

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 Submit written requests for a single hard copy of the draft guidance document entitled “Recommendations for Dual 510(k) and CLIA Waiver by Application Studies” to the Office of the Center Director, Guidance and Policy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.

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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

announced the availability of a guidance for industry entitled “Bioequivalence Recommendations for Specific Products” that explained the process that would be used to make product-specific guidances available to the public on FDA’s website. The guidances identified in this notice were developed using the process described in that guidance.

DATES: Submit either electronic or written comments on the draft guidance by January 28, 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-2007-D-0369 for “Product-Specific Guidances; Draft and Revised Draft Guidances for Industry.” 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)).

Submit written requests for single copies of the draft guidances to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance documents.

FOR FURTHER INFORMATION CONTACT:

Wendy Good, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4714, Silver Spring, MD 20993-0002, 240-402-1146.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled “Bioequivalence Recommendations for Specific Products” that explained the process that would be used to make product-specific guidances available to the public on FDA’s website at <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

As described in that guidance, FDA adopted this process as a means to develop and disseminate product-specific guidances and provide a meaningful opportunity for the public to consider and comment on those guidances. Under that process, draft guidances are posted on FDA’s website and announced periodically in the **Federal Register**. The public is encouraged to submit comments on those recommendations within 60 days of their announcement in the **Federal Register**. FDA considers any comments received and either publishes final guidances or publishes revised draft guidances for comment. Guidances were last announced in the **Federal Register** on October 10, 2018. This notice announces draft product-specific guidances, either new or revised, that are posted on FDA’s website.

II. Drug Products for Which New Draft Product-Specific Guidances Are Available

FDA is announcing the availability of new draft product-specific guidances for industry for drug products containing the following active ingredients:

TABLE 1—NEW DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS

Amphetamine.
 Atropine sulfate; Diphenoxylate hydrochloride.
 Dichlorphenamide.
 Doxepin hydrochloride.
 Ertugliflozin.
 Ertugliflozin; Metformin hydrochloride.
 Ertugliflozin; sitagliptin phosphate.
 Estradiol.
 Latanoprostene bunod.
 Letemovir (multiple Reference Listed Drugs).
 Levothyroxine sodium.
 Lifitegrast.
 Macimorelin acetate.
 Metoprolol succinate.
 Netarsudil dimesylate.
 Nitazoxanide.
 Penicillamine.
 Plecanatide.
 Reserpine.
 Ribociclib succinate.
 Thiothixene.

III. Drug Products for Which Revised Draft Product-Specific Guidances Are Available

for industry for drug products containing the following active ingredients:

FDA is announcing the availability of revised draft product-specific guidances

TABLE 2—REVISED DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS

Acetaminophen; Butalbital; Caffeine (multiple Reference Listed Drugs).
 Acetaminophen; Oxycodone HCl.
 Adapalene (multiple Reference Listed Drugs).
 Adapalene; Benzoyl peroxide (multiple Reference Listed Drugs).
 Asenapine maleate.
 Benzoyl peroxide; Clindamycin phosphate (multiple Reference Listed Drugs).
 Benzoyl peroxide; Erythromycin (multiple Reference Listed Drugs).
 Clindamycin phosphate (multiple Reference Listed Drugs).
 Clindamycin phosphate; Tretinoin.
 Dapsone (multiple Reference Listed Drugs).
 Everolimus.
 Isosorbide dinitrate.
 Metaxalone.
 Mycophenolic acid.
 Nitazoxanide.
 Sulfacetamide Sodium.
 Sulfamethoxazole; Trimethoprim.
 Sumatriptan.
 Tazarotene (multiple Reference Listed Drugs).
 Tretinoin (multiple Reference Listed Drugs and multiple .strengths).
 Triamterene.
 Zolmitriptan.

For a complete history of previously published **Federal Register** notices related to product-specific guidances, go to <https://www.regulations.gov> and enter Docket No. FDA–2007–D–0369.

These draft guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). These draft guidances, when finalized, will represent the current thinking of FDA on, among other things, the product-specific design of BE

studies to support ANDAs. They do not establish any rights for any person and are 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.

IV. Electronic Access

Persons with access to the internet may obtain the draft guidances at either

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>.

Dated: November 23, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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