Application and Update Form is used by health care providers to apply for NPIs and furnish updates to the information they supplied on their initial applications. The form is also used to deactivate their NPIs if necessary. The NPI Application/Update form has been revised to further assist in uniquely identifying health care providers and provide additional guidance on how to accurately complete the form. The form captures additional data elements that will assist with unique identification. It also includes more detailed instructions. *Form Number:* CMS–10114 (OMB #0938–0931); *Frequency:* Reporting—On occasion, one-time; *Affected Public:* Business or other for-profit, Not-for-profit institutions, and Federal government; *Number of Respondents:* 325,608; *Total Annual Responses:* 325,608; *Total Annual Hours:* 108,560.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995*, or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by *April 29, 2008:*

1. *Electronically.* You may submit your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number _____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: *February 21, 2008.*

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. E8–3839 Filed 2–28–08; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3196–N]

Medicare Program; Town Hall Meeting of the Medicare Evidence Development and Coverage Advisory Committee—April 30, 2008

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

ACTION: Notice of meeting.

SUMMARY: This notice announces a public meeting of the Medicare Evidence Development & Coverage Advisory Committee (MedCAC) (''Committee''). We are soliciting comments from the scientific community and the public on prioritizing research topics of importance to the Medicare population. This meeting is a follow up to the CMS Evidentiary Priorities MedCAC meeting, which was held on October 22, 2007 to establish a list of evidentiary priorities for research to improve the health of Medicare beneficiaries.

The Committee generally provides advice and recommendations about whether scientific evidence is adequate to determine whether certain medical items and services are reasonable and necessary under the Medicare statute.

Notice of this meeting is given under 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, April 30, 2008 from 7:30 a.m. until 4:30 p.m., e.s.t.

Deadline for Written Comments: Written comments must be received at the address specified in the **ADDRESSES** section of this notice by April 2, 2008, 5 p.m., e.s.t. Once submitted, comments are final. The meeting will not include PowerPoint presentations.

Deadline for Meeting Registration: Individuals may register by phone or e-mail by contacting the contact listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice by close of business on Monday April 21, 2008.

Deadline for Submitting 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 April 23, 2008.

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

Submission of Presentations and Comments: Written comments and those that will be presented verbally at the meeting must be submitted by 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.

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 via phone (410–786–0309) or e-mail at *Maria.Ellis@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On December 14, 1998, we published a notice in the **Federal Register** (63 FR 68780) to describe the Medicare Coverage Advisory Committee (MCAC), now known as the MedCAC, which provides advice and recommendations to CMS about clinical issues.

The purpose of the MedCAC meeting is to discuss the priorities for research topics that are important for the Medicare program and the Medicare population and to make recommendations to CMS. This public discussion may also provide useful information for researchers in the scientific community who are interested in developing research projects concerning Medicare beneficiaries. This meeting is a follow up to the CMS Evidentiary Priorities MedCAC meeting which was held on October 22, 2007. The purpose of the October 22, 2007 meeting was to establish a list of evidentiary priorities for research to improve the health of Medicare beneficiaries. Details on the October 22, 2007 meeting and the CMS Evidentiary Priorities can be found at *http://www.cms.hhs.gov/mcd/viewmcac.asp?where=index&mid=41.*

The Committee generally provides advice and recommendations about whether scientific evidence is adequate to determine whether certain medical items and services are reasonable and necessary and thus eligible for coverage under the Medicare statute.

II. Meeting Format

This meeting is open to the public. The Committee will hear oral presentations from the public for approximately 30 minutes. The Committee may limit the number and

duration of oral presentations to the time available. Your comments should consider the list of topics that we have proposed to the Committee and should focus on issues specific to those topics. 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.hhs.gov/mcd/index_list.asp?list_type=mcac*. We require that you declare at the meeting whether you have any financial involvement with manufacturers of any items or services being discussed (or with their competitors).

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 unscheduled open public session for any attendee 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

The Coverage and Analysis Group is coordinating meeting registration. While there is no registration fee, individuals must register to attend. You may register 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. You will be notified if the seating capacity has been reached.

This meeting is located on Federal property; therefore, for security reasons, any individuals wishing to attend this meeting must register by the date as specified in the **DATES** section of this notice.

IV. Security, Building, and Parking Guidelines

This meeting will be held in a Federal government building; therefore, Federal security measures are applicable. In planning your arrival time, we recommend that you arrive reasonably early 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.
- Interior and exterior inspection of vehicles (this includes engine and trunk inspection) at the entrance to the grounds. Parking permits and instructions will be issued after the vehicle inspection.
- Passing through a metal detector and inspection of items brought into the building. We note that all items brought to 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 30 to 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: February 14, 2008.

Barry M. Straube,

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

[FR Doc. E8–3829 Filed 2–28–08; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No FDA–2008–P–0125] (formerly Docket No. 2007P–0172)

Determination That MINOCIN (Minocycline Hydrochloride) Capsules Equivalent to 75 Milligrams Base Was 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) is announcing its determination that MINOCIN (minocycline hydrochloride) Capsules equivalent to (EQ) 75 milligrams (mg) base was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for minocycline hydrochloride capsules if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Carol E. Drew, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6306, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved 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). Regulations also provide that the agency must make a determination as to whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (§ 314.161(a)(1) (21 CFR 314.161(a)(1))). FDA may not approve an ANDA that does not refer to a listed drug.

On May 1, 2007, Kendle International, on behalf of Aurobindo Pharmaceuticals, Ltd., submitted a citizen petition (Docket No. 2007P–0172/CP1) to FDA under 21 CFR 10.30. The petition requests that the agency determine whether MINOCIN