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: Steven Fleischer, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0809, *steven.fleischer@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 24, 2018, FDA published a request for comments with a 90-day comment period to request comments on the design of studies intended to generate data to support substantial evidence of effectiveness for investigational new animal drugs intended for the prevention of heartworm disease in dogs. Comments received will inform FDA's current thinking regarding the design of studies intended to generate data to support substantial evidence of effectiveness for investigational new animal drugs intended for the prevention of heartworm disease in dogs.

The Agency has received a request for a 90-day extension of the comment period for the request for comments. The request conveyed concern that the current 90-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the request for comments.

FDA has considered the request and is extending the comment period for the request for comments for 90 days, until November 20, 2018. The Agency believes that a 90-day extension allows adequate time for interested persons to submit comments without significantly delaying further action on these important issues.

Dated: August 14, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–17858 Filed 8–17–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3000]

Pediatric 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 Advisory Committee (PAC). The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. FDA is establishing a docket for public comments on this document.

DATES: The meeting will be held on September 20, 2018, from 8:30 a.m. to 4 p.m. This is a reschedule of a postponed meeting announced in the **Federal Register** of January 2, 2018 (83 FR 125), originally scheduled for March 23, 2018.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31, Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation 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–2018–N–3000. The docket will close on September 19, 2018. Submit either electronic or written comments on this public meeting by that date. Please note that late, untimely comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of September 19, 2018. 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 September 6, 2018, will be provided to the committee. Comments received after that date will be taken into consideration by FDA. 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 Docket No. FDA–2018–N–3000 for ''Pediatric Advisory Committee; 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 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.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: Marieann Brill, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5154, Silver Spring, MD 20993, 240–402–3838, email: *marieann.brill@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 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: On Thursday, September 20, 2018, the PAC will meet to discuss pediatric-focused safety reviews, 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). Comments about the upcoming advisory committee meeting should be submitted to Docket No. FDA–2018–N–3000.

The PAC will meet to discuss the following Center for Drug Evaluation and Research products: INTUNIV and LEXAPRO.

The FDA will provide general safety updates including updates on the following topics without vote by the committee:

- Overview of the FDA Adverse Event Reporting System and lack of efficacy;
- Generic drug approval process; and discussion on trade versus generic drugs; exceptions;
- Summary of FDA completed review of pediatric safety issues and updated labeling changes for EXJADE (deferasirox);
- Update labeling change for inhaled corticosteroid long-acting β-2 agonists;
- Safety labeling for gadolinium.

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 at the location of the advisory committee meeting, and the background material will be posted on FDA's website 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. Written submissions may be made to the contact person on or before September 13, 2018. Oral presentations from the public will be scheduled between approximately 9 a.m. and 10 a.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 5, 2018. 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 6, 2018.

Persons attending FDA's advisory committee meetings are advised that FDA 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 accommodations due to a disability, please contact Marieann Brill (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: August 14, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–17857 Filed 8–17–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–2946]

Neurological Devices Panel Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) announces a forthcoming public Advisory Committee meeting of the Neurological Devices Panel (Committee). The general function of the Committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

DATES: The meeting will be held on September 27, 2018, from 8 a.m. to 5 p.m.

ADDRESSES: Hilton Washington, DC/North, Salons A, B, C, and D, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel's phone number is 301–977–8900 and website is: *http://www3.hilton.com/en/hotels/maryland/hilton-washington-dc-north-gaithersburg-GAIGHHF/index.html.* Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FOR FURTHER INFORMATION CONTACT: Aden Asefa, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire