We are requesting emergency clearance of a pilot study designed to elicit information from discharged patients concerning their hospital/acute care experience. Given the current momentum, enthusiasm and support expressed by hospitals and the hospital associations for public reporting of hospital quality information, it is important to provide the tools needed for reliable and valid data collection as soon as possible. CMS would like to take advantage of the opportunity of testing the H–CAHPS instrument in the Hospital State Pilots that has just started. It is important to provide hospitals a standard tool and data collection methodology by July/August 2003 to support this joint initiative. We are interested in receiving comments on the pilot during the course of the pilot, as well as during the comment period mentioned below. However, those received after the close of the comment period will not be included in the materials that OMB reviews in determining whether to approve the collection.

CMS is requesting OMB review and approval of this collection by February 21, 2003, with a 180-day approval period. Written comments and recommendations will be accepted from the public if received by the individuals designated below by February 20, 2003. During this 180-day period, we will publish a separate **Federal Register** notice announcing the initiation of an extensive 60-day agency review and public comment period on these requirements. We will submit the requirements for OMB review and an extension of this emergency approval.

Type of Information Collection Request: New collection; *Title of Information Collection:* Pilot Test of Hospital CAHPS Survey; *Form No.:* CMS–10083 (OMB #0938–XXXX); *Use:* CMS has requested a hospital survey as a way of providing comparison information for consumers who need to select a hospital and as a way of encouraging accountability of hospitals for the care they provide. With a standardized instrument consumers will be able to make ''apples to apples'' comparisons among hospitals, allow hospitals and hospital chains to self compare, and provide state oversight officials with useful data. A standardized instrument, developed under the CAHPS umbrella, will produce a reliable and valid instrument that any organization can use at no cost to obtain patient data about hospital experiences. This tool will be adopted by the National Hospital Voluntary Initiative; *Frequency:* Once; *Affected Public:* Individuals or households; *Number of Respondents:* 16,500; *Total Annual Responses:* 16,500; *Total Annual Hours:* 5,500.

We have submitted a copy of this notice to OMB for its review of these information collections. A notice will be published in the **Federal Register** when approval is obtained.

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://cms.hhs.gov/regulations/pra/default.asp* or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@hcfa.gov,* or call the Reports Clearance Office on (410) 786–1326.

Interested persons are invited to send comments regarding the burden or any other aspect of these collections of information requirements. However, as noted above, in order to be considered in the OMB approval process, comments on these information collection and recordkeeping requirements must be mailed and/or faxed to the designees referenced below, by February 20, 2003.

Centers for Medicare and Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances, Attn: Reports Clearance Officer, Room C5–16–03, 7500 Security Boulevard, Baltimore, MD 21244–1850. Fax Number: (410) 786–3064. Attn: Julie Brown; and

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Fax Number: (202) 395–6974 or (202) 395–5167, Attn: Brenda Aguilar, CMS Desk Officer.

Dated: January 30, 2003.

John P. Burke, III,

CMS Reports Clearance Officer, CMS, Office of Information Services, Security and Standards Group, Division of CMS Enterprise Standards.

[FR Doc. 03–2788 Filed 2–4–03; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–0109]

Medical Devices: Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test Systems; Guidance for Industry and FDA; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA.'' This guidance document was developed as a special control guidance to support the reclassification of the fully automated short-term incubation cycle antimicrobial susceptibility device from class III to class II. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule reclassifying the fully automated short-term incubation cycle antimicrobial susceptibility device from class III to class II.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance entitled ''Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. Submit written comments concerning this guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. Submit electronic comments to *http://www.fda.gov//dockets/ecomments.* See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Freddie M. Poole, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2096.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance document was developed as a special control guidance to support the reclassification of the fully automated short-term incubation cycle antimicrobial susceptibility device from class III to class II. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule to reclassify

this type of device from class III to class II. This guidance serves to update the information provided in the draft guidance entitled ''Guidance on Review Criteria for Assessment of Antimicrobial Susceptibility Devices'' (65 FR 12271, March 8, 2000). FDA considered the comments it received and made changes to the guidance as a result, including the revised document title to identify this guidance as a special control. FDA believes that special controls, when combined with the general controls, will be sufficient to provide reasonable assurance of the safety and effectiveness of the fully automated short-term incubation cycle antimicrobial susceptibility device. After the device is reclassified, a manufacturer who intends to market a device of this generic type must: (1) Comply with the general controls of the Federal Food, Drug, and Cosmetic Act, including the 510(k) requirements described in 21 CFR 807.81, (2) address the specific risks to health associated with the antimicrobial susceptibility test system, and (3) receive a substantial equivalence determination from FDA prior to marketing the device.

This guidance document identifies the classification, product code, and classification definition for fully automated short-term incubation cycle antimicrobial susceptibility devices. In addition, it identifies the risks to health and serves as a special control that, when followed and combined with the general controls of the act, will be sufficient to address the risks associated with this generic device type and lead to a timely review and clearance of a premarket notification under section 510(k) of the act (21 U.S.C. 360(k)).

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance represents the agency's current thinking on AST systems. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statutes and regulations. Following the effective date of the final classification rule (published elsewhere in this issue of the **Federal Register**), any firm submitting a 510(k) premarket notification for a fully automated short-term incubation cycle antimicrobial susceptibility device will need to address the issues covered in the special control guidance. However, the firm need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness.

III. Electronic Access

In order to receive ''Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA,'' you may either send a fax request to 301–443–8818 to receive a hard copy of the document, or send an e-mail to *GWA@CDRH.FDA.GOV* to request a hard copy or electronic copy. Please use the document number (631) to identify the guidance you are requesting.

Persons interested in obtaining a copy of the guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes the civil money penalty guidance documents package, device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH home page may be accessed at *http://www.fda.gov/cdrh*. Guidance documents are also available on the Dockets Management Branch Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Comments

Interested persons may submit to Dockets Management Branch (see **ADDRESSESS**) written or comments regarding this guidance. Two copies of any mailed comments, are to be submitted except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Electronic comments may be submitted at *http://www.fda.gov/opacom/backgrounders/voice.html*. The guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 9, 2003.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 03–2657 Filed 2–4–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Committee on Rural Health and Human Services; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given that the following committee will convene its forty-third meeting. The meeting will be open to the public.

Name: National Advisory Committee on Rural Health and Human Services.

Date and Time: March 2, 2003, 2 p.m.–5 p.m.; March 3, 2003, 8:30 a.m.–5 p.m.; March 4, 2003, 8:30 a.m.–3 p.m.

Place: Grand Hyatt Washington, 1000 H Street, NW., Washington, DC 20001–4520.

Purpose: The National Advisory Committee on Rural Health and Human Services provides advice and recommendations to the Secretary with respect to the delivery, research, development and administration of health and human services in rural areas.

Agenda: Sunday afternoon, March 2, at 2 p.m., the Chairperson, the Honorable David Beasley, will open the meeting and welcome the Committee. The first session will open with a discussion of the Meeting Agenda and Goals by the Office of Rural Health Policy (ORHP) Acting Deputy Director, Mr. Tom Morris. This will be followed by a discussion of the Committee's role in the Department, administrative business, and the Committee's 2003 Agenda.

Monday morning, March 3, at 8:30 a.m. the session will open with a presentation by the Deputy Administrator, Health Resources and Services Administration, and an update by ORHP. After the break, the Committee will discuss and approve the 2002 projects, the report on rural health care quality and the white paper on the rural workforce. After lunch, there will be presentations on three topics relating to the Committee's 2003 workplan.

The final session will be convened Tuesday morning, March 4, at 8:30 a.m. The Committee will discuss the strategic plan, future agenda, and the selection of a Steering Committee. The strategic planning will continue after lunch. The meeting will conclude with a discussion of the June and September meetings. The meeting will be adjourned at 3 p.m.

FOR FURTHER INFORMATION CONTACT: Anyone requiring information regarding the Committee should contact Tom Morris, MPA, Executive Secretary, National Advisory Committee on Rural Health and Human Services, Health Resources and Services Administration, Parklawn Building, Room 9A–55, 5600 Fishers Lane, Rockville, MD 20857, telephone (301) 443–0835, Fax (301) 443–2803.