



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-D-5570]

Recommendations for Clinical Laboratory Improvement Amendments of 1988 Waiver

Applications for Manufacturers of In Vitro Diagnostic Devices; Guidance for Industry and Food and Drug Administration Staff; 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 “Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices.” FDA has updated this guidance to implement the waiver improvements section of the 21st Century Cures Act (the Cures Act), which requires FDA to revise “Section V. Demonstrating Insignificant Risk of an Erroneous Result--Accuracy” of the guidance “Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices” (“2008 CLIA Waiver Guidance”) that was issued on January 30, 2008. The remainder of the 2008 CLIA Waiver Guidance, with exception of technical edits for consistency with the newly amended section V, has not been substantively changed. This final guidance provides additional and updated approaches for demonstrating that a test meets the statutory criteria for waiver and includes FDA’s revised thinking regarding “the appropriate use of comparable performance between a waived user and a moderately complex laboratory user to demonstrate accuracy.”

DATES: The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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-2017-D-5570 for "Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices." 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.

- 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.

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 “Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices” to the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002 or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Peter Tobin, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3435, Silver Spring, MD 20993-0002, 240-402-6169 or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

This final guidance revises the guidance titled “Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices” (“2008 CLIA Waiver Guidance”) that was issued on January 30, 2008, to implement section 3057 of the Cures Act (Pub. L. 114-255), which requires FDA to revise “Section V. Demonstrating Insignificant Risk of an Erroneous Result--Accuracy” of the 2008 CLIA Waiver Guidance. The remainder of the 2008 CLIA Waiver Guidance, with exception of technical edits for consistency with the newly amended section V, has not been substantively changed. This update provides additional approaches for demonstrating that a test meets the criteria in 42 U.S.C. 263a(d)(3)(A) and includes FDA’s revised thinking regarding “the appropriate use of comparable performance between a waived user and a moderately complex laboratory user to demonstrate accuracy.”

The Secretary of Health and Human Services has delegated to FDA the authority to determine whether particular tests are “simple” and have “an insignificant risk of an erroneous result” under CLIA and thus are eligible for CLIA waiver (69 FR 22849, April 27, 2004). The Centers for Medicare & Medicaid Services is responsible for oversight of clinical laboratories, which includes issuing Certificates of Waiver. CLIA requires that clinical

laboratories obtain a certificate before accepting materials derived from the human body for laboratory tests (42 U.S.C. 263a(b)).

The 2008 CLIA Waiver Guidance describes recommendations for device manufacturers about study design and analysis for CLIA Waiver by Application to support an FDA determination as to whether the device meets the statutory criteria for waiver.

On November 29, 2017, FDA issued a draft guidance titled “Select Updates for Recommendations for Clinical Laboratory Improvement Amendments of 1988 Waiver Applications for Manufacturers of In Vitro Diagnostic Devices.” This draft guidance proposed additional approaches for demonstrating that a test meets the criteria in 42 U.S.C. 263a(d)(3)(A). On November 29, 2018, FDA issued a revised draft guidance by the same title, which appeared in the *Federal Register* of November 29, 2018 (83 FR 61391), after considering comments received on the draft guidance issued November 29, 2017. This document revises section V of the guidance “Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices,” issued on January 30, 2008.

## II. Significance of Guidance

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 “Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices.” 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.

## III. 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> or <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>. This guidance document is also available at <https://www.regulations.gov>. Persons unable to download an electronic copy of “Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices” may send an email request to [CDRH-Guidance@fda.hhs.gov](mailto:CDRH-Guidance@fda.hhs.gov) to receive an electronic copy of the document. Please use the document number 16046 to identify the guidance you are requesting.

#### IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521). The collections of information in the following FDA regulations and guidance have been approved by OMB as listed in the following table:

21 CFR Part or Guidance	Topic	OMB Control No.
50, 56	Protection of Human Subjects: Informed Consent; Institutional Review Boards	0910-0755
54	Financial Disclosure by Clinical Investigators	0910-0396
803	Medical Device Reporting	0910-0437
809	Medical Device Labeling Regulations	0910-0485
812	Investigational Device Exemption	0910-0078
“Recommendations for Clinical	CLIA Waiver Applications	0910-0598

Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices”		
“Administrative Procedures for Clinical Laboratory Improvement Amendments of 1988 Categorization”	CLIA Categorizations	0910-0607
“Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program”	Q-submissions	0910-0756

Dated: February 21, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020-03860 Filed: 2/25/2020 8:45 am; Publication Date: 2/26/2020]