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://www07.grants.gov/applicants/register.jsp. 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]
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
   Coleslevam
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. Tenofivir disoproxil fumarate
Topiramate (multiple reference listed drugs and dosage forms)


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.

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0938]


AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.


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.

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.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled “ANDAs: Stability Testing of Drug Substances and Products.”