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 This guidance serves to update the information provided in the draft guidance entitled ''Guidance on Review Criteria for Assessment of Antimicrobial Susceptibility Devices'' (65 FR 12271, March 8, 2000).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

Persons interested in attending any portion of the meeting should contact Michele Pray-Gibson, Office of Rural Health Policy (ORHP), telephone (301) 443–0835. The Committee meeting agenda will be posted on ORHP's Web site *http://www.ruralhealth.hrsa.gov*.

Dated: January 29, 2003.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 03–2659 Filed 2–4–03; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program; List of Petitions Received

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (''the Program''), as required by Section 2112(b)(2) of the Public Health Service (PHS) Act, as amended. While the Secretary of Health and Human Services is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute with responsibility for considering and acting upon the petitions.

FOR FURTHER INFORMATION CONTACT: For information about requirements for filing petitions, and the Program in general, contact the Clerk, United States Court of Federal Claims, 717 Madison Place, NW., Washington, DC 20005; (202) 219–9657. For information on HRSA's role in the Program, contact the Director, National Vaccine Injury Compensation Program, 5600 Fishers Lane, Room 16C–17, Rockville, MD 20857; (301) 443–6593.

SUPPLEMENTARY INFORMATION: The Program provides a system of no-fault compensation for certain individuals who have been injured by specified childhood vaccines. Subtitle 2 of Title XXI of the PHS Act, 42 U.S.C. 300aa–10 *et seq.*, provides that those seeking compensation are to file a petition with the U.S. Court of Federal Claims and to serve a copy of the petition on the Secretary of Health and Human Services, who is named as the respondent in each proceeding. The Secretary has delegated his responsibility under the Program to HRSA. The Court is directed by statute to appoint special masters who take evidence, conduct hearings as appropriate, and make initial decisions as to eligibility for, and amount of, compensation.

A petition may be filed with respect to injuries, disabilities, illnesses, conditions, and deaths resulting from vaccines described in the Vaccine Injury Table (the Table) set forth at Section 2114 of the PHS Act or as set forth at 42 CFR 100.3, as applicable. This Table lists for each covered childhood vaccine the conditions which will lead to compensation and, for each condition, the time period for occurrence of the first symptom or manifestation of onset or of significant aggravation after vaccine administration. Compensation may also be awarded for conditions not listed in the Table and for conditions that are manifested after the time periods specified in the Table, but only if the petitioner shows that the condition was caused by one of the listed vaccines.

Section 2112(b)(2) of the PHS Act, 42 U.S.C. 300aa–12(b)(2), requires that the Secretary publish in the **Federal Register** a notice of each petition filed. Set forth below is a list of petitions received by HRSA on July 1, 2002, through September 30, 2002.

Section 2112(b)(2) also provides that the special master ''shall afford all interested persons an opportunity to submit relevant, written information'' relating to the following:

1. The existence of evidence ''that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition,'' and

2. Any allegation in a petition that the petitioner either:

(a) ''Sustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Table but which was caused by'' one of the vaccines referred to in the Table, or

(b) ''Sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Table the first symptom or manifestation of the onset or significant aggravation of which did not occur within the time period set forth in the Table but which was caused by a vaccine'' referred to in the Table.

This notice will also serve as the special master's invitation to all interested persons to submit written information relevant to the issues described above in the case of the petitions listed below. Any person choosing to do so should file an original and three (3) copies of the information with the Clerk of the U.S. Court of Federal Claims at the address listed above (under the heading ''For Further Information Contact''), with a copy to HRSA addressed to Director, Division of Vaccine Injury Compensation Program, Office of Special Programs, 5600 Fishers Lane, Room 16C–17, Rockville, MD 20857. The Court's caption (Petitioner's Name v. Secretary of Health and Human Services) and the docket number assigned to the petition should be used as the caption for the written submission.

Chapter 35 of title 44, United States Code, related to paperwork reduction, does not apply to information required for purposes of carrying out the Program.

List of Petitions

1. Carla Lowry on behalf of Tyler Lowry; Boston, Massachusetts; Court of Federal Claims Number 02–0753V
2. Scott Bagby on behalf of Trenton Bagby; Adrian, Missouri; Court of Federal Claims Number 02–0754V
3. Allison and Kenneth Byrd on behalf of Noah Byrd; California, Maryland; Court of Federal Claims Number 02–0755V
4. Barbara and William Whitman on behalf of Christian Whitman; Taylor, Pennsylvania; Court of Federal Claims Number 02–0763V
5. Kimberly Brox on behalf of Mary Kate Brox; Boston, Massachusetts; Court of Federal Claims Number 02–0765V
6. Kathy Maynard on behalf of Mikayla Maynard; Lecanto, Florida; Court of Federal Claims Number 02–0766V
7. Sandra Friedman; Shorewood, Wisconsin; Court of Federal Claims Number 02–0770V
8. Rhonda and Robert Evans on behalf of Kimberly Ann Evans; Fayetteville, North Carolina; Court of Federal Claims Number 02–0771V
9. Lisa and John Hedin on behalf of Jason Hedin; Austell, Georgia; Court of Federal Claims Number 02–0774V
10. AnnMarie and H. Dean Moore on behalf of Kathryn Moore; Philadelphia, Pennsylvania; Court of Federal Claims Number 02–0777V
11. Susan Iannuzzi on behalf of Peter Iannuzzi; Boston, Massachusetts; Court of Federal Claims Number 02–0780V
12. Alyson Feinberg on behalf of Jacob Feinberg; Boston, Massachusetts; Court of Federal Claims Number 02–0781V
13. Charles Wall on behalf of Christopher Wall; Boston,