

**ADDRESSES:** Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Peter C. Beckerman, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4238, Silver Spring, MD 20993. 301-796-4830. FAX: 301-847-3541. *e-mail:* [peter.beckerman@fda.hhs.gov](mailto:peter.beckerman@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In the *Federal Register* of August 9, 2010 (75 FR 47820), FDA published a notice of a public meeting on the development of a generic drug user fee program. In that notice, FDA posed several questions related to a user fee for human generic drugs, and sought public input on such a program. The Agency received submissions and presentations from the public meeting, which are now posted on FDA's Web site. In the *Federal Register* of November 4, 2010 (75 FR 67984), FDA subsequently reopened the comment period for 30 days to allow consideration of submissions received after the original docket closing date. Because FDA has since received multiple requests to reopen the docket, including requests from generic industry segments that did not previously comment, FDA has decided to reopen the docket to permit public input on all the submissions.

Interested persons were originally given until October 17, 2010, to comment on the development of a generic drug user fee program. FDA is now reopening the docket to permit comment until February 23, 2011.

**II. Request for Comments**

FDA has received several requests to allow interested persons additional time to comment. The requesters represent manufacturers of active pharmaceutical ingredients who did not previously respond to FDA's specific requests for comments. In light of these requests, FDA is reopening the comment period for an additional 30 days.

**III. How To Submit Comments**

Regardless of attendance at the public meeting interested persons may submit either electronic or written comments to the Division of Dockets Management (*see ADDRESSES*). It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments 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.

Dated: January 18, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-1274 Filed 1-21-11; 8:45 am]

**BILLING CODE 4160-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2010-N-0620]

**The National Antimicrobial Resistance Monitoring System Strategic Plan 2011-2015; Request for Comments**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability for public comment of a document for The National Antimicrobial Resistance Monitoring System (NARMS) entitled "NARMS Strategic Plan 2011-2015." The document outlines the strategic goals and objectives for 2011 through 2015 of the NARMS program developed by the participating Agencies (FDA, the Centers for Disease Control and Prevention (CDC), and the United States Department of Agriculture (USDA)) based on recommendations of an External Subcommittee of the Science Board to FDA. The Agency is soliciting public comment on the goals and objectives in the Strategic Plan and whether the goals and objectives meet the recommendations of the subcommittee.

**DATES:** Submit either electronic or written comments by March 25, 2011.

**ADDRESSES:** Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Patrick McDermott, Center for Veterinary Medicine (HFV-530), Food and Drug Administration, 8401 Muirkirk Rd., Laurel, MD 20708. 301-210-4213. *e-mail:* [patrick.mcdermott@fda.hhs.gov](mailto:patrick.mcdermott@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

NARMS is a national public health surveillance program that monitors the

susceptibility of enteric bacteria to antimicrobial agents of medical importance. The NARMS program, established in 1996, is a collaboration between FDA, CDC, USDA, and State and local health departments. NARMS also has established collaborations with scientists and surveillance systems monitoring antimicrobial resistance in other countries.

Foodborne diseases are an important cause of morbidity and mortality worldwide. Travel, migration, and distribution of contaminated food contribute to the problem of foodborne diseases. Non-typhoidal *Salmonella* and *Campylobacter* are the leading bacterial causes of foodborne illness in the United States and many countries. Each year over two million people in the United States are infected with these bacteria, resulting in tens of thousands of hospitalizations and hundreds of deaths. Certain populations, such as young children (<5 years), the elderly, and the immunocompromised, are at higher risk for infection. Most *Salmonella* and *Campylobacter* infections are self-limited, but antimicrobial agents are essential to treat severe illness. Antimicrobial resistance occurs among bacterial foodborne pathogens and is recognized as a global public health hazard. NARMS monitors antimicrobial susceptibility in enteric bacteria from humans, retail meats, and food-producing animals. The human isolate component of NARMS was initiated in 1996, and at that time tested only non-typhoidal *Salmonella* and *Escherichia coli* O157 isolates. In 1997, testing of *Campylobacter* isolates began, followed by *Salmonella* serotype Typhi and *Shigella* in 1999. The animal component of NARMS started in 1997, with monitoring of *Salmonella* isolated from chicken, turkey, cattle, and swine carcasses, and later expanded to include *Campylobacter* (1998), *E. coli* (2000), and *Enterococcus* (2003) isolated from chicken carcasses. The retail meat component of NARMS started in 2002 with testing of *Salmonella*, *Campylobacter*, *E. coli*, and *Enterococcus* isolates from meat commodities sold in retail stores.

In addition to monitoring, NARMS conducts epidemiologic and microbiologic research studies. Some studies examine risk factors and clinical outcomes of infections with specific bacterial serotypes or subsets of bacteria that exhibit particular resistance patterns. NARMS research studies also focus on understanding the genetic mechanisms of antimicrobial resistance in enteric bacteria and the mechanisms that permit the transfer of resistance

between bacteria, on improving methods for isolation and typing, and on developing new methods for antimicrobial susceptibility testing. Additionally, NARMS examines enteric bacteria for genetic interrelatedness using methods such as pulsed-field gel electrophoresis (PFGE) and multilocus sequence typing. NARMS scientists enter PFGE results into CDC's PulseNet database or USDA's VetNet database.

In March 2007, an External Subcommittee of the Science Board to FDA conducted a review of the NARMS program. This subcommittee made recommendations related to four areas of work performed by NARMS: (1) Sampling, (2) research, (3) international activities, and (4) data management and reporting. Included in the report was a recommendation to develop long-range strategic plans. In September 2008, NARMS held an interagency planning meeting in Athens, GA to prioritize the Science Board subcommittee's recommendations and implement measures to address them. In August 2009, a second meeting was held in Rockville, MD to report on progress, and to begin formulating the Strategic Plan that is the subject of this notice.

NARMS has established four strategic goals: (1) To develop, implement, and optimize a shared database, with advanced data acquisition, analysis, and reporting tools; (2) to make sampling more representative and more applicable to trend analysis; (3) to strengthen collaborative research projects; and (4) to support international activities that promote food safety, especially those that promote mitigation of the spread of antimicrobial-resistant bacteria and resistance determinants. These four goals are discussed more fully in the Strategic Plan and build on the progress made since NARMS' inception, with special emphasis on the recommendations made by the FDA Science Board subcommittee based on its review of the NARMS program in 2007.

## II. Comments

Interested persons may submit to the Division of Dockets Management (*see ADDRESSES*) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments 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. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/NationalAntimicrobialResistanceMonitoringSystem/default.htm> or <http://www.regulations.gov>.

Dated: January 11, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Advisory Committee on Interdisciplinary, Community-Based Linkages; 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:* Advisory Committee on Interdisciplinary, Community-Based Linkages (ACICBL).

*Dates and Times:* February 24, 2011, 8:30 a.m. to 5 p.m., EST. February 25, 2011, 8:30 a.m. to 4 p.m., EST.

*Place:* Hyatt Regency Bethesda, One Bethesda Metro Center (7400 Wisconsin Avenue), Bethesda, Maryland 20814. Telephone: (301) 657-1234.

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

*Purpose:* The members of the ACICBL will advance the planning required to develop their 11th Annual Report for the Secretary of the Department of Health and Human Services (the Secretary) and Congress, using the working topic, Continuing Education, Professional Development and Lifelong Learning for the 21st Century Health Care Workforce. The meeting will provide the planning and writing sub-committees with the opportunity to review the urgent issues related to the training programs, identify resources that will address the gaps and further strengthen the outcomes from these efforts, examine testimony from the experts in the field, and offer recommendations for improvement of these training programs to the Secretary and the Congress.

*Agenda:* The ACICBL agenda includes an overview of the Committee's general business activities, presentations by and dialogue with experts, and discussion sessions specific to the development of recommendations to be addressed in the 11th Annual ACICBL Report. Agenda items are subject to change as dictated by the priorities of the Committee.

*Supplementary Information:* Requests to make oral comments or to provide written comments to the ACICBL should be sent to Dr. Joan Weiss, Designated Federal Official,

at the contact information below. Individuals who plan to attend the meeting and need special assistance should notify Dr. Weiss at least 10 days prior to the meeting, using the address and phone number below. Members of the public will have the opportunity to provide comments at the meeting.

*For Further Information Contact:* Anyone requesting additional details should contact Dr. Joan Weiss, Designated Federal Official, within the Bureau of Health Professions of the Health Resources and Services Administration. Dr. Weiss may be reached in one of three following methods: (1) Via written request to: Dr. Joan Weiss, Designated Federal Official, Bureau of Health Professions, Health Resources and Services Administration, Parklawn Building, Room 9-36, 5600 Fishers Lane, Rockville, Maryland 20852; (2) via telephone at (301) 443-6950 or (3) via e-mail at [jweiss@hrsa.gov](mailto:jweiss@hrsa.gov). In the absence of Dr. Weiss, CAPT Norma J. Hatot, Senior Nurse Consultant, may be contacted via telephone at (301) 443-2681 or by e-mail at [nhatot@hrsa.gov](mailto:nhatot@hrsa.gov).

Dated: January 18, 2011.

**Robert Hendricks,**

*Director, Division of Policy and Information Coordination.*

[FR Doc. 2011-1349 Filed 1-21-11; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Center for Research Resources; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Center for Research Resources Special Emphasis Panel.  
*Date:* March 1, 2011.

*Time:* 12 p.m. to 2 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Conference Room 989, Bethesda, MD 20892.

*Contact Person:* Martha F. Matocha, PhD, Scientific Review Officer, Office of Review, National Center for Research Resources, National Institutes of Health, 6701 Democracy Blvd., 1 Democracy Plaza, Rm.