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

(minocycline hydrochloride) Capsules EQ 75 mg base (NDA 050–649), manufactured by Triax Pharmaceuticals, Ltd. (Triax), was withdrawn from sale for reasons of safety or effectiveness. MINOCIN is a tetracycline-class antibiotic medicine used to treat certain infections caused by bacteria. MINOCIN Capsules EQ 75 mg base was approved on February 12, 2001. Our records show that the 75 mg strength of this product was marketed for a short period of time in 2001. MINOCIN Capsules EQ 75 mg base were discontinued in September 2001 and the drug product was moved from the prescription drug product list to the ''Discontinued Drug Product List'' section of the Orange Book.

FDA has reviewed its records and, under § 314.161, has determined that MINOCIN Capsules EQ 75 mg base was not withdrawn from sale for reasons of safety or effectiveness. The petitioner identified no data or other information suggesting that MINOCIN Capsules EQ 75 mg base was withdrawn for reasons of safety or effectiveness. FDA has independently evaluated relevant literature and data for possible postmarketing adverse events and has found no information that would indicate that this product was withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list MINOCIN (minocycline hydrochloride) Capsules EQ 75 mg base in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to minocycline hydrochloride capsules EQ 75 mg base may be approved by the agency if all other legal and regulatory requirements for the approval of ANDAs are met. If FDA determines that labeling for this drug product should be revised to meet current standards, the agency will advise ANDA applicants to submit such labeling.

Dated: February 21, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E8–3879 Filed 2–28–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Cancer Care for Uninsured Individuals: A Feasibility Study (NCI)

Summary: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Cancer Institute (NCI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on December 21, 2007 (Vol. 72, No. 245, p. 72741 and allowed 60-days for public comment. One public comment was received that questioned why the study was not funded by University of Alabama (UAB) funds. A response was made on February 8, 2008, that indicated that UAB was funding this study. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: Cancer Care For Uninsured Individuals: A Feasibility Study. *Type of Information Collection Request:* New. *Need and Use of Information Collection:* The purpose of this information collection is to assess the feasibility of obtaining health insurance information for participants of the Prostate, Lung, Colon and Ovarian (PLCO) Cancer Screening Trial participants from health care providers and self reports. The ultimate objective is to compare the health care utilization of insured and uninsured PLCO participants. The PLCO data provides a unique opportunity to study health care seeking behavior after an abnormal cancer screening test and the effect of lack of health insurance. Participants who had positive cancer screening tests were referred to their doctors for follow-up care. No additional care was provided by the trial. The study collected detailed information on tests received for diagnosis, clinical presentation of disease, and cancer treatment. Since the PLCO original data collection had not recorded the health insurance of participants at the time of their screening, it is necessary to collect it retrospectively. This feasibility study will request information from 50 physicians and 150 participants. The aims are to determine the:

(1) Total number of physicians to be contacted to obtain insurance information on all PLCO participants who had a positive cancer screening test;

(2) Percentage of physicians willing and able to provide insurance information;

(3) Percentage of participants with and without insurance;

(4) Number of participants for whom insurance status can be only determined by self report;

(5) Percentage of PLCO participants who accept to respond to the survey;

(6) Percentage of individuals who are willing to provide information on insurance status; and,

(7) Potential proportion of PLCO participants without health insurance.

These results will be used to design a study to examine the health care behavior of insured and uninsured PLCO participants. This is relevant to understand the results of the PLCO Cancer Screening Trial and other screening trials currently being conducted in the U.S. The success of these trials is conditional on participants' access to care following a recommendation for follow-up. Uninsured individuals may be more likely to join these trials than insured ones in order to get free preventive care. They may also be more likely to not seek, or delay seeking, care after an abnormal screening test even though they are encouraged to get care and they may be highly motivated to receive the best care possible. It is relevant for other decision makers to understand whether uninsured persons are receiving appropriate care after abnormal screening results. The efforts to control cancer disease and the loss of life associated with it are concentrated on population wide screening. These endeavors may be compromised if a significant proportion of the population does not get appropriate follow-up after screening or does not get the care known to be effective for their disease. *Frequency of Response:* One time. *Affected Public:* Individuals and households; businesses or other for-profit. *Type of Respondents:* Individuals older than 55 who participated in the PLCO Screening trial and physicians who provided care for them. The annual reporting burden is shown in the following table.