Dated: February 2, 2009.

Carolyn M. Clancy,

Director.

[FR Doc. E9–2680 Filed 2–9–09; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee to the Director, Centers for Disease Control and Prevention (ACD, CDC)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the CDC announces the following meeting of the aforementioned committee:

Time and Date: 3 p.m.–4:30 p.m., February 24, 2009.

Place: The teleconference call will originate at the CDC. For details on accessing the teleconference is located in the supplementary information.

Status: Open to the public, teleconference access limited only by availability of telephone ports.

Purpose: The committee will provide advice to the CDC Director on strategic and other broad issues facing CDC.

Matters to be Discussed: The Advisory Committee to the Director will discuss and decide on recommendations from its Ethics Subcommittee, National Biosurveillance Advisory Subcommittee, and Budget Workgroup. The Ethics Subcommittee will make recommendations on using travel restrictions for individuals with infectious illnesses. The Ethics Subcommittee will also discuss a draft charge that clearly articulates the ethical foundation for focusing on health protection activities and examining the social determinants of health. The National Biosurveillance Advisory Subcommittee will seek approval on recommendations for latitude to share specific points with key members of the new administration. The Budget Workgroup will provide recommendations around principles for change, in terms of the budget and the budget structure and process for the CDC.

Agenda items are subject to change as priorities dictate.

Supplementary Information: This conference call is scheduled to begin at 3 p.m. Eastern Standard Time. To participate in the teleconference, please dial 1 (888) 323–9787 and enter conference code 4735949.

Contact Person for More Information: Brad Perkins, M.D., M.B.A., Executive Officer, ACD, CDC, 1600 Clifton Road, NE., M/S D–14, Atlanta, Georgia 30333. *Telephone:* (404) 639–7000.

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 the CDC and the Agency for Toxic Substances and Disease Registry.

Dated: February 3, 2009.

Elaine L. Baker,

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

[FR Doc. E9–2805 Filed 2–9–09; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Assessing the Accuracy of Self-Report of HIV Testing Behavior, Program Announcement Number (PA) 09–002

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the aforementioned meeting.

Time and Date: 8 a.m.–5 p.m., March 20, 2009 (Closed).

Place: Sheraton Gateway Hotel, Atlanta Airport, 1900 Sullivan Road, Atlanta, GA 30337, Telephone (770) 997–1100.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters to be Discussed: The meeting will include the review, discussion, and evaluation of ''Assessing the Accuracy of Self-Report of HIV Testing Behavior, Program Announcement Number (PA) 09–002.''

Contact Person for More Information: Gregory Anderson, M.P.H., M.S., Scientific Review Administrator, Strategic Science and Program Unit, Office of the Director, Coordinating Center for Infectious Diseases, CDC, 1600 Clifton Road, Mailstop E–60, Atlanta, GA 30333, *Telephone:* (404) 498–2275.

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 the Agency for Toxic Substances and Disease Registry.

Dated: February 3, 2009.

Elaine L. Baker,

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

[FR Doc. E9–2803 Filed 2–9–09; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0339]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Updating Labeling for Susceptibility Test Information in Systemic Antibacterial Drug Products and Antimicrobial Susceptibility Testing Devices

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 March 12, 2009.

ADDRESSES: 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: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–NEW and title ''Guidance for Industry on Updating Labeling for Susceptibility Test Information in Systemic Antibacterial Drug Products and Antimicrobial Susceptibility Testing Devices.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3792.

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.

Guidance for Industry on Updating Labeling for Susceptibility Test Information in Systemic Antibacterial Drug Products and Antimicrobial Susceptibility Testing Devices

In the **Federal Register** of June 12, 2008 (73 FR 33438), FDA announced the availability of a draft guidance for

industry entitled ''Updating Labeling for Susceptibility Test Information in Systemic Antibacterial Drug Products and Antimicrobial Susceptibility Testing Devices.'' FDA is now in the process of finalizing this guidance.

The Food and Drug Administration Amendments Act of 2007 (FDAAA) includes a requirement that FDA identify and periodically update susceptibility test interpretive criteria for antibacterial drug products and make those findings publicly available. The guidance informs industry of how FDA intends to comply with the FDAAA requirement. Specifically, the guidance describes procedures and responsibilities for updating information on susceptibility test interpretive criteria, susceptibility test methods, and quality control parameters in the labeling for systemic antibacterial drug products for human use. The guidance also describes procedures for making corresponding changes to susceptibility test interpretive criteria for antimicrobial susceptibility testing devices.

Description of Respondents: Respondents to this collection of information are holders of new drug applications and abbreviated new drug applications.

Burden Estimate: Application holders can use one of the following approaches to meet their responsibilities to update their product labeling under the guidance and FDA regulations: (1) Submit a labeling supplement that relies upon a standard recognized by FDA in a **Federal Register** notice or (2) submit a labeling supplement that includes data supporting a proposed change to the microbiology information in the labeling. In addition, application holders should include in their annual report an assessment of whether the information in the *Microbiology* subsection of their product labeling is current or changes are needed. For human drugs, this information collection is already approved by OMB under control number 0910–0572 (the requirement in 21 CFR 201.56(a)(2) to update labeling when new information becomes available that causes the labeling to become inaccurate, false, or misleading) and OMB control number 0910–0001 (the requirement in 21 CFR 314.70(b)(2)(v) to submit labeling supplements for certain changes in the product's labeling and the requirement in 21 CFR 314.81(b)(2)(i) to include in the annual report a brief summary of significant new information from the previous year that might affect the labeling of the drug product).

In addition, under the guidance, if the information in the applicant's product labeling differs from the standards recognized by FDA in the **Federal Register** notice, and the applicant believes that changes to the labeling are not needed, the applicant should provide written justification to FDA explainimg why the recognized standard does not apply to its drug product and why changes are not needed to the *Microbiology* subsection of the product's labeling. This justification should be submitted as general correspondence to the product's application, and a statement indicating that no change is currently needed and the supporting justification should be included in the annual report. Based on our knowledge of the need to update information on susceptibility test interpretive criteria, susceptibility test methods, and quality control parameters in the labeling for systemic antibacterial drug products for human use, we estimate that, annually, only two applicants will submit the written justification described on the previous sentences and in the guidance. FDA also estimates that each justification will take approximately 16 hours to prepare and submit to FDA as general correspondence and as part of the annual report.

No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

Reporting Burden	No. of Respondents	No. of Responses per Respondent	Total Responses	Hours per Response	Total Hours
Justification submitted as general correspondence and in the annual report	2	1	2	16	32

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: January 26, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–2682 Filed 2–9–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2008–E–0103, FDA–2008–E–0110, FDA–2008–E–0113, and FDA–2008–E–0114]

Determination of Regulatory Review Period for Purposes of Patent Extension; LETAIRIS

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for LETAIRIS and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of Patents and Trademarks, Department of Commerce, for the extension of patents which claim that human drug product.

ADDRESSES: Submit written comments and petitions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993–0002, 301–796–3602.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.