

Dated: October 30, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2007-D-0369]

#### Draft and Revised Draft Guidances for Industry Describing Product-Specific Bioequivalence Recommendations; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of additional draft and revised draft product-specific bioequivalence (BE) recommendations. The recommendations provide product-specific guidance on the design of 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,” which explained the process that would be used to make product-specific BE recommendations available to the public on FDA’s Web site. The BE recommendations identified in this notice were developed using the process described in that guidance.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comments on these draft and revised draft guidances before it begins work on the final versions of the guidances, submit either electronic or written comments on the draft and revised draft product-specific BE recommendations listed in this notice by January 6, 2014.

**ADDRESSES:** Submit written requests for single copies of the individual BE guidances to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, 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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance recommendations.

Submit electronic comments on the draft product-specific BE

recommendations to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Kris André, Center for Drug Evaluation and Research (HFD-600), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 240-276-8866.

#### 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,” which explained the process that would be used to make product-specific BE recommendations available to the public on FDA’s Web site at <http://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 BE recommendations and provide a meaningful opportunity for the public to consider and comment on those recommendations. Under that process, draft recommendations are posted on FDA’s Web site 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 recommendations or publishes revised draft recommendations for comment. Recommendations were last announced in the **Federal Register** on June 20, 2013 (78 FR 37230). This notice announces draft product-specific recommendations, either new or revised, that are being posted on FDA’s Web site concurrently with publication of this notice.

##### II. Drug Products for Which New Draft Product-Specific BE Recommendations Are Available

FDA is announcing new draft product-specific BE recommendations for drug products containing the following active ingredients:

TABLE 1—NEW DRAFT PRODUCT-SPECIFIC BE RECOMMENDATIONS FOR DRUG PRODUCTS

B .....	Bedaquiline fumarate.
	Bupropion hydrochloride.
C .....	Clobazam.
E .....	Etodolac (multiple reference listed drugs and dosage forms).

TABLE 1—NEW DRAFT PRODUCT-SPECIFIC BE RECOMMENDATIONS FOR DRUG PRODUCTS—Continued

M .....	Mesna. Methenamine hippurate. Methocarbamol.
N .....	Nicotine (multiple reference listed drugs). Nicotine polacrilex (multiple reference listed drugs).
P .....	Phentermine hydrochloride. Prednisone.

##### III. Drug Products for Which Revised Draft Product-Specific BE Recommendations Are Available

FDA is announcing revised draft product-specific BE recommendations for drug products containing the following active ingredients:

TABLE 2—REVISED DRAFT PRODUCT-SPECIFIC BE RECOMMENDATIONS FOR DRUG PRODUCTS

A .....	Acitretin. Amphetamine aspartate; Amphetamine sulfate; Dextroamphetamine saccharate; Dextroamphetamine sulfate.
B .....	Bumetanide. Bupropion hydrobromide. Bupropion hydrochloride (multiple reference listed drugs and dosage forms).
C .....	Cefixime. Celecoxib. Colesevelam hydrochloride.
D .....	Doxorubicin hydrochloride. Drospirenone; Ethinyl estradiol.
L .....	Lanthanum carbonate. Lenalidomide.
O .....	Oxybutynin chloride.
R .....	Rivastigmine.
T .....	Tacrolimus (multiple strengths). Testosterone (multiple reference listed drugs and dosage forms).

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

These draft and revised draft guidances are being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). These guidances represent the Agency’s current thinking on product-specific design of BE studies to support ANDAs. They do not create or confer any rights for or on any person and do not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

#### IV. Comments

Interested persons may submit either electronic comments on any of the specific BE recommendations posted on FDA's Web site to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. The guidances, notices, and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

#### V. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: October 31, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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### DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### Food and Drug Administration

[Docket No. FDA-2012-N-1021]

#### Medical Device User Fee and Modernization Act; Notice to Public of Web Site Location of Fiscal Year 2014 Proposed Guidance Development

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is announcing the Web site location where the Agency will post two lists of guidance documents the Center for Devices and Radiological Health (CDRH) is intending to publish in Fiscal Year (FY) 2014. In addition, FDA has established a docket where stakeholders may provide comments and/or propose draft language for those topics, suggest new or different guidance documents, and comment on the priority of topics for guidance.

**DATES:** Submit either electronic or written comments at any time.

**ADDRESSES:** Submit electronic comments on the proposed guidance to <http://www.regulations.gov>. Submit written comments to the Division of

Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Philip Desjardins, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5452, Silver Spring, MD 20993-0002, 301-796-5678.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

During negotiations over the Medical Device User Fee Amendments of 2012 (MDUFA III), Title II, Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144), FDA agreed, in return for additional funding from industry, to meet a variety of quantitative and qualitative goals intended to help get safe and effective medical devices to market more quickly. These commitments include annually posting a list of prioritized medical device guidance documents that the Agency intends to publish within 12 months of the date this list is published each fiscal year (the "A-list") and a list of device guidance documents that the Agency intends to publish, as the Agency's guidance-development resources permit each fiscal year (the "B-list"). In addition to posting lists of prioritized device guidance documents, FDA has committed to updating its Web site in a timely manner to reflect the Agency's review of previously published guidance documents, including the deletion of guidance documents that no longer represent the Agency's interpretation of, or policy on, a regulatory issue, and notation of guidance documents that are under review by the Agency. Fulfillment of this commitment will be reflected through the issuance of updated guidance on existing topics, removal of guidances that no longer reflect FDA's current thinking on a particular topic, and annual updates to the A-list and B-list announced in this notice.

This notice announces the Web site location of the two lists of guidance documents which CDRH is intending to publish during FY 2014. We note that the Agency is not required to publish every guidance on either list if the resources needed would be to the detriment of meeting quantitative review timelines and statutory obligations. The Agency is not precluded from issuing guidance documents that are not on either list.

FDA and CDRH priorities are subject to change at any time. Topics on this and past guidance priority lists may be removed or modified based on current priorities. CDRH's experience in

guidance development has shown that there are many reasons that CDRH staff may not complete the entire agenda of guidances it undertakes. Staffs are frequently diverted from guidance development to other priority activities. In addition, at any time new issues may arise to be addressed in guidance that could not have been anticipated at the time the annual list is generated. These may involve newly identified public health issues.

FDA anticipates that feedback from stakeholders, including draft language for guidance documents, will allow CDRH to better prioritize and more efficiently draft guidances that will be useful to industry and other stakeholders. FDA intends to update the list each year.

FDA invites interested persons to submit comments on any or all of the guidance documents on the lists. FDA has established a docket where comments on the FY 2014 lists, draft language for guidance documents on those topics, suggestions for new or different guidances, and relative priority of guidance documents may be submitted (see **ADDRESSES**). FDA believes this docket is an important tool for receiving information from interested parties and for sharing this information with the public. Similar information about planned guidance development is included in the annual Agency-wide notice issued under its good guidance practices (21 CFR 10.115(f)(5)). The CDRH lists, however, will be focused exclusively on device-related guidances and will be made available on FDA's Web site at the beginning of each FY from 2013 to 2017. To access the lists of guidance documents CDRH is intending to publish in FY 2014, visit FDA's Web site <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MDUFAIII/ucm321367.htm>.

##### II. Request for Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.