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 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 for an extension to allow interested persons additional time to consider the proposal. 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 extending the comment period on the proposed rule published November 4, 2019 (84 FR 59452). Submit either electronic or written comments on the proposed rule by April 6, 2020. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 (PRA) by April 6, 2020 (see the "Paperwork Reduction Act of 1995" section).
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 April 6, 2020. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 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:

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, Staff Director, 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: 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 (OMB)
under the PRA (44 U.S.C. 3501-3521).

FDA has received a request for a 30-day extension of the comment period on the
proposed rule to allow interested persons additional time to consider the proposal. FDA has
considered the request and is granting the extension of the comment period to allow interested persons additional opportunity to consider the proposal. We also are extending the comment 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. The Agency believes that this extension allows adequate time for any interested persons to fully consider the proposal and submit comments.


Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020-03944 Filed: 2/27/2020 8:45 am; Publication Date: 2/28/2020]