

be scheduled between approximately 1:30 p.m. and 2:30 p.m. Those desiring to make 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 October 9, 2009. 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 October 12, 2009.

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 Minh Doan 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: September 18, 2009.

**David Horowitz,**

*Assistant Commissioner for Policy.*

[FR Doc. E9-23143 Filed 9-24-09; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-3216-N]

#### Medicare Program; Request for Nominations for Members of the Medicare Evidence Development & Coverage Advisory Committee

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Notice.

**SUMMARY:** This notice announces the request for nominations for consideration for membership on the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC). Among other things, the MEDCAC advises the Secretary of the Department of Health and Human Services (the Secretary) and the Administrator of the Centers for Medicare & Medicaid Services, as requested by the Secretary, whether medical items and services are "reasonable and necessary" and therefore eligible for coverage under Title XVIII of the Social Security Act.

We are requesting nominations for both voting and nonvoting members to serve on the MEDCAC. Nominees are selected based upon their individual qualifications and not as representatives of professional associations or societies. We have a special interest in ensuring that women, minority groups, and physically challenged individuals are adequately represented on the MEDCAC. Therefore, we encourage nominations of qualified candidates from these groups.

The MEDCAC reviews and evaluates medical literature, reviews technology assessments, and examines data and information on the effectiveness and appropriateness of medical items and services that are covered or eligible for coverage under Medicare.

**DATES:** Nominations will be considered if postmarked by Monday, October 26, 2009 and mailed to the address specified in the **ADDRESSES** section of this notice.

**ADDRESSES:** You may mail nominations for membership to the following address: Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, Attention: Maria Ellis, 7500 Security Boulevard, Mail Stop: Central Building 1-09-06, Baltimore, MD 21244.

**FOR FURTHER INFORMATION CONTACT:** Maria Ellis, Executive Secretary for MEDCAC, Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, Coverage and Analysis Group, C1-09-06, 7500 Security Boulevard, Baltimore, MD 21244 or contact Ms. Ellis by phone (410-786-0309) or via e-mail at [Maria.Ellis@cms.hhs.gov](mailto:Maria.Ellis@cms.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

On December 14, 1998, we published a notice in the **Federal Register** (63 FR 68780) announcing establishment of the Medicare Coverage Advisory Committee (MCAC). The Secretary signed the initial charter for the Medicare Coverage

Advisory Committee on November 24, 1998. On January 26, 2007 the Secretary published a notice in the **Federal Register** (72 FR 3853), changing the Committee's name to the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC). The charter for the committee was renewed by the Secretary and will terminate on November 24, 2010, unless renewed again by the Secretary.

The MEDCAC is governed by provisions of the Federal Advisory Committee Act, Public Law 92-463, as amended (5 U.S.C. App. 2), which sets forth standards for the formulation and use of advisory committees, and is authorized by section 222 of the Public Health Service Act as amended (42 U.S.C. 217A).

The MEDCAC consists of a pool of 100 appointed members including: 6 patient advocates, who are standard voting members, and 6 representatives of industry interests, who are nonvoting members. Members are selected from among authorities in clinical medicine of all specialties, administrative medicine, public health, biologic and physical sciences, health care data and information management and analysis, patient advocacy, the economics of health care, medical ethics, and other related professions such as epidemiology and biostatistics, and methodology of trial design.

The MEDCAC functions on a committee basis. The committee reviews and evaluates medical literature, reviews technology assessments, and examines data and information on the effectiveness and appropriateness of medical items and services that are covered or eligible for coverage under Medicare. The Committee works from an agenda provided by the Designated Federal Official that lists specific issues, and develops technical advice to assist us in determining reasonable and necessary applications of medical services and technology when we make national coverage decisions for Medicare. The Committee also advises CMS as part of Medicare's coverage evidence development activities.

##### II. Provisions of the Notice

As of December 2009, there will be 45 terms of membership expiring, 3 of which are nonvoting industry representatives.

Accordingly, we are requesting nominations for both voting and nonvoting members to serve on the MEDCAC. Nominees are selected based upon their individual qualifications and not as representatives of professional associations or societies. We have a special interest in ensuring that women,

minority groups, and physically challenged individuals are adequately represented on the MEDCAC. Therefore, we encourage nominations of qualified candidates from these groups.

All nominations must be accompanied by curricula vitae. Nomination packages must be sent to Maria Ellis at the address listed in the ADDRESSES section of this notice. Nominees for voting membership must also have expertise and experience in one or more of the following fields:

- Clinical medicine of all specialties.
- Administrative medicine.
- Public health.
- Patient advocacy.
- Biologic and physical sciences.
- Health care data and information management and analysis.
- The economics of health care.
- Medical ethics.
- Other related professions such as epidemiology and biostatistics, and methodology of clinical trial design.

We are looking for experts in a number of fields. Our most critical needs are for experts in hematology; genomics; end of life care; Bayesian statistics; clinical epidemiology; clinical trial methodology; knee, hip, and other joint replacement surgery; ophthalmology; psychopharmacology; registries; rheumatology; screening and diagnostic testing analysis; and stroke. We also need experts in biostatistics in clinical settings, cardiovascular epidemiology, cost effectiveness analysis, dementia, endocrinology, geriatrics, gynecology, minority health, observational research design, stroke, epidemiology, and women's health.

The nomination letter must include a statement that the nominee is willing to serve as a member of the MEDCAC and appears to have no conflict of interest that would preclude membership. We are requesting that all curricula vitae include the following:

- Date of birth.
- Place of birth.
- Social security number.
- Title and current position.
- Professional affiliation.
- Home and business address.
- Telephone and fax numbers.
- E-mail address.
- List of areas of expertise.

In the nominations letter, we are requesting that the nominee specify whether applying for a Voting position or Industry Representative. Potential candidates will be asked to provide detailed information concerning such matters as financial holdings, consultancies, and research grants or contracts in order to permit evaluation of possible sources of conflict of interest.

Members are invited to serve for overlapping 2-year terms. A member may serve after the expiration of the member's term until a successor takes office. Any interested person may nominate one or more qualified persons. Self-nominations are also accepted.

The current Secretary's Charter for the MEDCAC is available on the CMS Web site at: <http://www.cms.hhs.gov/FACA/Downloads/medcaccharter.pdf>, or you may obtain a copy of the charter by submitting a request to the contact listed in the **FOR FURTHER INFORMATION** section of this notice.

**Authority:** 5 U.S.C. App. 2, section 10(a)(1) and (a)(2).

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: September 21, 2009.

**Barry M. Straube,**

*CMS Chief Medical Officer, Director, Office of Clinical Standards and Quality, Centers for Medicare & Medicaid Services.*

[FR Doc. E9-23257 Filed 9-24-09; 8:45 am]

**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Notice of Listing of Members of the National Institutes of Health's Senior Executive Service 2009 Performance Review Board (PRB)

The National Institutes of Health (NIH) announces the persons who will serve on the National Institutes of Health's Senior Executive Service 2009 Performance Review Board. This action is being taken in accordance with Title 5, U.S.C., Section 4314(c)(4), which requires that members of performance review boards be appointed in a manner to ensure consistency, stability, and objectivity in performance appraisals and requires that notice of the appointment of an individual to serve as a member be published in the **Federal Register**.

The following persons will serve on the NIH Performance Review Board, which oversees the evaluation of performance appraisals of NIH Senior Executive Service (SES) members: Ms. Colleen Barros (Chair); Dr. Michael Gottesman; Ms. Lenora Johnson; Ms. Robin Kawazoe; Dr. Raynard Kington; Ms. Janis Mullaney; Dr. Sally Rockey.

For further information about the NIH Performance Review Board, contact the Office of Human Resources, Workforce Relations Division, National Institutes of

Health, Building 31, Room B3C07, Bethesda, Maryland 20892, telephone 301-402-9203 (not a toll-free number).

Dated: September 20, 2009.

**Francis S. Collins,**

*Director, National Institutes of Health.*

[FR Doc. E9-23265 Filed 9-24-09; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2009-N-0026]

#### Apothecon et al.; Withdrawal of Approval of 103 New Drug Applications and 35 Abbreviated New Drug Applications; Correction

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

**ACTION:** Notice; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of February 11, 2009 (74 FR 6896). The document announced the withdrawal of approval of 103 new drug applications (NDAs) and 35 abbreviated new drug applications (ANDAs). The document published with an error in the identification of the ANDA for Amiodarone Hydrochloride Injection, 50 milligrams/milliliter, held by Hospira, Inc. This document corrects that error.

**DATES:** Effective March 13, 2009.

**FOR FURTHER INFORMATION CONTACT:** Florine P. Purdie, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6366, Silver Spring, MD 20993-0002, 301-796-3601.

**SUPPLEMENTARY INFORMATION:** In FR Doc. E9-2901, appearing on page 6896 in the **Federal Register** of Wednesday, February 11, 2009, the following correction is made:

On page 6900, in the first column of the table, third item from the bottom of the page, the entry "ANDA 75-108" is corrected to read "ANDA 76-108".

Dated: September 9, 2009.

**Douglas C. Throckmorton,**

*Deputy Director, Center for Drug Evaluation and Research.*

[FR Doc. E9-23170 Filed 9-24-09; 8:45 am]

**BILLING CODE 4160-01-S**