4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1, 11, 16, and 129

[Docket No. FDA-2019-N-3325]

RIN 0910-AH31

Laboratory Accreditation for Analyses of Foods; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; extension of comment period for the proposed rule and for its information collection provisions.

SUMMARY: The Food and Drug Administration (FDA or we) is extending for a second time the comment period for the proposed rule, and for the information collection related to the proposed rule, entitled "Laboratory Accreditation for Analyses of Foods" that appeared in the *Federal Register* of November 4, 2019. We are taking this action in response to a request from several food industry associations to extend open comment periods while their members focus on continuity of critical infrastructure operations due to the recent COVID-19 public health declaration. We also are taking this action to keep the comment period for the information collection provisions associated with the rule consistent with the comment period for the proposed rule.

DATES: FDA is further extending the comment period on the proposed rule published November 4, 2019 (84 FR 59452), which was first extended February 28, 2020 (85 FR 11893). Submit either electronic or written comments on the proposed rule by July 6, 2020. Submit

comments on information collection issues under the Paperwork Reduction Act of 1995 (PRA) by July 6, 2020 (see the "Paperwork Reduction Act of 1995" section of the proposed rule).

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 July 6, 2020. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of July 6, 2020. 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-2019-N-3325 for "Laboratory Accreditation for Analyses of Foods." 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." 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 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.

FOR FURTHER INFORMATION CONTACT: Timothy McGrath, Food and Feed Laboratory Operations, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rm. 3142, Rockville, MD 20857, 301-796-6591, email: timothy.mcgrath@fda.hhs.gov.

With regard to the information collection: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, email: PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the *Federal Register* of November 4, 2019 (84 FR 59452), we published a proposed rule entitled "Laboratory Accreditation for Analyses of Foods" with a 120-day comment period on the provisions of the proposed rule and on the information collection provisions that are subject to review by the Office of Management and Budget under the PRA (44 U.S.C. 3501-

3521). In the *Federal Register* of February 28, 2020 (85 FR 11893), we published an extension of the comment period for the proposed rule, and for the information collection related to the proposed rule, until April 6, 2020. The purpose of the first extension was to allow interested persons an additional opportunity to consider the proposal.

After we extended the comment period by 30 days, the outbreak of COVID-19, the disease caused by the novel coronavirus, caused the World Health Organization to declare a global pandemic.[1] The President subsequently proclaimed that the COVID-19 outbreak in the United States constitutes a national emergency.[2] Soon thereafter the U.S. Department of Homeland Security Cybersecurity and Infrastructure Security Agency issued guidance identifying, for the COVID-19 pandemic, which infrastructure sectors are critical to maintain necessary services and functions; one is the food and agriculture sector.[3]

FDA has received a request for a 120-day extension of all open comment periods for food-related proposed regulations, draft guidance documents, and *Federal Register* notices to allow the food industry to focus its efforts on COVID-19 response efforts and assuring that food production continues without pause (Ref. 1). FDA has considered the request in light of the role of the Food and Agriculture Sector in maintaining critical infrastructure and recognizing that the comment period currently is scheduled to close during the acute response to COVID-19. We have concluded that it is reasonable to extend for approximately 90 days the comment period for the Laboratory Accreditation for Analyses of Foods proposed rule. The Agency believes that this extension, together with the original 30-day extension, allows adequate time for any interested persons to consider the proposal fully and submit comments. We also are extending the comment

[1] See https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020.
[2] See https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/.
[3] See https://www.cisa.gov/identifying-critical-infrastructure-during-covid-19.

period for the information collection provisions to make the comment period for the information collection provisions the same as the comment period for the provisions of the proposed rule. To clarify, FDA is requesting comment on all issues raised by the proposed rule.

II. Reference

The following reference is on display at the Dockets Management Staff (see ADDRESSES) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at https://www.regulations.gov.

1. Letter from Food & Beverage Issue Alliance to Frank Yiannas, Deputy Commissioner for Food Policy and Response, and Susan T. Mayne, Director of the Center for Food Safety and Applied Nutrition, March 23, 2020.

Dated: April 1, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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