

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:** Gillian Robert-Baldo, Center for Food Safety and Applied Nutrition (HFS-850), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1451.

**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](mailto: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]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2013-N-1147]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by December 21, 2016.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to [oira\\_submission@omb.eop.gov](mailto:oira_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0541. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition—OMB Control Number 0910-0541—Extension

As an integral part of its decision making process, we are obligated under the National Environmental Policy Act of 1969 (NEPA) to consider the environmental impact of our actions, including allowing notifications for food contact substances to become effective and approving food additive petitions,

color additive petitions, GRAS affirmation petitions, requests for exemption from regulation as a food additive, and actions on certain food labeling citizen petitions, nutrient content claims petitions, and health claims petitions. In 1997, we amended our regulations in part 25 (21 CFR part 25) to provide for categorical exclusions for additional classes of actions that do not individually or cumulatively have a significant effect on the human environment (62 FR 40570, July 29, 1997). As a result of that rulemaking, we no longer routinely require submission of information about the manufacturing and production of our regulated articles. We also have eliminated the previously required Environmental Assessment (EA) and abbreviated EA formats from the amended regulations. Instead, we have provided guidance that contains sample formats to help industry submit a claim of categorical exclusion or an EA to the Center for Food Safety and Applied Nutrition (CFSAN). The guidance document entitled “Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition” identifies, interprets, and clarifies existing requirements imposed by statute and regulation, consistent with the Council on Environmental Quality regulations (40 CFR 1507.3). It consists of recommendations that do not themselves create requirements; rather, they are explanatory guidance for our own procedures in order to ensure full compliance with the purposes and provisions of NEPA.

The guidance provides information to assist in the preparation of claims of categorical exclusion and EAs for submission to CFSAN. The following questions are covered in this guidance: (1) What types of industry-initiated actions are subject to a claim of categorical exclusion? (2) What must a claim of categorical exclusion include by regulation? (3) What is an EA? (4) When is an EA required by regulation and what format should be used? (5) What are extraordinary circumstances? and (6) What suggestions does CFSAN have for preparing an EA? Although CFSAN encourages industry to use the EA formats described in the guidance because standardized documentation submitted by industry increases the efficiency of the review process, alternative approaches may be used if these approaches satisfy the requirements of the applicable statutes and regulations. We are requesting the extension of OMB approval for the