SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled “Recommendations for Dual 510(k) and Clinical Laboratory Improvement Amendment Studies (CLIA) Waiver by Application Studies.”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 This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by February 27, 2019 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.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.
• 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,

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
(MDUFSA 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
collections of information in the
following FDA regulations and guidance
have been approved by OMB as listed in
the following table:

<table>
<thead>
<tr>
<th>21 CFR part; guidance; or FDA form</th>
<th>Topic</th>
<th>OMB Control No.</th>
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<tr>
<td>807, subpart E</td>
<td>Premarket notification</td>
<td>0910–0120</td>
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| “Recommendations for Clinical Laboratory Improvement
  Amendments of 1988 (CLIA) Waiver Applications for
  Manufacturers of In Vitro Diagnostic Devices” |   | 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
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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