to the meeting to be considered by the NAC. Written comments or statements received after this date may not be provided to the NAC until its next meeting.

Verbal Comments or Statements: Pursuant to 41 CFR 102–3.140d, the NAC is not obligated to allow a member of the public to speak or otherwise address the NAC during the meeting. Members of the public are invited to provide verbal comments or statements during the NAC meeting only at the time and manner described below. All requests to speak or otherwise address the NAC during the meeting must be submitted to the NAC's DFO at least 15 days prior to the meeting, via email, the preferred mode of submission, at *adonald@nhttac.org.* The request should include a brief statement of the subject matter to be addressed by the comment and should be relevant to the stated agenda of the meeting or in regard to the NAC's mission in general. The DFO will log each request in the order received. A period near the end of the meeting will be available for verbal public comments. The time allotted will depend on the number of public comments or statements received and the NAC's agenda items. To provide time for as many people to speak as possible, speaking time for each individual will be limited to 3 minutes.

Minutes: The minutes of this meeting will be available for public review and copying within 90 days at: *https://www.acf.hhs.gov/otip/partnerships/the-national-advisory-committee.*

Dated: August 14, 2018.

Steven Wagner,

Acting Assistant Secretary for Children and Families.

[FR Doc. 2018–17891 Filed 8–17–18; 8:45 am]

BILLING CODE 4184–40–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1558]

Food and Drug Administration's Evaluation of Approaches To Demonstrate Effectiveness of Heartworm Preventatives for Dogs; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is extending the comment period for the request for comments that appeared in the **Federal Register** of May 24, 2018. In the request for comments, FDA requested 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. The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the request for comments published May 24, 2018 (83 FR 24122). Submit either electronic or written comments by November 20, 2018.

ADDRESSES: 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 20, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of November 20, 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.

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–2018–N–1558 for ''FDA's Evaluation of Approaches to Demonstrate Effectiveness of Heartworm Preventatives for Dogs.'' 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: 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