

stakeholders, including patients, researchers, healthcare providers, manufacturers, interested industry, professional organizations, and the public. The Agency has determined that a public meeting is the most appropriate way to ensure public engagement on the draft guidance. FDA welcomes any relevant information that stakeholders wish to share.

III. Participating in the Public Meeting

Registration: To register for the public meeting, please visit the following website: https://fdalimitedpoppathwayantibacterial_antifungal.eventbrite.com by July 1, 2019, at 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. Persons interested in attending this public meeting must register by July 1, 2019, at 11:59 p.m. Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. If time and space permit, onsite registration on the day of the public meeting/public workshop will be provided beginning at 8:15 a.m. We will let registrants know if registration closes before the day of the public meeting/public workshop.

If you need special accommodations due to a disability, please contact Sarah Walinsky (see **FOR FURTHER INFORMATION CONTACT**) no later than July 1, 2019, at 11:59 p.m. Eastern Time.

Requests for Oral Presentations: During online registration you may indicate which topic(s) you wish to address, and an approximate desired length of your presentation, so that FDA can consider this information in organizing the presentations. 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, or submit requests for designated representatives to present. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and we will select and notify participants. All requests to make oral presentations must be received by the close of registration on July 1, 2019, at 11:59 p.m. Eastern Time. If selected for presentation, any presentation materials must be emailed to the Sarah Walinsky

(see **FOR FURTHER INFORMATION CONTACT**) no later than 12 p.m. Eastern Time July 8, 2019. No commercial or promotional material will be permitted to be presented or distributed at the public meeting. Presenters are encouraged to submit a copy of their presentation and related written material to the docket (see **ADDRESSES**) in advance of the public meeting.

Streaming Webcast of the public meeting: This public meeting will also be webcast via <https://collaboration.fda.gov/lppaadpm0719>.

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 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/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm631810.htm>.

Dated: March 28, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-1215]

Post-Marketing Pediatric-Focused Product Safety Reviews; 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) is establishing a public docket to collect comments related to the post-marketing pediatric-focused safety reviews of products posted between October 12, 2018, and April 1, 2019, on FDA's website but not presented at the April 8, 2019, Pediatric Advisory Committee (PAC) meeting.

These reviews are intended to be available for review and comment by members of the PAC, interested parties (such as academic researchers, regulated industries, consortia, and patient groups), and the general public.

DATES: Submit either electronic or written comments by April 15, 2019.

ADDRESSES: FDA is establishing a docket for public comment on this document. The docket number is FDA-2019-N-1215. The docket will close on April 15, 2019. Submit either electronic or written comments by that date. Please note that late, untimely comments will not be considered. Electronic comments must be submitted on or before April 15, 2019. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of April 15, 2019. 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.

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 make 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-2019-N-1215 for “Post-Marketing Pediatric-Focused Product Safety Reviews; 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.

- **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 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:

Amy Odegaard, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5151, Silver Spring, MD 20993, 301-796-8627, amy.odegaard@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our Nation’s food supply, cosmetics, and products that emit radiation. FDA also has responsibility for regulating the manufacturing, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors.

FDA has established a public docket, Docket No. FDA-2019-N-1215, to receive input on post-marketing pediatric-focused safety reviews of products posted between October 12, 2018, and April 1, 2019, available on FDA’s website at <https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/PediatricAdvisoryCommittee/ucm510701.htm> but not presented at the April 8, 2019, PAC meeting. FDA welcomes comments by members of the PAC, as mandated by the Best Pharmaceuticals for Children Act (Pub. L. 107-109) and the Pediatric Research Equity Act of 2003 (Pub. L. 108-155), interested parties (such as academic researchers, regulated industries, consortia, and patient groups), and the general public. The docket number is FDA-2019-N-1215. The docket will open on April 2, 2019, and remain open until April 15, 2019. The post-marketing pediatric-focused safety reviews are for the following products from the following centers at FDA:

Center for Biologics Evaluation and Research

1. ADYNOVATE (Antihemophilic Factor [recombinant])
2. IXINITY (Coagulation Factor IX [Recombinant])
3. EPICEL (cultured epidermal autografts) (Humanitarian Device Exemption [HDE])

Center for Drug Evaluation and Research

1. ACZONE GEL (dapsone)
2. AIRDUO RESPICLICK (fluticasone propionate and salmeterol) and ARMONAIR RESPICLICK (fluticasone propionate)
3. AVELOX (moxifloxacin hydrochloride)

4. CALDOLOR INJECTION (ibuprofen)
5. CUBICIN INJECTION (daptomycin)
6. DEXILANT (dexlansoprazole)
7. EUCRISA OINTMENT (crisaborole)
8. LILETTA (levonorgestrel-releasing intrauterine system)
9. LYRICA (pregabalin)
10. NARCAN NASAL SPRAY (naloxone hydrochloride)
11. OFIRMEV (acetaminophen)
12. SELZENTRY (maraviroc)
13. SPIRIVA RESPIMAT (tiotropium bromide)
14. SYMBICORT INHALATION AEROSOL (budesonide/formoterol fumarate dehydrate)
15. TARCEVA (erlotinib hydrochloride)
16. VELCADE (bortezomib)

Center for Devices and Radiological Health

1. FLOURISH™ PEDIATRIC ESOPHAGEAL ATRESIA DEVICE (HDE)
2. LIPOSORBER LA-15 SYSTEM (HDE)
3. MEDTRONIC ACTIVA DYSTONIA THERAPY (HDE)

Dated: March 28, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0179]

Training Program for Regulatory Project Managers; Information Available to Industry

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration’s (FDA or the Agency) Center for Drug Evaluation and Research (CDER) is announcing the continuation of the Regulatory Project Management Site Tours and Regulatory Interaction Program (the Site Tours Program). The purpose of this document is to invite pharmaceutical companies interested in participating in this program to contact CDER.

DATES: Pharmaceutical companies may send proposed agendas to the Agency by June 3, 2019.

FOR FURTHER INFORMATION CONTACT: Dan Brum, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5480, Silver Spring, MD 20993-0002, 301-796-0578, dan.brum@fda.hhs.gov.