4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. FDA-2014-N-1021]

Food Labeling; Gluten-Free Labeling of Fermented or Hydrolyzed Foods; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of the comment period.

SUMMARY: In the Federal Register of November 18, 2015, the Food and Drug Administration (FDA) published a proposed rule entitled "Food Labeling; Gluten-Free Labeling of Fermented or Hydrolyzed Foods." The proposed rule would establish requirements concerning "gluten-free" labeling for foods that are fermented or hydrolyzed or that contain fermented or hydrolyzed ingredients. We are taking this action to reopen the comment period in response to requests to allow interested persons additional time to submit comments.

DATES: FDA is reopening the comment period on the proposed rule published November 18, 2015 (80 FR 71990). Submit either electronic or written comments by [INSERT DATE 60 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

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-2014-N-1021 for "Food Labeling; Gluten-Free Labeling of Fermented or Hydrolyzed Foods." 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." 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 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: Carol D'Lima, Center for Food Safety and Applied Nutrition (HFS-820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-2371, FAX: 301-436-2636.

SUPPLEMENTARY INFORMATION: The proposed rule would establish requirements concerning "gluten-free" labeling for foods that are fermented or hydrolyzed or that contain fermented or hydrolyzed ingredients. These additional requirements for the "gluten-free" labeling rule are needed to help ensure that individuals with celiac disease are not misled and receive truthful and accurate information with respect to fermented or hydrolyzed foods labeled as "gluten-free." We provided a 90-day comment period for the proposed rule.

We received multiple requests for a 60-day extension of the comment period and one request for a 90-day extension of the comment period for the proposed rule. Each request conveyed concern that the original 90-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the proposed rule. We have considered the requests and are reopening the comment period for the proposed rule until [INSERT DATE 60 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]. We believe that an additional 60-day period allows adequate time for interested persons to submit comments without significantly delaying rulemaking on these important issues. The period for comments regarding information collection issues under the Paperwork Reduction Act of 1995 remains unchanged, where comments were to be submitted until February 22, 2016 (see 81 FR 3751, January 22, 2016).

Dated: February 18, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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