

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 This guidance serves to update the information provided in the draft guidance entitled "Guidance on Review Criteria for Assessment of Antimicrobial Susceptibility Devices" (65 FR 12271, March 8, 2000).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 **ADDRESSES**) 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.