

merely makes technical corrections to the title and effective date of the Notice of CMS ruling, we believe it is unnecessary to undergo further notice and comment procedures. In addition, we believe it is in the public interest to have the correct information and to have it as soon as possible and not delay its dissemination. For the reasons stated above, we find that both notice and comment procedures and the 30-day delay in effective date for this correction document are unnecessary and contrary to the public interest. Therefore, we find there is good cause to waive notice and comment procedures and the 30-day delay in effective date for this correction document.

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

Dated: July 15, 2011.

Dawn L. Smalls,

Executive Secretary to the Department.

[FR Doc. 2011-18424 Filed 7-21-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3251-N]

Medicare Program; Meeting of the Medicare Evidence Development and Coverage Advisory Committee—September 21, 2011

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

ACTION: Notice of meeting.

SUMMARY: This notice announces that a public meeting of the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) (“Committee”) will be held on Wednesday, September 21, 2011. The Committee generally provides advice and recommendations concerning the adequacy of scientific evidence needed to determine whether certain medical items and services can be covered under the Medicare statute. This meeting will focus on the currently available evidence regarding antivasular endothelial growth factor (anti-VEGF) treatment of diabetic macular edema (DME). This meeting is open to the public in accordance with the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)).

DATES: *Meeting Date:* The public meeting will be held on Wednesday,

September 21, 2011 from 7:30 a.m. until 4:30 p.m., Daylight Saving Time (D.S.T.).

Deadline for Submission of Written Comments: Written comments must be received at the address specified in the **ADDRESSES** section of this notice by 5 p.m. D.S.T., Monday, August 22, 2011. Once submitted, all comments are final.

Deadlines for Speaker Registration and Presentation Materials: The deadline to register to be a speaker and to submit PowerPoint presentation materials and writings that will be used in support of an oral presentation, is 5 p.m., D.S.T. on Monday, August 22, 2011. Speakers may register by phone or via e-mail by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice. Presentation materials must be received at the address specified in the **ADDRESSES** section of this notice.

Deadline for All Other Attendees Registration: Individuals may register online at <http://www.cms.gov/apps/events/upcomingevents.asp?strOrderBy=1&type=3> or by phone by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice by 5 p.m. D.S.T., Friday, September 16, 2011.

We will be broadcasting the meeting live via Webcast at <http://www.cms.gov/live/>.

Deadline for Submitting a Request for Special Accommodations: Persons attending the meeting who are hearing or visually impaired, or have a condition that requires special assistance or accommodations, are asked to contact the Executive Secretary as specified in the **FOR FURTHER INFORMATION CONTACT** section of this notice no later than 5 p.m., D.S.T. Friday, September 2, 2011.

ADDRESSES: *Meeting Location:* The meeting will be held in the main auditorium of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244.

Submission of Presentations and Comments: Presentation materials and written comments that will be presented at the meeting must be submitted via e-mail to MedCACpresentations@cms.hhs.gov or by regular mail to the contact listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice by the date specified in the **DATES** section of this notice.

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, S3-02-01, 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.

SUPPLEMENTARY INFORMATION:

I. Background

MEDCAC, formerly known as the Medicare Coverage Advisory Committee (MCAC), provides advice and recommendations to CMS regarding clinical issues. (For more information on MCAC, see the December 14, 1998 **Federal Register** (63 FR 68780).) This notice announces the September 21, 2011, public meeting of the Committee. During this meeting, the Committee will discuss the currently available evidence regarding antivasular endothelial growth factor (anti-VEGF) treatment of diabetic macular edema (DME). Background information about this topic, including panel materials, is available at <http://www.cms.gov/medicare-coverage-database/indexes/medcac-meetings-index.aspx?bc=BAAAAAAAAAAAA&>. CMS will no longer be providing paper copies of the handouts for the meeting. Electronic copies of all the meeting materials will be on the CMS Web site no later than 2 business days before the meeting. We encourage the participation of appropriate organizations with expertise in the treatment of diabetic retinopathy (DR) and DME.

II. Meeting Format

This meeting is open to the public. The agenda for the day of the meeting offers two opportunities for the public to participate as either a registered scheduled speaker or an unscheduled speaker. The Committee will hear oral presentations from the registered scheduled speakers for approximately 45 minutes. 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, CMS 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 August 25, 2011. Your comments should focus on issues specific to the list of topics that we have proposed to the Committee. The list of research topics to be discussed at the meeting will be available on the following Web site prior to the meeting: <http://www.cms.gov/medicare-coverage-database/indexes/medcac-meetings-index.aspx?bc=BAAAAAAAAAAAA&>. We require that you declare at the meeting whether you have any financial involvement with manufacturers (or

their competitors) of any items or services being discussed.

The Committee will deliberate openly on the topics under consideration. Interested persons may observe the deliberations, but the Committee will not hear further comments during this time except at the request of the chairperson. The Committee will also allow a 15-minute open public session for any unscheduled speaker to address issues specific to the topics under consideration. At the conclusion of the day, the members will vote and the Committee will make its recommendation(s) to CMS.

III. Registration Instructions

CMS' Coverage and Analysis Group is coordinating meeting registration. While there is no registration fee, individuals must register to attend. You may register online at http://www.cms.gov/apps/events/upcoming_events.asp?strOrderBy=1&type=3 or by phone by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice by the deadline listed in the **DATES** section of this notice. Please provide your full name (as it appears on your state-issued driver's license), address, organization, telephone, fax number(s), and e-mail address. You will receive a registration confirmation with instructions for your arrival at the CMS complex or you will be notified the seating capacity has been reached.

IV. Security, Building, and Parking Guidelines

This meeting will be held in a Federal government building; therefore, Federal security measures are applicable. We recommend that confirmed registrants arrive reasonably early, but no earlier than 45 minutes prior to the start of the meeting, to allow additional time to clear security. Security measures include the following:

- Presentation of government-issued photographic identification to the Federal Protective Service or Guard Service personnel.
- Inspection of vehicle's interior and exterior (this includes engine and trunk inspection) at the entrance to the grounds. Parking permits and instructions will be issued after the vehicle inspection.
- Inspection, via metal detector or other applicable means of all persons brought entering the building. We note that all items brought into CMS, whether personal or for the purpose of presentation or to support a presentation, are subject to inspection. We cannot assume responsibility for coordinating the receipt, transfer,

transport, storage, set-up, safety, or timely arrival of any personal belongings or items used for presentation or to support a presentation.

Note: Individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meeting. The public may not enter the building earlier than 45 minutes prior to the convening of the meeting. All visitors must be escorted in areas other than the lower and first floor levels in the Central Building.

Authority: 5 U.S.C. App. 2, section 10(a). (Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: July 18, 2011.

Patrick Conway,

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

[FR Doc. 2011-18562 Filed 7-21-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2010-P-0577 and FDA-2010-P-0579]

Determination That NUVIGIL (Armodafinil) Tablets, 100 Milligrams and 200 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that NUVIGIL (armodafinil) Tablets, 100 milligrams (mg) and 200 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for armodafinil tablets, 100 mg and 200 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Molly Flannery, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6237, Silver Spring, MD 20993-0002, 301-796-3543.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417)

(the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is known generally as the "Orange Book." Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

NUVIGIL (armodafinil) Tablets, 100 mg and 200 mg, are the subject of NDA 21-875, held by Cephalon, Inc., and initially approved on June 15, 2007. NUVIGIL is indicated to improve wakefulness in patients with excessive sleepiness associated with obstructive sleep apnea, narcolepsy, and shift work disorder.

NUVIGIL (armodafinil) Tablets, 100 mg and 200 mg, are currently listed in the "Discontinued Drug Product List" section of the Orange Book.

Actavis, Inc., submitted a citizen petition dated November 9, 2010 (Docket No. FDA-2010-P-0579), under 21 CFR 10.30, requesting that the Agency determine that NUVIGIL (armodafinil) Tablets, 100 mg and 200 mg, were not voluntarily withdrawn for safety or efficacy reasons. Watson Laboratories, Inc., also submitted a