II. Award Information/Funds Available

A. Award Amount

The Center for Food Safety and Applied Nutrition at FDA intends to fund one award up to $2 million for FY13, with the possibility of four additional years of support, subject to the availability of funds. Future year amounts will depend on annual appropriations and successful performance.

B. Length of Support

The award will provide 1 year of support, with the possibility of four additional years of support, contingent upon satisfactory performance in the achievement of project and program reporting objectives during the preceding year and the availability of Federal fiscal year appropriations.

III. Paper Application, Registration, and Submission Information

To submit a paper application in response to this FOA, applicants should first review the full announcement located at *www.fda.gov/food/newsevents/default.htm.* (FDA has verified the Web site addresses throughout this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.) Persons interested in applying for a grant may obtain an application at *http://grants.nih.gov/grants/forms.htm.* For all paper application submissions, the following steps are required:

- Step 1: Obtain a Dun and Bradstreet (DUNS) Number
- Step 2: Register With System for Award Management (SAM)
- Step 3: Register With Electronic Research Administration (eRA) Commons

Steps 1 and 2, in detail, can be found at *http://www07.grants.gov/applicants/organization_registration.jsp.* Step 3, in detail, can be found at *https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp.* After you have followed these steps, submit paper applications to the Grants Management Officer/Specialist listed above.

Dated: June 14, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–14673 Filed 6–19–13; 8:45 am]

BILLING CODE 4160–01–P

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 August 19, 2013.

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, 7519 Standish Pl., Rockville, MD 20855, 240–276–9326.

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** of December 17, 2012 (77 FR 74669). 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:

A
Apixaban
Artemether; Lumefantrine
Asenapine maleate
B
Balsalazide disodium
C
Cycloserine
Cyclosporine
E
Eltrombopag olamine
F
Fluoxetine
H
Hydrochlorothiazide; Triamterene
M
Medroxyprogesterone (multiple reference listed drugs)
Methyltestosterone

Mirabegron
S
Sodium ferric gluconate
T
Timolol maleate
Trientine

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:

A
Albuterol sulfate (multiple reference listed drugs)
Ambrisentan
C
Carbidopa; Entacapone; Levodopa
Colesevelam
D
Dexamethasone; Tobramycin (multiple reference listed drugs and dosage forms)
Didanosine
Drospirenone; Estradiol
E
Entacapone
F
Fentanyl citrate
I
Isotretinoin
M
Minocycline hydrochloride
P
Phentermine hydrochloride; Topiramate
T
Tenofovir disoproxil fumarate
Topiramate (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 number 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: June 14, 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–D–0938]

Guidance for Industry; Guidance on Abbreviated New Drug Applications: Stability Testing of Drug Substances and Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance entitled ''ANDAs: Stability Testing of Drug Substances and Products.'' FDA is recommending generic drug manufacturers follow the stability testing recommendations in the International Conference on Harmonisation (ICH) guidances Q1A (R2) through Q1E. The use of these ICH recommendations will standardize FDA's stability testing policies, which will help make the abbreviated new drug application (ANDA) review process more efficient.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance 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 the office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the 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: Radhika Rajagopalan, Center for Drug Evaluation and Research, Food and Drug Administration, 7500 Standish Pl., MPN2, rm. 243, HFD–640, Rockville, MD 20855, 240–276–8546.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''ANDAs: Stability Testing of Drug Substances and Products.'' Because of increases in the number and complexity of ANDAs and FDA's desire to standardize generic drug review, FDA is recommending that the generic drug industry follow the approach in the following stability related ICH guidances: (1) ''Q1A (R2) Stability Testing of New Drug Substances and Products,'' November 2003; (2) ''Q1B Photostability Testing of New Drug Substances and Products,'' November 1996; (3) ''Q1C Stability Testing for New Dosage Forms,'' November 1996; (4) ''Q1D Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products,'' January 2003; and (5) ''Q1E Evaluation of Stability Data,'' June 2004. These guidances can be found on the FDA Guidances (Drugs) Web site under International Conference on Harmonisation—Quality at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm065005.htm*. FDA also recommends that industry follow the ICH outlined definitions, glossaries, references, and attachments.

Although the ICH stability guidances were developed for new drug applications to ensure the stability of new drug substances and products, FDA believes the recommendations provided in the ICH guidances on stability testing also are appropriate for ANDAs. FDA is recommending that applicants follow the ICH stability guidances for all ANDA submissions under section 505(j) of the Federal Food Drug, and Cosmetic Act (21 U.S.C. 355(j)) and relying on drug master files.

This guidance also replaces stability study storage condition recommendations made by the Office of Generic Drugs (OGD) in an August 18, 1995, letter to all ANDA applicants.