DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
[Docket No. FDA–2012–N–0001]

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 May 23, 2012, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at http://www.fda.gov/AdvisoryCommittees/default.htm; under the heading “Resources for You,” click on “Public Meetings at the FDA White Oak Campus.” Please note that visitors to the White Oak Campus must enter through Building 1.

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, email: 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 hotline/phone line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss supplemental new drug application (sNDA) 202439/S–002, XARELTO (rivaroxaban), submitted by Janssen Pharmaceuticals, Inc., to reduce the risk of thrombotic cardiovascular events in patients with acute coronary syndrome (ACS) [ST elevation myocardial infarction (STEMI), non-ST elevation myocardial infarction (NSTEMI), or unstable angina (UA)] in combination with aspirin alone or with aspirin plus clopidogrel or ticlopidine.

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 May 9, 2012. 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 May 1, 2012. 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 conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by May 2, 2012.

Persons attending FDA’s advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Kristina Toliver at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 9, 2012.

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–2012–N–0001]

Request for Notification From Industry Organizations Interested in Participating in the Selection Process for Nonvoting Industry Representative on the Blood Products Advisory Committee, and Request for Nominations for Nonvoting Industry Representatives on the Blood Products Advisory Committee

AGENCY: Food and Drug Administration (FDA).

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 the Blood Products Advisory Committee for the Center for Biologics Evaluation and Research (CBER) notify FDA in writing. FDA is also requesting nominations for a nonvoting industry representative to serve on the Blood Products Advisory Committee. A nominee may either be self-nominated...
or nominated by an organization to serve as a nonvoting industry representative. Nominations 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 May 14, 2012, for the vacancy listed in this notice. Concurrently, nomination materials for prospective candidates should be sent to FDA by May 14, 2012.

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

FOR FURTHER INFORMATION CONTACT:

SUPPLEMENTARY INFORMATION: The Agency intends to add a nonvoting industry representative to the following advisory committee:

I. Blood Products Advisory Committee for the Center for Biologics Evaluation and Research

Members are selected by the Commissioner of Food and Drugs (the Commissioner) or designee from among authorities knowledgeable in the fields of clinical and administrative medicine, hematology, immunology, blood banking, surgery, internal medicine, biochemistry, engineering, biological and physical sciences, biotechnology, computer technology, statistics, epidemiology, sociology/ethics, and other related professions.

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 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. Contact information, 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 30 days of publication of this document (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 blood and blood products manufacturing industry.

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: April 9, 2012.

Jill Hartzler Warner,
Acting Associate Commissioner for Special Medical Programs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities; Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMSHA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. chapter 35). To request a copy of these documents, call the SAMSHA Reports Clearance Officer on (240) 276–1243.

Project: Notification of Intent To Use Schedule III, IV, or V Opioid Drugs for the Maintenance and Detoxification Treatment of Opiate Addiction Under 21 U.S.C. 823(g)(2) (OMB No. 0930–0234)—Extension

The Drug Addiction Treatment Act of 2000 (”DATA,” Pub. L. 106–310) amended the Controlled Substances Act (21 U.S.C. 823(g)(2)) to permit practitioners (physicians) to seek and obtain waivers to prescribe certain approved narcotic treatment drugs for the treatment of opiate addiction. The legislation sets eligibility requirements and certification requirements as well as an interagency notification review process for physicians who seek waivers. The legislation was amended in 2005 to eliminate the patient limit for physicians in group practices, and in 2006, to permit certain physicians to treat up to 100 patients.

To implement these provisions, SAMSHA developed a notification form (SMA–167) that facilitates the submission and review of notifications. The form provides the information necessary to determine whether practitioners (i.e., independent physicians) meet the qualifications for waivers set forth under the new law. Use of this form will enable physicians to know they have provided all information needed to determine whether practitioners are eligible for a waiver.

However, there is no prohibition on use of other means to provide requisite information. The Secretary will convey notification information and determinations to the Drug Enforcement Administration (DEA), which will assign an identification number to qualifying practitioners; this number will be included in the practitioner’s registration under 21 U.S.C. 823(f).

Practitioners may use the form for three types of notification: (a) New, (b) immediate, and (c) to notify of their intent to treat up to 100 patients. Under “new” notifications, practitioners may make their initial waiver requests to SAMSHA. “Immediate” notifications inform SAMSHA and the Attorney General of a practitioner’s intent to prescribe immediately to facilitate the treatment of an individual (one) patient under 21 U.S.C. 823(g)(2)(E)(ii). Finally, the form may be used by physicians with waivers to certify their need and intent to treat up to 100 patients.

The form collects data on the following items: Practitioner name; state medical license number and DEA registration number; address of primary location; telephone and fax numbers; email address; name and address of...