comment session and which topic(s) you would like to address. FDA will do its best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations. Following the close of registration, FDA will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin and will select and notify participants by March 27, 2019. All requests to make oral presentations must be received by the close of registration at 11:59 on March 22, 2019, Eastern Time. If selected for presentation, any presentation materials must be emailed to *cderdatastandards@fda.hhs.gov* no later than April 3, 2019. No commercial or promotional material will be permitted to be presented or distributed at the public meeting.

If you need special accommodations due to a disability, please contact Chenoa Conley, 301–796–0035, email *Chenoa.Conley@fda.hhs.gov,* no later than April 3, 2019.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at *https:/www.fda.gov/forindustry/userfees/prescriptiondruguserfee/ucm446608.htm.*

Dated: November 26, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–25958 Filed 11–28–18; 8:45 am]

BILLING CODE 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Recommendations for Dual 510(k) and Clinical Laboratory Improvement Amendments Waiver by Application Studies; Draft Guidance for Industry and Food and Drug Administration Staff; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled ''Recommendations for Dual 510(k) and Clinical Laboratory Improvement Amendments (CLIA) Waiver by Application Studies.''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 waiver. 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 waiver 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 February 27, 2019 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 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 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. 5657, Silver Spring, MD 20993–0002, 240–402–6169.

SUPPLEMENTARY INFORMATION:

I. Background

Typically, in an application for CLIA waiver (CLIA Waiver by Application) a manufacturer submits evidence to FDA that a previously cleared or approved 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. This means that historically a CLIA Waiver by Application has followed clearance or approval of an IVD test.

While a premarket notification (510(k)) and CLIA Waiver by Application each include discrete elements not required in the other, both submissions generally include comparison and reproducibility studies. For a 510(k), such studies are often performed by trained operators (*i.e.,* test operators 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, we believe such studies need to be conducted by the intended user (*i.e.,* test operators in waived settings and with limited or no training or hands-on experience in conducting laboratory testing; sometimes referred to as ''untrained operators'' or ''waived users'') (see 42 U.S.C. 263a(d)(3)).

An applicant may choose to conduct a single set of comparison and reproducibility studies with untrained operators to satisfy certain requirements to establish both substantial equivalence under section 513(i) of the FD&C Act (21 U.S.C. 360c(i) for 510(k) clearance and simplicity and insignificant risk of erroneous results under 42 U.S.C. 263a(d)(3) for CLIA waiver. 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 by Application within a single submission with a reduced overall review time compared to sequential submissions.

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.* This guidance document is 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 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. 3501–3520). 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; guidance; or FDA form	Topic	OMB Control No.
807, subpart E	Premarket notification	0910–0120
''Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices''.	CLIA Waiver Applications	0910–0598
''Administrative Procedures for CLIA Categorization''	CLIA Categorizations	0910–0607
''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff''.	Q-Submissions	0910–0756

Dated: November 26, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–25960 Filed 11–28–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369]

Product-Specific Guidances; Draft and Revised Draft Guidances for Industry; 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 additional draft and revised draft product-specific guidances. The guidances provide product-specific recommendations on, among other things, the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs). In the **Federal Register** of June 11, 2010, FDA