B. Need and Uses

This clearance covers the information that offerors and contractors must submit to comply with the following FAR requirements:

1. FAR 15.407–2(e), Make-or-buy programs. When prospective contractors are required to submit proposed make-or-buy program plans for negotiated acquisitions, paragraph (e) requires the following information in their proposal:

(a) A description of each major item or work effort;

(b) Categorization of each major item or work effort as ''must make,'' ''must buy,'' or ''can either make or buy'';

(c) For each item or work effort categorized as ''can either make or buy,'' a proposal either to ''make'' or to ''buy'';

(d) Reasons for categorizing items and work efforts as ''must make'' or ''must buy,'' and proposing to ''make'' or to ''buy'' those categorized as ''can either make or buy'';

(e) Designation of the plant or division proposed to make each item or perform each work effort, and a statement as to whether the existing or proposed new facility is in or near a labor surplus area;

(f) Identification of proposed subcontractors, if known, and their location and size status;

(g) Any recommendations to defer make-or-buy decisions when categorization of some items or work efforts is impracticable at the time of submission; and

(h) Any other information the contracting officer requires in order to evaluate the program.

2. FAR 52.215–1(c)(2)(iv)—Authorized Negotiators. This provision requires firms offering supplies or services to the Government under negotiated solicitations to provide the names, titles, and telephone and facsimile numbers (and electronic addresses if available) of authorized negotiators to assure that discussions are held with authorized individuals.

Contracting officers use this information during contract negotiations and it becomes part of the official contract file.

3. FAR 52.215–9, Changes or Additions to Make-or-Buy Program. This clause requires the contractor to submit, in writing, for the contracting officer's advance approval a notification and justification of any proposed change in the make-or-buy program incorporated in the contract.

Contracting officers use the information collected regarding make-or-buy programs at FAR 15.407–2(e) and 52.215–9 to ensure negotiation of reasonable contract prices, satisfactory performance, or implementation of socioeconomic policies.

4. FAR 52.215–14—Integrity of Unit Prices. This clause requires offerors and contractors under negotiated solicitations and contracts to identify those supplies which they will not manufacture or to which they will not contribute significant value, if requested by the contracting officer or when contracting without adequate price competition.

When a contract action is priced on the basis of a cost estimate, contracting officers use this information to determine whether the intrinsic value of an item has been distorted through allocation of overhead costs and whether such items should be considered for breakout.

5. FAR 52.215–19—Notification of Ownership Changes. This clause requires contractors to notify the administrative contracting officer when the contractor becomes aware that a change in its ownership has occurred, or is certain to occur, that could result in changes in the valuation of its capitalized assets in the accounting records.

The notification of ownership change enables the Government to adequately administer the cost principle at FAR 31.205–52, Asset valuations resulting from business combinations, which addresses the allowability of certain costs resulting from asset valuations following business combinations.

6. FAR 52.215–22, Limitations on Pass-Through Charges—Identification of Subcontract Effort. This provision requires offerors submitting a proposal for a contract, task order, or delivery order to provide the following information with their proposal:

(a) The total cost of the work to be performed by the offeror, and the total cost of the work to be performed by each subcontractor;

(b) If the offeror intends to subcontract more than 70 percent of the total cost of work to be performed, the amount of the offeror's indirect costs and profit/fee applicable to the work to be performed by the subcontractor(s), and a description of the value added by the offeror as related to the work to be performed by the subcontractor(s); and

(c) If any subcontractor proposed intends to subcontract to a lower-tier subcontractor more than 70 percent of the total cost of work to be performed, the amount of the subcontractor's indirect costs and profit/fee applicable to the work to be performed by the lower-tier subcontractor(s) and a description of the added value provided by the subcontractor as related to the work to be performed by the lower-tier subcontractor(s).

7. FAR 52.215–23, Limitations on Pass-Through Charges. This clause requires contractors to provide a description of the value added by the contractor or subcontractor, as applicable, as related to the subcontract effort if the effort changes from the amount identified in the proposal such that it exceeds 70 percent of the total cost of work to be performed.

Contracting officers use the information collected at FAR 52.215–22 and 52.215–23 to assess the value added by a contractor or subcontractor in relation to proposed, billed, or claimed indirect costs or profit/fee on work performed by a subcontractor. This information is required to ensure that pass-through charges under contracts and subcontracts are not excessive.

C. Annual Burden

Respondents: 122,097.

Total Annual Responses: 139,074.

Total Burden Hours: 43,027 (43,022 reporting hours + 5 recordkeeping hours).

Obtaining Copies: Requesters may obtain a copy of the information collection documents from the GSA Regulatory Secretariat Division by calling 202–501–4755 or emailing *GSARegSec@gsa.gov.* Please cite OMB Control No. 9000–0048, Certain Federal Acquisition Regulation Part 15 Requirements.

Janet Fry,

Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2024–27314 Filed 11–20–24; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–2565]

510(k) Third Party Review Program and Third Party Emergency Use Authorization Review; Guidance for Industry, Food and Drug Administration Staff, and Third Party Review Organizations; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled ''510(k) Third Party

Review Program and Third Party Emergency Use Authorization (EUA) Review.'' This guidance provides FDA's current thinking regarding the 510(k) Third Party (3P510k) Review Program and review of EUA requests by a third party review organization (3PEUA review). The 3P510k Review Program and 3PEUA review create an alternative process for manufacturers to seek review of 510(k) submissions and EUA requests to assist FDA in reviewing in a timely manner.

DATES: The announcement of the guidance is published in the **Federal Register** on November 21, 2024.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

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–2016–D–2565 for ''510(k) Third Party Review Program and Third Party Emergency Use Authorization (EUA) Review.'' Received comments 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''510(k) Third Party Review Program and Third Party Emergency Use Authorization (EUA) Review'' to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Joshua Nipper, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2438, Silver Spring, MD 20993–0002, 301–796–6524.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of the ''510(k) Third Party Review Program and Third Party Emergency Use Authorization (EUA) Review'' guidance. This guidance updates the previously issued ''510(k) Third Party Review Program'' guidance to further clarify the 3P510k Review Program and outline how FDA may use third party review organizations to conduct an initial review of EUA requests for all devices, including in vitro diagnostics, under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360bbb–3) and consistent with section 565(i) of the FD&C Act (21 U.S.C. 360bbb–4(i)).

This guidance distinguishes FDA's expectations for the 3P510k Review Program and for 3PEUA review; describes the factors FDA will use in determining device type eligibility for review by 3P510k Review Organizations; describes FDA's expectations for third party review organizations when conducting substantial reviews of 510(k) submissions and EUA requests; outlines FDA's process for the recognition, rerecognition, suspension, and withdrawal of recognition for 3P510k Review Organizations; and describes the expectations regarding compensation to third party review organizations. This guidance also outlines FDA's current thinking on leveraging the International Medical Device Regulators Forum's documents for the 3P510k Review Program. This guidance supersedes ''510(k) Third Party Review Program; Guidance for Industry, Food and Drug Administration Staff, and Third Party Review Organizations'' issued on March 12, 2020 (85 FR 14489).

A notice of availability of the draft guidance appeared in the **Federal Register** of December 21, 2023 (88 FR

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]

BILLING CODE 4164–01–P

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