submitted by Johnson & Johnson Pharmaceutical Research and Development, L.L.C., on behalf of Ortho-McNeil-Janssen-Pharmaceuticals, for the prevention of stroke and systemic embolism (blood clots other than in the head) in patients with nonvalvular atrial fibrillation (abnormally rapid contractions of the atria, the upper chambers of the heart).

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee link.

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 on or before August 24, 2011. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person 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 on or before August 16, 2011. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may