

Board of Governors of the Federal Reserve System, November 15, 2018.

**Yao-Chin Chao,**

*Assistant Secretary of the Board.*

[FR Doc. 2018-25338 Filed 11-20-18; 8:45 am]

**BILLING CODE 6210-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Community Living

#### Administration on Intellectual and Developmental Disabilities, President's Committee for People With Intellectual Disabilities

**AGENCY:** Administration for Community Living, HHS.

**ACTION:** Notice.

**SUMMARY:** The President's Committee for People with Intellectual Disabilities (PCPID) will host a webinar/conference call for its members to discuss the potential topics of the Committee's 2019 Report to the President. All the PCPID meetings, in any format, are open to the public. This virtual meeting will be conducted in a discussion format.

**DATES:** *Webinar/Conference Call:* Wednesday, December 5, 2018 from 9:00 a.m. to 10:00 a.m. (EST).

**FOR FURTHER INFORMATION CONTACT:** Ms. Allison Cruz, Director, Office of Innovation, 330 C Street SW, Switzer Building, Room 1114, Washington, DC 20201. Telephone: 202-795-7334. Fax: 202-795-7334. Email: [Allison.Cruz@acl.hhs.gov](mailto:Allison.Cruz@acl.hhs.gov).

**SUPPLEMENTARY INFORMATION:** The purpose of this virtual meeting is to discuss the Committee's preparation of the PCPID 2019 Report to the President, including its content and format, and related data collection and analysis required to complete the writing of the Report.

*Webinar/Conference Call:* The webinar/conference call is scheduled for Wednesday, December 5, 2018, 9:00 a.m. to 10:00 a.m. (EST) and may end early if discussions are finished.

*Instructions to Participate in the Webinar/Conference Call on Wednesday, December 5, 2018:* Please dial: (888) 949-2790; Pass Code: 1989852

*Background Information on the Committee:* The PCPID acts in an advisory capacity to the President and the Secretary of Health and Human Services on a broad range of topics relating to programs, services and support for individuals with intellectual disabilities. The PCPID executive order stipulates that the Committee shall: (1)

Provide such advice concerning intellectual disabilities as the President or the Secretary of Health and Human Services may request; and (2) provide advice to the President concerning the following for people with intellectual disabilities: (A) Expanding employment opportunities; (B) connecting people to services; (C) supporting families and caregivers; (D) strengthening the networks; and (E) protecting rights and preventing abuse.

Dated: November 15, 2018.

**Julie Hocker,**

*Commissioner, Administration on Disabilities (AoD).*

[FR Doc. 2018-25375 Filed 11-20-18; 8:45 am]

**BILLING CODE 4154-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2018-N-3522]

#### Use of the Names of Dairy Foods in the Labeling of Plant-Based Products; Extension of Comment Period

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

**ACTION:** Notice; extension of comment period.

**SUMMARY:** The Food and Drug Administration (FDA or we) is extending the comment period for the notice that appeared in the **Federal Register** of September 28, 2018. In the notice, FDA invited interested parties to provide information on specific topics related to the labeling of plant-based products with names that include the names of dairy foods such as "milk," "cultured milk," "yogurt," and "cheese." We are extending the comment period to give interested parties more time to comment.

**DATES:** FDA is extending the comment period on the notice published in the **Federal Register** of September 28, 2018 (83 FR 49103). Submit either electronic or written comments by January 28, 2019.

**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 January 28, 2019. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 28, 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.

#### 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-3522 for "Use of the Names of Dairy Foods in the Labeling of Plant-Based Products." 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." 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 <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:** Mabel Lee, Center Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2371.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of September 28, 2018 (83 FR 49103), FDA published a notice with a 60-day comment period inviting interested parties to provide information on specific topics related to the labeling of plant-based products with names that include the names of dairy foods such as "milk," "cultured milk," "yogurt," and "cheese." The information will inform our development of an approach to the labeling of plant-based products that consumers may substitute for dairy foods. We asked that comments be submitted by November 27, 2018.

We have received requests for a 120-day extension of the comment period for the notice. The requests conveyed concern that the current 60-day comment period does not allow sufficient time to develop meaningful or thoughtful responses to the questions

that appeared in the notice requesting data and other evidence in support of answers.

We have considered the requests and are extending the comment period for another 60 days, until January 28, 2019. We believe that a 60-day extension allows adequate time for interested persons to submit comments without significantly delaying any potential further action on these important issues.

Dated: November 15, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018-25347 Filed 11-20-18; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2008-N-0500]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; General Licensing Provisions; Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products

**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, 2018.

**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 [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0572. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794, [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.

#### Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products

*OMB Control Number 0910-0572—Extension*

FDA's regulations governing the content and format of labeling for human prescription drug and biological products were revised in the **Federal Register** of January 24, 2006 (71 FR 3922) (the 2006 labeling rule) to require that the labeling of new and recently approved products contain highlights of prescribing information, a table of contents for prescribing information, reordering of certain sections, minor content changes, and minimum graphical requirements. These revisions were intended to make it easier for health care practitioners to access, read, and use information in prescription drug labeling; to enhance the safe and effective use of prescription drug products; and to reduce the number of adverse reactions resulting from medication errors because of misunderstood or incorrectly applied drug information.

Currently, § 201.56 (21 CFR 201.56) requires that prescription drug labeling contain certain information in the format specified in either § 201.57 (21 CFR 201.57) or § 201.80 (21 CFR 201.80), depending on when the drug was approved for marketing. Section 201.56(a) sets forth general labeling requirements applicable to all prescription drugs. Section 201.56(b) specifies the categories of new and more recently approved prescription drugs subject to the revised content and format requirements in §§ 201.56(d) and 201.57. Section 201.56(c) sets forth the schedule for implementing these revised content and format requirements. Section 201.56(e) specifies the sections and subsections, required and optional, for the labeling of older prescription drugs not subject to the revised format and content requirements.

Section 201.57(a) requires that prescription drug labeling for new and more recently approved prescription drug products include a "Highlights of Prescribing Information" section. The "Highlights" section provides a concise extract of the most important information required under § 201.57(c) (the Full Prescribing Information (FPI)), as well as certain additional information important to prescribers. Section 201.57(b) requires a table of contents to