on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project 1. Survey of Grant Recipients—NEW—The Office of Grants and Acquisition Management (OGAM) in compliance with Executive Order 12862 conduct surveys to collect data from grant recipients regarding the performance of the grants management operations of the Department's Operating Divisions (OPDIVs) and their awarding components. These surveys will provide OGAM and OPDIVs and their awarding components a necessary tool for the evaluation of the awarding components' operational performance. Respondents: State and local government, Businesses or other for profit organizations, non-profit institutions, small businesses; *Total Annual Number of Respondents:* 2,667; *Frequency of Response:* one time; *Average Burden per Response:* 15 minutes; Estimated Annual Burden 667 hours.

Send comments to Cynthia Agens Bauer, OS Reports Clearance Officer, Room 503H, Humphrey Building, 200 Independence Avenue S.W., Washington DC, 20201. Written comments should be received within 60 days of this notice.

Dated: March 1, 2000.

Dennis P. Williams,

Deputy Assistant Secretary, Budget.

[FR Doc. 00–5636 Filed 3–7–00; 8:45 am]

BILLING CODE 4150–04–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Citizens Advisory Committee on Public Health Service Activities and Research at Department of Energy (DOE) Sites: Fernald Health Effects Subcommittee

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Agency for Toxic Substances and Disease Registry (ATSDR) and the Centers for Disease Control and Prevention (CDC) announce the following meeting.

NAME: Citizens Advisory Committee on Public Health Service Activities and Research at DOE Sites: Fernald Health Effects Subcommittee.

TIMES AND DATES: 1 pm—8:30 p.m., March 22, 2000. 9 am—5 p.m., March 23, 2000.

PLACE: The Plantation, 9660 Dry Fork Road, Harrison, Ohio 45020, telephone 513/367–5610.

STATUS: Open to the public, limited only by the space available. The meeting room accommodates approximately 50 people.

BACKGROUND: Under a Memorandum of Understanding (MOU) signed in December 1990 with DOE and replaced by an MOU signed in 1996, the Department of Health and Human Services (HHS) was given the responsibility and resources for conducting 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 use. HHS delegated program responsibility to CDC.

In addition, a memo was signed in October 1990 and renewed in November 1992 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 form 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.

PURPOSE: This subcommittee is charged with providing advice and recommendations to the Director, CDC, and the Administrator, ATSDR, regarding community, American Indian Tribes, and labor concerns pertaining to CDC's and ATSDR's public health activities and research at this DOE site. The purpose of this meeting is to provide a forum for community, American Indian Tribal, and labor interaction and serve as a vehicle for community concern to be expressed as advice and recommendations to CDC and ATSDR.

MATTERS TO BE DISCUSSED: Agenda items include presentations from ATSDR on the draft public health assessment and the Fernald uranium recycle sources and potential exposures at Fernald from major constituents; a report from ATSDR on the Health Professionals Seminar; a progress report from the University of Cincinnati on radon and cigarette smoking assessment in Fernald workers; a presentation on cancer mortality due to radiation and chemical exposure among Fernald workers; and a discussion of the evaluation project progress.

Agenda items are subject to change as priorities dictate.

CONTACT PERSONS FOR MORE INFORMATION: Mike R. Donnelly, Radiation Studies Branch, Division of Environmental Hazards and Health Effects, National Center for Environmental Health, CDC, 1600 Clifton Road, NE, M/S E–39, Atlanta, Georgia 30333, telephone 404/639–2550, fax 404/639–2575.

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 ATSDR.

Dated: March 2, 2000.

Carolyn J. Russell,

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

[FR Doc. 00–5584 Filed 3–7–00; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Head Start Grant Application and Budget Instrument

OMB No.: 0970–0207

Description: The Head Start program is promulgating a Head Start Grant Application and Budget Instrument to standardize the grant application information which is also instituting a three year grant funding cycle so that applications will only submit full applications in their first year of their three year funding cycle. In addition, the Grant Application and Budget Instrument will be available on a data disk and can be transmitted electronically to Regional Offices. The Administration Children, Youth and Families believes that, in promulgating this application document, the process of applying for grants for the Head Start program will be more efficient for the applicants.

Respondents: Head Start Grantees.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Head Start GABI	1,513	1	33	49,929

Estimated Total Annual Burden Hours: 49,929.

Additional Information: Copies of the proposed collection may be obtained by writing to The Administration for Children and Families, Office of Information Services, Division of Information Resource Management Services, 370 L'Enfant Promenade, SW, Washington, DC 20447, Attn: ACF Reports Clearance Officer.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW, Washington, DC 20503, Attn: Desk Officer for ACF.

Dated: March 2, 2000.

Bob Sargis,

Reports Clearance Officer.

[FR Doc. 00–5540 Filed 3–7–00; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00B–0108]

Microbiology Devices; Reclassification of Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility Devices From Class III to Class II

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of panel recommendation.

SUMMARY: The Food and Drug Administration (FDA) is announcing for public comment the recommendation of the Microbiology Devices Panel (the Panel) to reclassify the fully automated short-term incubation cycle antimicrobial susceptibility devices from class III to class II. The Panel made this recommendation after reviewing the reclassification petition submitted by bioMeAE1rieux Vitek, Inc., and other publicly available information. FDA is also announcing for public comment its tentative findings on the Panel's recommendation. After considering any public comments on the Panel's recommendation and FDA's tentative findings, FDA will approve or deny the reclassification petition by order in the form of a letter to the petitioner. FDA's decision on the reclassification petition will be announced in the **Federal Register**. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of availability of a guidance document that would serve as a special control for the reclassified device.

DATES: Submit written comments by June 7, 2000.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Joseph L. Hackett, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3084.

SUPPLEMENTARY INFORMATION:

I. Background (Regulatory Authorities)

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94–295), the Safe Medical Devices Act of 1990 (Pub. L. 101–629), and the FDA Modernization Act of 1997 (Pub. L. 105–115), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), generally referred to as preamendments devices, are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976, generally referred to as postamendments devices, are classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until the device is reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, under section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously offered devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR part 807 of the regulations.

A preamendments device that has been classified into class III may be marketed, by means of premarket notification procedures, without submission of a premarket approval application until FDA issues a final regulation under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval.

Reclassification of classified postamendments devices is governed by section 513(f)(2) of the act. This section provides that FDA may initiate the reclassification of a device classified into class III under section 513(f)(1) of the act, or the manufacturer or importer of a device may petition the Secretary of Health and Human Services (the Secretary) for the issuance of an order classifying the device in class I or class II. FDA's regulations in § 860.134 (21 CFR 860.134) set forth the procedures for the filing and review of a petition for reclassification of such class III devices. In order to change the classification of the device, it is necessary that the