4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. FDA-2014-N-0053]

RIN 0910-AI44

Requirements for Additional Traceability Records for Certain Foods; Extension of Comment Period; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; extension of comment period; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is extending the comment period for the proposed rule and reopening the comment period for the information collection related to the proposed rule entitled "Requirements for Additional Traceability Records for Certain Foods" that appeared in the *Federal Register* of September 23, 2020. We are taking this action in response to a request from stakeholders to extend the comment period to allow additional time for interested persons to submit comments on the proposed rule. 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 September 23, 2020 (85 FR 59984). Submit either electronic or written comments on the proposed rule by February 22, 2021. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 (PRA) by February 22, 2021.

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 February 22, 2021. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 22, 2021. 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.

To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review--Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0560. Also include the FDA docket number found in brackets in the heading of this document.

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-2014-N-0053 for "Requirements for Additional Traceability Records for Certain 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, 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." 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, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: *Regarding the proposed rule*: Brian Pendleton, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-4614, Brian.Pendleton@fda.hhs.gov.

Regarding 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, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

In the *Federal Register* of September 23, 2020 (85 FR 59984), we published a proposed rule entitled "Requirements for Additional Traceability Records for Certain Foods" with a 120-day comment period on the provisions of the proposed rule and a 60-day comment period on the information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (44 U.S.C. 3501-3521).

FDA has received a request for a 60-day extension of the comment period for the provisions of the proposed rule and an extension of the comment period for the information collection provisions to align with the end of the comment period for the provisions of the proposed rule. The request conveyed concern that the current 120-day comment period does not allow stakeholders time to thoroughly analyze the rule due to its complexity and competing priorities. The request also noted that stakeholders cannot provide meaningful feedback on the information collection burden of the proposed rule without first having given the entire proposed

rule thorough consideration, and therefore asked that the comment period for the information collection provisions be extended to align with the comment period for the provisions of the proposed rule. We have concluded that it is reasonable to extend for 30 days the comment period for the provisions of the proposed rule. The Agency believes that this extension allows adequate time for any interested persons to submit comments on the proposed rule. We also are extending the comment period for the information collection provisions to February 22, 2021, to align the comment period for the information collection provisions with the comment period for the provisions of the proposed rule.

Dated: December 2, 2020

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Stephen M. Hahn,

Commissioner of Food and Drugs.

Dated: December 11, 2020.

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Alex M. Azar II,

Secretary,

Department of Health and Human Services.

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