considerations regarding antimicrobial drug development for gonorrhea.

Discussions are planned around the following topic areas:

- Animal models;
- Clinical pharmacology considerations; and
- Trial design considerations for gonorrhea, such as enrollment strategies, choice of comparators, and site of infection.

The Agency encourages healthcare providers, other U.S. Government Agencies, academic experts, industry, and other stakeholders to attend this public workshop.

III. Participating in the Public Workshop

Registration: Persons interested in attending this public workshop must register online, using the internet link noted in the *Transcripts* section below, by April 21, 2021, 11:59 p.m. Eastern Time. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Registrants will receive confirmation when they have been accepted.

If you need special accommodations due to a disability, please contact Antoinette Ziolkowski or Lori Benner (see **FOR FURTHER INFORMATION CONTACT**) no later than April 20, 2021.

Requests for Oral Presentations: During online registration you may indicate if you wish to present during the virtual public comment session and which topic(s) you wish to address. All requests to make oral presentations must be received by April 15, 2021. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations and request time for a joint presentation. We will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin and will select and notify participants by April 16, 2021. If selected for presentation, any presentation materials must be emailed to *ONDPublicMTGSupport@fda.hhs.gov* no later than April 19, 2021. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Streaming Webcast of the Public Workshop: This public workshop will also be webcast at the following site: *https://collaboration.fda.gov/cderond042321/.*

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 website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites 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 (see **ADDRESSES**). A link to the transcript will also be available on the internet at *https://www.fda.gov/drugs/news-events-human-drugs/development-considerations-antimicrobial-drugs-treatment-gonorrhea-04232021-04232021.*

Dated: April 7, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–07548 Filed 4–12–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1302]

Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee. The general function of the subcommittee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held virtually on May 11, 2021, from 10 a.m. to 3 p.m. Eastern Time and May 12, 2021, from noon to 5 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of this COVID–19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2020–N–1302. The docket will close on May 10, 2021. Submit either electronic or written comments on this public meeting by May 10, 2021. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before May 10, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 10, 2021. 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.

Comments received on or before April 28, 2021, will be provided to the subcommittee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments as follows:

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–2020–N–1302 for ''Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; 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, 240–402–7500.

- 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.'' FDA 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 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 the 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.govinfo.gov/content/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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: She-Chia Chen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9034, email: *ODAC@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 FDA's website 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 meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. On May 11, 2021, the subcommittee will discuss the development and successful implementation of the Pediatric Patient-Reported Outcomes Version of the Common Terminology Criteria for Adverse Events (PRO–CTCAE) as a tool for eliciting the patient's voice in oncology clinical trials to more accurately determine tolerability and toxicity of drugs under investigation. The subcommittee will also address the challenges of capturing this type of data across the age spectrum of the pediatric population and possible generalizability of the data. It will consider approaches to address concerns about excluding the patient voice of young children deemed incapable of self-reporting. The subcommittee will also focus on approaches to investigators and commercial sponsors to use the Pediatric PRO–CTCAE in toxicity assessment moving forward.

On May 12, 2021, the subcommittee will discuss real-world evidence (RWE) for regulatory use in pediatrics, real-world data (RWD) resources, and RWD and RWE to advance pediatric safety assessments of oncology drug products in children within the context of the FDA framework for RWE. Potential data sources and publicly available platforms, including those made possible through the development and implementation of the National Cancer Institute's Childhood Cancer Data Initiative, will be discussed. The potential for use of data sources to construct external controls to evaluate effectiveness of investigational products will be considered given the frequent dependence on single-arm studies due to extremely small study populations, now exaggerated by molecularly defined subtypes of the rare cancer types that occur in children.

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 website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting. Background material and the link to the online teleconference meeting room will be available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before April 28, 2021, will be provided to the subcommittee. Oral presentations from the public will be scheduled between approximately 1:35 p.m. to 2:05 p.m. Eastern Time on May 11, 2021. Oral presentations from the public will also be scheduled between approximately 3:30 p.m. to 4 p.m. Eastern Time on May 12, 2021. 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 April 19, 2021. 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 April 20, 2021.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

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 accommodations due to a disability, please contact She-Chia Chen (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website 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: April 8, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–07546 Filed 4–12–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Solicitation of Nominations for Membership To Serve on the Advisory Committee on Training in Primary Care Medicine and Dentistry

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

ACTION: Request for nominations.

SUMMARY: HRSA is seeking nominations of qualified candidates for consideration for appointment as members of the Advisory Committee on Training in Primary Care Medicine and Dentistry (ACTPCMD or Committee).

DATES: Nominations for membership on the ACTPCMD must be received on or before the end of the fiscal year.

ADDRESSES: Nomination packages must be electronically submitted to the Designated Federal Official, Shane Rogers, via this email: *BHWAdvisoryCouncil@hrsa.gov.*

FOR FURTHER INFORMATION CONTACT: Shane Rogers, Designated Federal Official, Division of Medicine and Dentistry, Bureau of Health Workforce, email at *SRogers@hrsa.gov* or telephone at 301–443–5260.

SUPPLEMENTARY INFORMATION: The ACTPCMD provides advice and recommendations to the Secretary of Health and Human Services (Secretary); the Senate Committee on Health, Education, Labor and Pensions; and the House of Representatives' Committee on Energy and Commerce concerning the medicine and dentistry activities authorized under section 747 of the PHS Act, as it existed upon the enactment of Section 749 of the PHS Act in 1998. The ACTPCMD is responsible for preparing and submitting an annual report to the Secretary and Congress describing the activities of the Committee, including findings and recommendations made by the Committee. In addition, the ACTPCMD develops, publishes, and implements performance measures; develops and publishes guidelines for longitudinal evaluations; and recommends appropriation levels for programs under Part C of Title VII of the PHS Act. ACTPCMD currently focuses on the following targeted program areas and/or disciplines: Family medicine, general internal medicine, general pediatrics, physician assistants, general dentistry, pediatric dentistry, public health dentistry, and dental hygiene. The Committee meets at least twice a year. A copy of the current committee membership, charter, and reports can be obtained by accessing the ACTPCMD website at *https://www.hrsa.gov/advisory-committees/primarycare-dentist/index.html.*

Nominations: HRSA is requesting nominations for voting members to serve as Special Government Employees (SGEs). The Secretary appoints ACTPCMD members with the expertise needed to fulfill the duties of the Committee. The membership requirements are set forth at section 749 of the PHS Act (42 U.S.C. 293*l*). Nominees sought include, but are not limited to, representatives from the disciplines of allopathic medicine; osteopathic medicine; family medicine; general internal medicine; general pediatrics; physician assistants; general dentistry; pediatric dentistry; public health dentistry; and dental hygiene. Interested applicants may self-nominate or be nominated by another individual or organization.

Individuals selected for appointment to the Committee will be invited to serve for 3 years. Members of the ACTPCMD, as SGEs, receive compensation for performance of their duties on the Committee and reimbursement for per diem and travel expenses incurred for attending ACTPCMD meetings and conducting other business on behalf of the ACTPCMD.

The following information must be included in the package of materials submitted for each individual nominated for consideration:

(1) A letter of nomination that clearly states the name and affiliation of the nominee, the basis for the nomination (*i.e.,* specific attributes that qualify the nominee for service in this capacity), and a statement that the nominee is willing to serve as a member of the Committee and appears to have no conflict of interest that would preclude membership.

(2) The nominator's name, address, daytime telephone number, and the home or work address, telephone number, and email address of the individual being nominated.

(3) A current copy of the nominee's curriculum vitae.

(4) A statement of interest from the nominee including any experience with Title VII medicine and dentistry training programs, expertise in the field, and personal desire in participating on a National Advisory Committee.

Nomination packages may be submitted directly by the individual being nominated or by the person/organization nominating the candidate.

HHS endeavors to ensure that the membership of the ACTPCMD is fairly balanced in terms of points of view represented and between the health professions, a broad representation of geographic areas, including balance between urban and rural members, gender, and ethnic and minority groups, as well as individuals with disabilities. At least 75 percent of the members of the Committee are health professionals. Appointments shall be made without discrimination on the basis of age, race, color, national origin, sex, disability, or religion.

Individuals who are selected to be considered for appointment will be required to provide detailed information regarding their financial holdings, consultancies, and research grants or contracts. Disclosure of this information is required in order for ethics officials to determine whether there is a potential conflict of interest between the SGE's public duties as a member of the ACTPCMD and their private interests, including an appearance of a loss of impartiality as defined by federal laws and regulations, and to identify any