



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. FDA-2016-D-2335]

RIN 0910-AI13

Food Labeling: Nutrient Content Claims; Definition of Term “Healthy;” Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the comment period for the proposed rule entitled “Food Labeling: Nutrient Content Claims; Definition of Term ‘Healthy;’” that appeared in the *Federal Register* of September 29, 2022. We are taking this action in response to a request from stakeholders to extend the comment period to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the proposed rule published September 29, 2022 (87 FR 59168). Either electronic or written comments must be submitted on the proposed rule by February 16, 2023.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 16, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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-2016-D-2335 for "Food Labeling: Nutrient Content Claims; Definition of Term 'Healthy'." 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, 240-402-7500.

- 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.govinfo.gov/content/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, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Vincent de Jesus, Office of Nutrition and Food Labeling, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD, 20740, 240-402-1450, vincent.dejesus@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of September 29, 2022 (87 FR 59168), we published a proposed rule entitled “Food Labeling: Nutrient Content Claims; Definition of Term ‘Healthy’.” This action opened a docket with a 90-day comment period to receive information and comments related to the definition for the implied nutrient content claim “healthy.”

FDA has received a request for a 90-day extension for this comment period in order to allow additional time for interested persons to develop and submit comments. The request conveyed concern that the current 90-day comment period does not allow sufficient time to develop meaningful comments to the proposed rule. In the interest of balancing the public health importance of the nutrient content claim and definition of the term “healthy” and granting additional time to submit comments before we finalize the proposed rule, we have concluded that it is reasonable to extend the comment period for 50 days, until February 16, 2023. We believe that this extension allows adequate time for interested persons to submit comments.

Dated: November 22, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-26002 Filed: 11/28/2022 8:45 am; Publication Date: 11/29/2022]