for an extension to allow interested persons additional time to submit comments.

DATES: Submit either electronic or written comments by February 21, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions
Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to http://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 http://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): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, 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–2016–D–2241 for “Substantiation for Structure/Function Claims Made in Infant Formula Labels and Labeling.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at http://www.regulations.gov or at the Division of Dockets Management 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.” We will review this copy, including the claimed confidential information, in our 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 http://www.regulations.gov. Submit both copies to the Division of Dockets Management. 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: http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

SUPPLEMENTARY INFORMATION: In the Federal Register of September 9, 2016 (81 FR 62509), we published a notice announcing the availability of a draft guidance entitled, “Substantiation for Structure/Function Claims Made in Infant Formula Labels and Labeling.” Although you can comment on any guidance at any time, to ensure that we consider comments on this draft guidance before we begin work on the final version, interested persons were originally given until November 8, 2016, to comment on the draft guidance.

Following publication of the September 9, 2016, notice of availability, we received a request for a 90-day extension of the comment period. The request expressed concern that the current 60-day comment period does not allow sufficient time to develop a thoughtful and comprehensive response to the draft guidance. We have considered the request and are reopening the comment period for an additional 90 days, until February 21, 2017. We believe that this reopening allows adequate time for interested persons to submit comments without significantly delaying finalizing the guidance.

Dated: November 15, 2016.

Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2016–27941 Filed 11–18–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1050]

Report of the Center for Veterinary Medicine Working Group on the Regulation of Animal Drug Availability Act Combination Drug Medicated Feeds; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a report of a Center for Veterinary Medicine (CVM) working group proposing possible changes to the current review processes for new animal drug applications (NADAs) providing for the use of multiple new animal drugs in combination drug medicated feeds. This report was developed for the use of the CVM committee that will be participating in discussions concerning the reauthorization of the animal drug user fee program for 5 additional years through fiscal year 2023 (per the Animal Drug User Fee Amendments (ADUFA) IV).

ADDRESSES: 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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
Submit written requests for single copies of the report to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the document.

FOR FURTHER INFORMATION CONTACT:
Linda M. Wilmot, Center for Veterinary Medicine, (HFV–120), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0829, linda.wilmot@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the Federal Register of September 9, 2014 (79 FR 53431), CVM announced that it was beginning to explore possible changes to the current review processes for NADAs for the use of multiple new animal drugs in combination drug medicated feeds. In the same Federal Register notice, FDA announced the opening of a docket to receive input from the public on this issue. This effort is consistent with the stated performance goal in the Animal Drug User Fee Amendments of 2013 (ADUFA III) goals letter.

In the Federal Register of April 29, 2016 (81 FR 25677), FDA published a notice of availability of a draft CVM report, giving interested persons until July 29, 2016, to comment. Those comments were considered as the CVM working group report was finalized without substantive changes. This report was developed for the discussions with the regulated industry for reauthorization of ADUFA.

Persons with access to the Internet may obtain this document on the CVM ADUFA Meetings Web page: http://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/ucm042891.htm.

Dated: November 15, 2016.

Leslie Kux,
Associate Commissioner for Policy.
[FR Doc. 2016–27942 Filed 11–18–16; 8:45 am]