and met with stakeholders in December 2002 to seek their input.

The guidance was initiated in response to industry's request for a formal dispute resolution process to resolve differences related to scientific and technical issues that arise between investigators and pharmaceutical manufacturers during FDA inspections. In addition to encouraging manufacturers to use currently available dispute resolution processes, the guidance describes a formal two-tiered dispute resolution process that provides a mechanism for requesting review and decision on issues that arise during inspections.

On September 5, 2003 (68 FR 52777), the FDA announced the availability of the draft version of this guidance. The public comment period closed on March 5, 2004. A number of comments were received, which the agency considered carefully as it finalized the guidance and made appropriate changes. The agency conducted a pilot program with industry for a 12-month period. During that time, the agency received one Tier 1 request for dispute resolution and it was resolved. In addition, FDA met with representatives from industry trade associations in September 2004, near the end of the pilot period, to discuss the draft guidance and receive input.

Most of the changes to the guidance were made to clarify statements in the draft guidance. The following changes in the final guidance are noteworthy: (1) The time period for manufacturers to ask for clarification of a disputed scientific or technical issue was extended from 10 to 30 days; (2) if a request for formal dispute resolution reaches the agency's Dispute Resolution Panel and is considered appropriate for review, the panel will schedule a meeting to discuss the issue within 90 days of the request instead of the indefinite time period indicated in the draft guidance; (3) the guidance directs manufacturers to the Center for Devices and Radiological Health for disputes involving combination products when medical device components are the focus of the dispute, but clarifies that disputes solely involving medical devices are outside the scope of this guidance; and (4) the guidance clarifies that, during the dispute resolution process, a manufacturer may include relevant information that was not presented during the inspection, if FDA determines that a reasonable explanation was given on why the information was not presented during the inspection.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on formal dispute resolution: scientific and technical issues related to pharmaceutical CGMP. 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 requirements of the applicable statutes and regulations.

## II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

## III. The Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in this guidance was approved under OMB control number 0910–0563.

## IV. Electronic Access

Persons with access to the Internet may obtain the guidance document at the following *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm* or *http://www.fda.gov/cber/guidelines.htm* or *http://www.fda.gov/cvm/guidance/guidance.html*.

Dated: January 4, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E6–233 Filed 1–11–06; 8:45 am]

**BILLING CODE 4160–01–S**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### National Advisory Council on Migrant Health; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

*Name:* National Advisory Council on Migrant Health.

*Dates and Times:* January 30, 2006, 9 a.m. to 5 p.m. January 31, 2006, 9 a.m. to 5 p.m.

*Place:* 5600 Fishers Lane, Conference Room C, 3rd Floor, Rockville, Maryland 20857.

*Status:* The meeting will be open to the public.

*Agenda:* The agenda includes an overview of the Council's general business activities. The Council will also develop recommendations to the Secretary of Health and Human Services. Finally, the Council will hear presentations from experts on farmworker issues, including the status of farmworker health at the local and national level.

Agenda items are subject to change as priorities indicate.

*For Further Information Contact:* Anyone requiring information regarding the Council should contact Gladys Cate, Office of Minority and Special Populations, staff support to the National Advisory Council on Migrant Health, Bureau of Primary Health Care, Health Resources and Services Administration, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 594–0367.

Dated: January 5, 2006.

**Tina M. Cheatham,**

*Director, Division of Policy Review and Coordination.*

[FR Doc. E6–171 Filed 1–11–06; 8:45 am]

**BILLING CODE 4165–15–P**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

### Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the