Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 100 people.

Purpose: This committee is charged with providing scientific and technical advice and guidance to the Secretary of Health and Human Services, the Assistant Secretary for Health, and the Director, CDC, regarding the need for, and the nature of, revisions to the standards under which clinical laboratories are regulated; the impact on medical and laboratory practice of proposed revisions to the standards; and the modification of the standards to accommodate technological advances.

Matters to be Discussed: The agenda will include updates from CDC, the Centers for Medicare & Medicaid Services, and the Food and Drug Administration; and presentations and discussion on non-regulatory approaches to laboratory improvement.

Agenda items are subject to change as priorities dictate.

Providing Oral or Written Comments: It is the policy of CLIAC to accept written public comments and provide a brief period for oral public comments whenever possible. Oral Comments: In general, each individual or group requesting to make an oral presentation will be limited to a total time of five minutes (unless otherwise indicated). Speakers must also submit their comments in writing for inclusion in the meeting's Summary Report. To assure adequate time is scheduled for public comments, individuals or groups planning to make an oral presentation should, when possible, notify the contact person below at least one week prior to the meeting date. Written Comments: For individuals or groups unable to attend the meeting, CLIAC accepts written comments until the date of the meeting (unless otherwise stated). However, the comments should be received at least one week prior to the meeting date so that the comments may be made available to the Committee for their consideration and public distribution. Written comments, one hard copy with original signature, should be provided to the contact person below. Written comments will be included in the meeting's Summary Report.

Contact Person for Additional Information: Rhonda Whalen, Chief, Laboratory Practice Standards Branch, Division of Laboratory Systems, Public Health Practice Program Office, CDC, 4770 Buford Highway, NE., Mailstop F–11, Atlanta, Georgia 30341–3717; telephone (770) 488–8042; fax (770) 488-8279; or via e-mail at *RWhalen@cdc.gov.*

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** Notices pertaining to announcements of meetings and other committee management activities, for CDC and the Agency for Toxic Substances and Disease Registry.

Dated: August 3, 2004.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 04–18992 Filed 8–18–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Agency for Toxic Substances and Disease Registry Public Meeting of the Citizens Advisory Committee on Public Health Service (PHS) Activities and Research at Department of Energy Sites (DOE): Oak Ridge Reservation Health Effects Subcommittee

Name: Public meeting of the Citizens Advisory Committee on PHS Activities and Research at DOE Sites: Oak Ridge Reservation Health Effects Subcommittee (ORRHES).

Time and Date: 12 p.m.–6:30 p.m., September 14, 2004.

Place: Oak Ridge Mall, Alpine Meeting Room, 333 East Main Street, Oak Ridge, Tennessee.

Background: Under a Memorandum of Understanding (MOU) was signed in October 1990 and renewed in September 2000 between ATSDR and DOE. The MOU delineates the responsibilities and procedures for ATSDR's public health activities at DOE sites required under sections 104, 105, 107, and 120 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or ''Superfund''). These activities include health consultations and public health assessments at DOE sites listed on, or proposed for, the Superfund National Priorities List and at sites that are the subject of petitions from the public; and other health-related activities such as epidemiologic studies, health surveillance, exposure and disease registries, health education, substance-specific applied research, emergency response, and preparation of toxicological profiles.

In addition, under an MOU signed in December 1990 with DOE and replaced by an MOU signed in 2000, the Department of Health and Human Services (HHS) has been given the responsibility and resources for conducting analytic epidemiologic investigations of residents of communities in the vicinity of DOE facilities, workers at DOE facilities, and other persons potentially exposed to radiation or to potential hazards from non-nuclear energy production and use. HHS, has delegated program responsibility to CDC. Community involvement is a critical part of ATSDR's and CDC's energy-related research and activities and input from members of the ORRHES is part of these efforts.

Purpose: The purpose of this meeting is to address issues that are unique to community involvement with the ORRHES, and agency updates.

Matters to be Discussed: Agenda items will include a presentation and discussion on the ORRHES Web site, and updates and recommendations from the Public Health Assessment, Communications and Outreach, Agenda, Guidelines and Procedures, and the Health Education Needs Assessment Workgroups, and agency updates.

Agenda items are subject to change as priorities dictate.

Contact Persons for More Information: Marilyn Horton, Designated Federal Official and Committee Management Specialist, Division of Health Assessment and Consultation, ATSDR, 1600 Clifton Road, NE M/S E–32 Atlanta, Georgia 30333, telephone 1–888–42–ATSDR (28737), fax (404) 498–1744.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and ATDSR.

Dated: August 13, 2004.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 04–18993 Filed 8–18–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[Document Identifier: CMS–10113]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare and Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS) (formerly known as the Health Care Financing Administration (HCFA)), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of currently approved collection.

Title of Information Collection: Application for Participation in Medicare Replacement Drug Demonstration.

Use: Section 641 of the MMA mandated a demonstration that would pay for drugs/biologicals prescribed as replacements for existing covered Medicare drugs. A report to Congress evaluating the impact of this demonstration was also mandated. In order to enroll in this demonstration, a beneficiary will be required to submit the application forms. Beneficiaries who wish to be considered for a low-income subsidy must also provide the information on the ''Application for Financial Assistance.''

Form Number: CMS–10113

OMB#: 0938–0924.

Frequency: One per beneficiary.

Affected Public: Individuals or Households.

Number of Respondents: 50,000.

Total Annual Responses: 50,000.

Total Annual Hours: 20,417.

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.gov/regs/prdact95.htm*, 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 at (410) 786–1326.

Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the CMS Paperwork Clearance Officer designated at the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances, Attention: Pam Gulliver, CMS–10113, Room C5–10–06, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: August 12, 2004.

John P. Burke, III,

Paperwork Reduction Act Team Leader, Office of Strategic Operations and Strategic Affairs, Division of Regulations Development and Issuances.

[FR Doc. 04–19017 Filed 8–18–04; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0204]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Patent Term Restoration, Due Diligence Petitions, Filing, Format, and Content of Petitions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by September 20, 2004.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Patent Term Restoration, Due Diligence Petitions, Filing, Format, and Content of Petitions—21 CFR Part 60 (OMB Control Number 0910–0233)—Extension

FDA's patent extension activities are conducted under the authority of the Drug Price Competition and Patent Term Restoration Act of 1984 and the Animal Drug and Patent Term Restoration Act of 1988 (35 U.S.C. 156). New human drugs, animal drugs, human, biological, medical device, food additive, or color additive products regulated by FDA must undergo FDA safety, or safety and effectiveness, review before marketing is permitted. Where the product is covered by a patent, part of the patent's term may be consumed during this review, which diminishes the value of the patent. In enacting 35 U.S.C. 156, Congress sought to encourage development of new, safer, and more effective medical and food additive products. It did so by authorizing the U.S. Patent and Trademark Office (PTO) to extend the patent term by a portion of the time during which FDA's safety and effectiveness review prevented marketing of the product. The length of the patent term extension is generally limited to a maximum of 5 years, and is calculated by PTO based on a statutory formula. When a patent holder submits an application for patent term extension to PTO, PTO requests information from FDA, including the length of the regulatory review period for the patented product. If PTO concludes that the product is eligible for patent term extension, FDA publishes a document in the **Federal Register**, which describes the length of the regulatory review period, and the dates used to calculate that period. Interested parties may request, under § 60.24 (21 CFR 60.24), revision of the length of the regulatory review period, or may petition under § 60.30 (21 CFR 60.30) to reduce the regulatory review period by any time where marketing approval was not pursued with ''due diligence.'' The statute defines due diligence as ''that degree of attention, continuous directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period.'' As provided in § 60.30(c), a due diligence petition ''shall set forth sufficient facts, including dates if possible, to merit an investigation by FDA of whether the applicant acted with due diligence.'' Upon receipt of a due diligence petition, FDA reviews the petition and evaluates whether any change in the regulatory review period is necessary. If so, the corrected regulatory review period is published in the **Federal Register**. A due diligence petitioner not satisfied with FDA's decision regarding the petition may, under § 60.40 (21 CFR 60.40), request an informal hearing for reconsideration of the due diligence determination. Petitioners are likely to include persons or organizations having knowledge that FDA's marketing permission for that product was not actively pursued throughout the regulatory review period. The information collection for which an extension of approval is being sought is the use of the statutorily created due diligence petition.

Since 1992, seven requests for revision of the regulatory review period