

well-established, trusted presence, access to 191 Member Nations, and an ability to coordinate capacity building programs at a regional and international level, it is uniquely qualified to further the global food safety capacity building objectives of this cooperative agreement. This ability to advance the objectives of this cooperative agreement through Member Country engagement and leveraging is a requisite for success.

## II. Award Information/Funds Available

### A. Award Amount

The Center for Food Safety and Applied Nutrition intends to fund one award up to \$750,000 total costs (direct plus indirect costs) for FY 2013. Future year amounts will depend on annual appropriations and successful performance.

### B. Length of Support

The award will provide 1 year of support and include future recommended support for 4 additional years, 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. Electronic Application, Registration, and Submission

Only electronic applications will be accepted. To submit an electronic application in response to this FOA, applicants should first review the full announcement located at [www.fda.gov/food/newsevents/default.htm](http://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.) For all electronically submitted applications, 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: Obtain Username & Password
- Step 4: Authorized Organization Representative (AOR) Authorization
- Step 5: Track AOR Status
- Step 6: Register With Electronic Research Administration (eRA) Commons

Steps 1 through 5, in detail, can be found at [http://www07.grants.gov/applicants/organization\\_registration.jsp](http://www07.grants.gov/applicants/organization_registration.jsp). Step 6, in detail, can be found at <https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp>. After you have followed these steps,

submit electronic applications to: <http://www.grants.gov>.

Dated: July 29, 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 Guidance for Industry on Bioequivalence Recommendations for Mesalamine Rectal Suppositories; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Bioequivalence Recommendations for Mesalamine." The recommendations provide specific guidance on the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs) for mesalamine rectal suppositories. The draft guidance is a revised version of a previously issued draft guidance on the same subject.

**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 this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by October 1, 2013.

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

Submit electronic comments on the draft 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:** Kris Andre, 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. This notice announces the availability of a draft guidance on mesalamine (Draft Mesalamine Rectal Suppository BE Recommendations of 2013).

CANASA (Mesalamine, USP) Rectal Suppositories, new drug application 021252, 500 milligram (mg) and 1,000 mg strengths were approved by FDA in January 2001 and November 2004, respectively. The 500 mg strength is no longer marketed. There are no approved ANDAs for this product.

In May 2007, FDA posted on its Web site a draft guidance for industry on the Agency's recommendations for BE studies to support ANDAs for mesalamine rectal suppositories (Draft Mesalamine Rectal Suppository BE Recommendations of May 2007). In that draft guidance, FDA recommended in vivo studies to demonstrate BE of generic mesalamine rectal suppositories: A BE study with clinical endpoints and a fasting BE study with pharmacokinetic endpoints. FDA has reconsidered the recommendations in the Draft Mesalamine Rectal Suppository BE Recommendations of May 2007 and has decided to revise it. In March 2013, FDA withdrew the Draft Mesalamine Rectal Suppository BE Recommendations of May 2007 and posted on its Web site a revised draft guidance for industry, the Draft Mesalamine Rectal Suppository BE Recommendations of 2013. In this revised draft guidance, FDA recommends in vivo and in vitro studies to demonstrate BE of generic mesalamine rectal suppositories: A fasting BE study with pharmacokinetic endpoints and comparative in vitro studies (melting point, differential scanning calorimetry, density, and viscosity). FDA is no longer

recommending a BE study with clinical endpoints for demonstration of BE of generic mesalamine rectal suppositories.

In July 2007, Axcan Scandipharm (Axcan), manufacturer of CANASA, submitted a citizen petition requesting that FDA withhold approval of any ANDA application for a generic version of CANASA (mesalamine rectal suppositories) unless certain studies that demonstrated BE were conducted (Docket No. FDA-2007-P-0010, formerly 2007P-0302/CP1). FDA is reviewing the issues raised in the petition and is also reviewing the supplemental information submitted to the docket for this petition. FDA will consider any comments on the Draft Mesalamine Rectal Suppository BE Recommendations of 2013 before responding to Axcan's citizen petition.

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 Agency's current thinking on the design of BE studies to support ANDAs for mesalamine rectal suppositories. It does not create or confer any rights for or on any person and does 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.

## II. 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>.

## III. 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: July 29, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2013-N-0007]

### Food Safety Modernization Act Domestic and Foreign Facility Reinspection, Recall, and Importer Reinspection Fee Rates for Fiscal Year 2014

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the fiscal year (FY) 2014 fee rates for certain domestic and foreign facility reinspections, failures to comply with a recall order, and importer reinspections that are authorized by the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the FDA Food Safety Modernization Act (FSMA). These fees are effective on October 1, 2013, and will remain in effect through September 30, 2014.

**FOR FURTHER INFORMATION CONTACT:** Hunter Herrman, Office of Resource Management, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., rm. 2049, Rockville, MD 20857, 240-402-3102, email: [Hunter.Herrman@fda.hhs.gov](mailto:Hunter.Herrman@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

#### I. Background

Section 107 of FSMA (Pub. L. 111-353) added section 743 to the FD&C Act (21 U.S.C. 379j-31) to provide FDA with the authority to assess and collect fees from, in part: (1) The responsible party for each domestic facility and the U.S. agent for each foreign facility subject to a reinspection, to cover reinspection-related costs; (2) the responsible party for a domestic facility and an importer who does not comply with a recall order, to cover food<sup>1</sup> recall activities associated with such order; and (3) each importer subject to a reinspection to cover reinspection-related costs (sections 743(a)(1)(A), (B), and (D) of the FD&C Act). Section 743 of the FD&C Act directs FDA to establish fees for each of these activities based on an estimate of 100 percent of the costs of each activity for each year (section 743(b)(2)(A), (B), and (D)), and these fees must be made available solely to pay for the costs of each activity for which the fee was incurred (section 743(b)(3)). These fees are effective on October 1, 2013, and

<sup>1</sup> The term "food" for purposes of this document has the same meaning as such term in section 201(f) of the FD&C Act (21 U.S.C. 321(f)).

will remain in effect through September 30, 2014. Section 743(b)(2)(B)(iii) of the FD&C Act directs FDA to develop a proposed set of guidelines in consideration of the burden of fee amounts on small businesses. As a first step in developing these guidelines, FDA invited public comment on the potential impact of the fees authorized by section 743 of the FD&C Act on small businesses (76 FR 45818, August 1, 2011). The comment period for this request ended November 30, 2011. As stated in FDA's September 2011 "Guidance for Industry: Implementation of the Fee Provisions of Section 107 of the FDA Food Safety Modernization Act," (<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm274176.htm>), because FDA recognizes that for small businesses the full cost recovery of FDA reinspection or recall oversight could impose severe economic hardship, FDA intends to consider reducing certain fees for those firms. FDA is currently developing a guidance document to outline the process through which firms may request such a reduction of fees. FDA does not intend to issue invoices for reinspection or recall order fees until this guidance document has been published.

In addition, as stated in the September 2011 Guidance, FDA is in the process of considering various issues associated with the assessment and collection of importer reinspection fees. FDA is currently developing a guidance document that will provide information regarding fees that the Agency may assess and collect from importers to cover reinspection-related costs. The fee rates set forth in this notice will be used to determine any importer reinspection fees assessed in FY 2014.

#### II. Estimating the Average Cost of a Supported Direct FDA Work Hour for FY 2014

FDA is required to estimate 100 percent of its costs for each activity in order to establish fee rates for FY 2014. In each year, the costs of salary (or personnel compensation) and benefits for FDA employees account for between 50 and 60 percent of the funds available to, and used by, FDA. Almost all of the remaining funds (or the operating funds) available to FDA are used to support FDA employees for paying rent, travel, utility, information technology, and other operating costs.