



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Select Updates for Recommendations for Clinical Laboratory Improvement Amendments of 1988 Waiver Applications for Manufacturers of In Vitro Diagnostic Devices; Draft Guidance for Industry and Food and Drug Administration Staff; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled “Select Updates for Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices.” FDA has developed this draft guidance to implement a section of the 21st Century Cures Act (Cures Act) that requires FDA to revise “V. Demonstrating Insignificant Risk of an Erroneous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. This draft guidance updates FDA’s thinking regarding the appropriate use of comparable performance between a waived user and a moderately complex laboratory user to demonstrate accuracy. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure

that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.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-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.gpo.gov/fdsys/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 draft 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 the Center Director, 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. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Marina Kondratovich, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4672, Silver Spring, MD 20993-0002, 301-796-6036; or Peter Tobin, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5657, Silver Spring, MD 20993-0002, 301-796-6169.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has developed this draft guidance to implement section 3057 of the Cures Act (Pub. L. 114-255), which requires FDA to revise “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. This draft guidance updates FDA’s thinking regarding the appropriate use of comparable performance between a waived user and a moderately complex laboratory user to demonstrate accuracy. The 2008 CLIA Waiver Guidance remains in effect, in its current form, until this draft guidance is finalized, at which time the updates in section III of this draft guidance will supersede the recommendations in section V of the 2008 CLIA Waiver Guidance.

FDA will incorporate the updates of the final version of this draft guidance into “V. Demonstrating Insignificant Risk of an Erroneous Result--Accuracy” of the 2008 CLIA Waiver Guidance. The remainder of the 2008 CLIA Waiver Guidance will not be changed by this update and will remain in effect.

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 are thus eligible for waiver categorization (69 FR 22849, April 27, 2004). The Centers for Medicare & Medicaid Services (CMS) 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)). Laboratories that perform only tests that are “simple” and

that have an “insignificant risk of an erroneous result” may obtain a certificate of waiver (42 U.S.C. 263a(d)(2)).

CLIA, 42 U.S.C. 263a(d)(3) Examinations and Procedures, as modified by the Food and Drug Administration Modernization Act of 1997 (FDAMA), reads as follows regarding tests that may be performed by laboratories with a Certificate of Waiver:

“The examinations and procedures [that may be performed by a laboratory with a Certificate of Waiver]... are laboratory examinations and procedures that have been approved by the Food and Drug Administration for home use or that, as determined by the Secretary, are simple laboratory examinations and procedures that have an insignificant risk of an erroneous result, including those that--(A) employ methodologies that are so simple and accurate as to render the likelihood of erroneous results by the user negligible, or (B) the Secretary has determined pose no unreasonable risk of harm to the patient if performed incorrectly.”

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 described above. This update provides additional details and pathways for demonstrating that a test has an insignificant risk of erroneous result which is a key element for obtaining a CLIA Waiver by Application.

In developing this specific update, we have considered interactions with stakeholders since the issuance of the final guidance on January 30, 2008.

II. Significance of Guidance

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 “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.

This draft guidance is not subject to Executive Order 12866.

III. 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/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are 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 to receive an electronic copy of the document. Please use the document number GUD1627 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. The collections of information in this guidance were approved under OMB control number 0910-0598. The collections of information in 21 CFR part 54 have been approved under 0910-0396, and the collections of information in 21 CFR parts 50 and 56 have been approved under OMB control number 0910-0755.

Dated: November 22, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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