



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510(k) Third Party Review Program and Third Party Emergency Use Authorization (EUA) Review; Draft Guidance for Industry, Food and Drug Administration Staff, and Third Party Review Organizations; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled “510(k) Third Party Review Program and Third Party Emergency Use Authorization (EUA) Review.” This draft guidance provides FDA’s current thinking regarding the 510(k) Third Party (3P510k) Review Program and review of Emergency Use Authorizations (EUA) requests by a third party review organizations (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. This draft guidance is not final nor is it for implementation at this time.

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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 draft 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 a draft guidance entitled “510(k) Third Party Review Program and Third Party Emergency Use Authorization (EUA) Review.” This draft 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 review EUA requests 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 draft 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 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 draft guidance, when final, will also outline FDA’s current thinking on leveraging the International Medical Device Regulators Forum’s documents for the 3P510k Review Program. When finalized, this guidance will supersede the final guidance entitled “510(k) Third Party Review Program; Guidance for

Industry, Food and Drug Administration Staff, and Third Party Review Organizations” published in the *Federal Register* of March 12, 2020 (85 FR 14489).

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent 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 draft 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
807, subpart E	Premarket notification	0910-0120
“Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program”	Q-submissions and Early Payor Feedback Request Programs for Medical Devices	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”	Appeals Process	0910-0738

Dated: December 18, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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