88395). FDA considered comments received and revised the guidance as appropriate in response to the comments, including clarifying the relationship between 510k Review Organizations and EUA Third Party Review Organizations, and conflicts of interest requirements for personnel of Third Party Review Organizations.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on 510(k) Third Party Review Program and Third Party Emergency Use Authorization (EUA) Review. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov* and *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Persons unable to download an electronic copy of ''510(k) Third Party Review Program and Third Party Emergency Use Authorization (EUA) Review'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number GUI01500013 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in the following table have been approved by OMB:

21 CFR part; guidance; or FDA form	Topic	OMB control No.
''510(k) Third Party Review Program''	510(k) Third Party Review Program	0910–0375
''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff''.	Q-submissions	0910–0756
''Emergency Use Authorization of Medical Products and Related Authorities; Guidance for Industry and Other Stakeholders''.	Emergency Use Authorization	0910–0595
''Guidance for Industry and Food and Drug Administration Staff; Center for Devices and Radiological Health Appeals Processes''.	CDRH Appeals Processes	0910–0738

Dated: November 12, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–27085 Filed 11–20–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3609]

Development of an Enhanced Systematic Process for the Food and Drug Administration's Post-Market Assessment of Chemicals in Food; Public Meeting; Request for Comments; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the comment period for the notice of public meeting; request for comments, published in the **Federal Register** of August 12, 2024. In that notice, FDA announced a public meeting entitled ''Development of an Enhanced Systematic Process for the Food and Drug Administration's Post-Market Assessment of Chemicals in Food.'' FDA hosted the public meeting on September 25, 2024, and is now extending the comment period to allow interested persons additional time to submit comments about approaches to systematic post-market assessment of chemicals in food.

DATES: FDA is extending the comment period announced in the notice of public meeting; request for comments published August 12, 2024 (89 FR 65633). Either electronic or written comments must be submitted by January 21, 2025.

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 January 21, 2025. 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–2024–N–3609 for ''Development of an Enhanced Systematic Process for the Food and Drug Administration's Post-Market Assessment of Chemicals in Food; Public Meeting; Extension of the Comment Period.'' 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: Keronica Richardson, Office of Policy, Regulations, and Information, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2371.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 12, 2024, we published a notice announcing a public meeting entitled ''Development of an Enhanced Systematic Process for FDA's Post-Market Assessment of Chemicals in Food.'' The notice explained that the public meeting would address a variety of topics related to development of an enhanced systematic process for FDA's post-market assessment of chemicals in food, including:

- Principles for the post-market assessment process,
- Steps in the post-market assessment process,
- Prioritizing chemicals for post-market assessment, and
- Engaging stakeholders throughout the post-market assessment process (89 FR 65633 at 65635). We also provided an opportunity for public comment during the meeting. The docket for public comments was scheduled to close on December 6, 2024.

On September 25, 2024, we hosted the public meeting at the FDA White Oak Campus. A transcript of the meeting is available at *https://www.fda.gov/media/182622/download?attachment.*

We have received a request for a 60-day extension of the comment period. In general, the request explained that trade associations representing various parts of the food supply chain faced significant challenges to providing comment by December 6, 2024, and noted that the comment period overlapped with the holiday season and other FDA initiatives.

We have considered the requests and are extending the comment period until January 21, 2025. We believe that the extension will allow adequate time for interested persons to submit comments.

Dated: November 13, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–27289 Filed 11–20–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Inclusion of Terrain Factors in the Definition of Rural Area for Federal Office of Rural Health Policy Grants

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Final notice.

SUMMARY: HRSA's Federal Office of Rural Health Policy (FORHP) is modifying the definition of ''rural area'' for the purposes of determining geographic eligibility to apply for or receive services funded by FORHP's rural health grants. With a data-driven methodology, this update to the definition of rural area will integrate the new Road Ruggedness Score (RRS) released in 2023 by the Economic Research Service of the U.S. Department of Agriculture. This notice responds to comments received on proposed modifications to HRSA's FORHP definition published in the **Federal Register** on April 26, 2024.

DATES: All changes will go into effect as of November 21, 2024, and will apply to FORHP's Notices of Funding Opportunity released in Fiscal Year (FY) 2025 and future years.

FOR FURTHER INFORMATION CONTACT: Greta Stuhlsatz, Statistician, Policy Research Division, FORHP, HRSA, 5600 Fishers Lane, Rockville, Maryland 20857; (301) 443–0835 and *ruralpolicy@hrsra.gov.*

SUPPLEMENTARY INFORMATION: This notice updates the definition of rural area used for HRSA's FORHP rural health grants programs. HRSA published a notice in the **Federal Register** on April 26, 2024, seeking public comment on proposed modifications to the definition of rural area for the purposes of determining eligibility for its rural health grant programs (89 FR 32451). HRSA proposed a data-driven methodology to update the definition of rural area by integrating the new RRS released in 2023 by the Economic Research Service of the U.S. Department of Agriculture. The RRS characterizes topographic variability, or ruggedness, of roads. A