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This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on “Recommendations for Dual 510(k) and CLIA Waiver by Application Studies.”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Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet.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:

<table>
<thead>
<tr>
<th>21 CFR part; guidance; or FDA form</th>
<th>Topic</th>
<th>OMB Control No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Promarket notification ..................</td>
<td>CLIA Waiver Applications ..................</td>
<td>0910–0120 ..</td>
</tr>
<tr>
<td>CLIA Categorizations ..................</td>
<td>Q-Submissions ..................</td>
<td>0910–0607 ..</td>
</tr>
</tbody>
</table>

Dated: November 26, 2018.

Leslie Kux,
Associate Commissioner for Policy.

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

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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 a copy of the draft guidance at any time (see 21 CFR 10.115(g)(5)).

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.
Letermovir (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

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

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.
Myophenolic acid.
Nitazoxanide.
Sulfacetamide Sodium.
Sulfamethoxazole; Trimethoprim.
Sumatriptan.
Tazarotene (multiple Reference Listed Drugs).
Tretinoin (multiple Reference Listed Drugs and multiple strengths).
Triamterene.
Zolmitriptan.


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.


Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2018–25950 Filed 11–28–18; 8:45 am]

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