SUPPLEMENTARY INFORMATION:

I. Background

The purpose of this public workshop is to provide an opportunity for relevant stakeholders, including clinicians, academia, industry, and FDA, to discuss alternative trial designs for product development in pediatric heart failure.

II. Topics for Discussion at the Public Workshop

Specifically, the workshop will include application of pediatric extrapolation in drug development for pediatric heart failure and a discussion of alternative approaches to establishing effectiveness in pediatric heart failure, including the use of Bayesian approaches. Cases will be presented to exemplify various approaches.

The agenda is located at *http://www.cersi.umd.edu/events/index.php?mode=4&id=12500.*

III. Participating in the Public Workshop

Registration: To register for the public workshop, visit the following Web site: *http://www.cersi.umd.edu/events/index.php?mode=4&id=12500.* Registrants will receive confirmation when they have been accepted. There will be no onsite registration.

There is a registration fee to attend this public workshop in person. Seats are limited and registration will be on a first-come, first-served basis. The cost to attend in person is as follows:

Category	Cost
Industry Representative	$50
Nonprofit Organization and Academic Other Than University of Maryland	50
University of Maryland, College Park and Baltimore	0
Federal Government	0

If you need special accommodations due to a disability, please contact Jacquline Yancy (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance.

Streaming Webcast of the Public Workshop: This public workshop will also be webcast. There is no registration fee for attending the workshop via the webcast, but registration is still required. Information regarding access to the webcast link is available at *http://www.cersi.umd.edu/events/index.php?mode=4&id=12500.*

If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *https://www.adobe.com/go/connectpro_overview.* FDA has verified the Web site addresses in this document, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff Office (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: September 15, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–20106 Filed 9–20–17; 8:45 a.m.]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–5056]

2017 Scientific Meeting of the National Antimicrobial Resistance Monitoring System; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we), together with the NARMS partner agencies, is announcing a public meeting entitled ''2017 Scientific Meeting of the National Antimicrobial Resistance Monitoring System.'' The purpose of the public meeting is to discuss the current status of the National Antimicrobial Resistance Monitoring System (NARMS) and directions for the future.

DATES: The public meeting will be held on October 24 and 25, 2017, from 8:30 a.m. to 5 p.m. Eastern Time. Submit either electronic or written comments on this public meeting by November 24, 2017. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held at the Jefferson Auditorium in the South Building, U.S. Department of Agriculture (USDA), 14th and Independence Avenue SW., Washington, DC 20250. The South Building is a Federal facility, and attendees should plan adequate time to pass through the security screening systems. Attendance is free. Non-USDA employees must enter through the Wing 3 entrance on Independence Avenue. Attendees must be pre-registered for the meeting (and check-in outside the day of the meeting) and show a valid photo ID to enter the building. Only registered attendees will be permitted to enter the building. For parking and security information, please refer to *https://smithsonianassociates.org/ticketing/help/locations/jefferson.htm.*

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before November 24, 2017. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of November 24, 2017. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2017–N–5056 for ''2017 Scientific Meeting of the National Antimicrobial Resistance Monitoring System; Public Meeting; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Laura Bradbard, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl. (HFV–1), Rockville, MD 20855, 240–402–5672, email: *laura.bradbard@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background and Topics for Discussion

NARMS periodically conducts public meetings to inform stakeholders of NARMS activities and receive comments on ways to improve. The last NARMS public meeting (held in 2014) focused on the achievement of several 2012–2016 NARMS Strategic Plan objectives and interagency research. The purpose of this meeting will be to summarize NARMS progress since that meeting, to present recommendations made by the recent FDA Science Board review of NARMS in 2017, and to explore new directions for NARMS within a One Health paradigm. Items that will be discussed during this meeting include an update on the development of new analytical and reporting tools, the latest advances in the use of DNA sequencing technologies, and new surveillance results. The meeting agenda will be posted no later than 5 days before the meeting at *https://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/NationalAntimicrobialResistanceMonitoringSystem/ucm576281.htm.*

In addition to discussion generated through this public meeting, FDA and the NARMS partners are interested in receiving stakeholder input on the following questions through electronic or written comments, which can be submitted to the Dockets Management Staff (see **ADDRESSES**).

1. Recently, NARMS modified its Integrated Reports and online data display tools (*https://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/NationalAntimicrobialResistanceMonitoringSystem/ucm416741.htm*). Do you find this more user-friendly and informative? Please explain.

2. How can NARMS accomplish better stakeholder engagement, which modes of engagement are preferred, and how frequent?

3. Where should the NARMS program focus over the next 5–10 years? What are the top three gaps in the NARMS program and how should they be addressed?

4. Which of the Science Board recommendations do you see as highest priority, and how should they be achieved?

At the conclusion of this meeting, a separate interagency meeting on whole genome sequencing will be held in the Jefferson Auditorium on October 26 and 27, 2017. A notice will be published in the **Federal Register** by the Food Safety Inspection Service to announce this meeting.

II. Participating in the Public Meeting

Registration: Persons interested in attending this public meeting must register online by October 10, 2017. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

There is no fee to register for the public meeting, but pre-registration by October 10, 2017, is mandatory for participants attending in person. Onsite registration will not be permitted. Early registration is recommended as space is limited. All attendees must pre-register online by emailing *laura.bradbard@fda.hhs.gov* with the subject line ''NARMS Public Meeting 2017'' with information including name, title, organization, address, and telephone and Fax numbers. If you need special accommodations due to a disability, please contact Laura Bradbard (see **FOR FURTHER INFORMATION CONTACT**) no later than October 2, 2017.

Requests for Oral Presentations: Interested persons may make oral presentations on the topic of the discussion of the meeting. Oral presentations from the public during the open public comment period will be scheduled between 4:00 p.m. and 4:50 p.m. on October 25, 2017. Those desiring to make oral presentations should notify Laura Bradbard (see **FOR FURTHER INFORMATION CONTACT**) by October 2, 2017, and submit a brief statement of the general nature of information they wish to present. In an effort to accommodate all who desire to speak, time allotted for each presentation may be limited. The contact person will inform each speaker of their schedule prior to the meeting. If selected for presentation, speakers will be contacted by October 13, 2017, and presentation material should be submitted by email to Laura Bradbard (see **FOR FURTHER INFORMATION CONTACT**) by October 20, 2017. No commercial or promotional material will be permitted to be presented or distributed at the public meeting.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management

Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at *https://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/NationalAntimicrobialResistanceMonitoringSystem/ucm059172.htm*.

Dated: September 15, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–20108 Filed 9–20–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Single-Award Deviation From Competition Requirements for the Severe Combined Immunodeficiency (SCID) Newborn Screening Program at the Jeffrey Modell Foundation

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice of award.

SUMMARY: HRSA announces the award of an extension in the amount of $2,000,000 for the Severe Combined Immunodeficiency (SCID) Newborn Screening program at the Jeffrey Modell Foundation (JMF). The extension will allow JMF, the cooperative agreement recipient, during the budget period of May 1, 2017 to April 30, 2018, to provide technical assistance and support to states for the implementation of population based newborn screening for SCID.

FOR FURTHER INFORMATION CONTACT: Jill F. Shuger, ScM, Division of Services for Children with Special Health Needs, MCHB, HRSA, 5600 Fishers Lane, Rockville, Maryland 20857, Phone: (301) 443–3247, Email: *JShuger@hrsa.gov.*

SUPPLEMENTARY INFORMATION:

Intended Recipient of the Award: Jeffrey Modell Foundation.

Amount of Non-Competitive Awards: $2,000,000.

Budget Period of Supplemental Funding: May 1, 2017 to April 30, 2018.

CFDA Number: 93.110.

Authority: Public Health Service Act, § 1109, as amended by the Newborn Screening Saves Lives Reauthorization Act of 2014 (Public Law 110–204) (42 U.S.C. 300b–8).

Justification: The Maternal and Child Health Bureau (MCHB) is proposing that JMF continue activities under the current cooperative agreement to ensure the implementation of newborn screening for SCID in all 50 states, particularly in the states that have yet to implement SCID screening (*i.e.,* Alabama, Arizona, Indiana, Kansas, Louisiana, Nevada and North Carolina). Using its resources and centers, JMF will provide technical assistance in areas of funding, state government education, and linkage to expert care and patient access to a national network of specialized treatment centers. Further, JMF will continue to support states with implementation of SCID screening and follow up as well as the immediate treatment of infants identified with SCID. JMF will use the data collected from the states to educate clinical immunologists, neonatologists and other providers on effective screening for SCID. Additionally, JMF will continue to support education and awareness of newborn screening for SCID to families and health care providers and provide education to primary care providers and medically underserved populations.

Grantee/organization name	Grant No.	State	Fiscal year 2017 authorized funding level	Fiscal year 2017 estimated supplemental funding
Jeffrey Modell Foundation	UG5MC28325	UT	$2,000,000	$2,000,000

Dated: September 7, 2017.

George Sigounas,

Administrator.

[FR Doc. 2017–20116 Filed 9–20–17; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, 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 Institute of Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel; T32 Institutional Training Grant Review.

Date: October 6, 2017.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Dental and Craniofacial Research, Democracy One, 6701 Democracy Blvd., Suite 602, Bethesda, MD 20892.

Contact Person: Kan Ma, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute of Arthritis, Musculoskeletal and Skin Diseases, NIH, 6701 Democracy Boulevard, Suite 814, Bethesda, MD 20892, 301–451–4838, *mak2@mail.nih.gov.*

Name of Committee: National Institute of Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel; Division of Musculoskeletal Diseases RISK R61/R33 Peer Review.

Date: October 11, 2017.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Rd, Bethesda, MD 20852.

Contact Person: Xincheng Zheng, MD, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute of Arthritis, Musculoskeletal and Skin Diseases, NIH, 6701 Democracy Boulevard, Suite 820, Bethesda, MD 20892, 301–451–4838, *xincheng.zheng@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: September 15, 2017.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–20095 Filed 9–20–17; 8:45 am]

BILLING CODE 4140–01–P