4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-D-5625]

Recommendations for Dual 510(k) and Clinical Laboratory Improvement Amendments Waiver by Application Studies; Draft Guidance for Industry and Food and Drug Administration Staff; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled "Recommendations for Dual 510(k) and Clinical Laboratory Improvement Amendments (CLIA) Waiver by Application Studies." It describes study designs for generating data that supports *both* 510(k) clearance and CLIA waived categorization. Use of the Dual 510(k) and CLIA Waiver by Application pathway is optional; however, FDA believes this pathway is in many instances the least burdensome and fastest approach for manufacturers to obtain a CLIA waived categorization in addition to 510(k) clearance for new In Vitro Diagnostic (IVD) devices. FDA believes increased use of this pathway will speed up the process of bringing simple and accurate IVD devices to CLIA waived settings, which will better serve patients and providers. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure

that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.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-5625 for "Recommendations for Dual 510(k) and CLIA Waiver by Application Studies." 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 21CFR 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 Dual 510(k) and CLIA Waiver by Application Studies" 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: Peter Tobin, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5645, Silver Spring, MD 20993-0002, 240-402-6169.

SUPPLEMENTARY INFORMATION:

I. Background

In an application for CLIA waived categorization (CLIA Waiver by Application) a manufacturer submits evidence to FDA that a test, initially categorized as moderate complexity, meets the

CLIA statutory criteria for waiver, 42 U.S.C. 263a(d)(3), and requests that FDA categorize the test as waived. Historically, CLIA Waiver by Application has followed clearance or approval of an IVD test. This stepwise approach currently remains the most utilized path by manufacturers. For additional information, please see FDA's Guidance, "Administrative Procedures for CLIA Categorization" (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM070889).

While a premarket notification (510(k)) and CLIA Waiver by Application each include discrete elements not required in the other, both submissions include comparison and reproducibility studies. For a 510(k), such studies are often performed by trained operators (i.e., laboratory professionals who meet the qualifications to perform moderate complexity testing and with previous training in performing the test; sometimes referred to as "moderate complexity users"). For a CLIA Waiver by Application, such studies must be conducted by untrained operators (i.e., operators in waived settings with limited or no training or hands on experience in conducting laboratory testing; sometimes referred to as "waived users").

An applicant may choose to conduct a single set of comparison and reproducibility studies with untrained operators to satisfy associated requirements for both 510(k) and CLIA Waiver by Application. To streamline the review of such data, the Dual 510(k) and CLIA Waiver by Application (Dual Submission) pathway, was established as part of the Medical Device User Fee Amendments of 2012 (MDUFA III), allowing the review of both a 510(k) and CLIA Waiver Application within a single submission with a reduced overall review time.

This guidance leverages FDA's experience implementing this pathway in MDUFA III in order to make the Dual Submission pathway least burdensome. Use of this guidance is expected

to reduce study-related costs and provide time savings for manufacturers of certain Class II IVD devices intended for CLIA waived settings.

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 Dual 510(k) and CLIA Waiver by Application Studies. 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 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 Dual 510(k) and CLIA Waiver by Application Studies" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 16038 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR 54 have been approved under 0910-0396; the collections of information in 21 CFR Parts 50 and 56 have been approved under OMB

control number 0910-0755, the collections of information in 21 CFR 807 have been approved under 0910-0120; the collections of information in the guidance document entitled "Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices" have been approved under 0910-0598, the collections of information in the guidance document entitled "Requests for Feedback on Medical Device Submissions" have been approved under 0910-0756; and the collections of information in the guidance document entitled "Administrative Procedures for Clinical Laboratory Improvement Amendments of 1988 Categorization" have been approved under 0910-0607.

Dated: November 22, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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