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: LaToya Bonner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, email: *DODAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The committee will discuss the safety and efficacy of new drug application (NDA) 208254, for netarsudil ophthalmic solution 0.02%, submitted by Aerie Pharmaceuticals Inc., for the proposed indication to reduce elevated intraocular pressure (IOP) in patients with open-angle glaucoma (OAG) or ocular hypertension (OHT).

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions submitted to the Docket (see the **ADDRESSES** section) on or before September 28, 2017, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before September 20, 2017. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by September 21, 2017.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require special accommodations due to a disability, please contact LaToya Bonner at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 15, 2017.

Anna K. Abram,

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

[FR Doc. 2017–20105 Filed 9–20–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–0001]

Drug Development in Pediatric Heart Failure: Extrapolation, Clinical Trial Design, and Endpoints; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public workshop entitled ''FDA-University of Maryland CERSI Drug Development in Pediatric Heart Failure: Extrapolation, Clinical Trial Design, and Endpoints.'' The purpose of the public workshop is to address challenges related to the evaluation of products in pediatric heart failure including population to study, endpoints, and extrapolation of adult efficacy data. The workshop will also provide a forum for discussion on the use of registry data, as well as alternative trial designs and statistical methods.

DATES: The public workshop will be held on Friday, October 27, 2017, from 8 a.m. to 5 p.m.

ADDRESSES: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Rm. 1503A, Silver Spring, MD 20993–0002. Entrance for the public workshop participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For parking and security information, please refer to *https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

FOR FURTHER INFORMATION CONTACT: Jacqueline Yancy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6319, Silver Spring, MD 20993–0002, 301–796–7068, *Jacqueline.Yancy@fda.hhs.gov.*

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.