TABLE 1—FEE SCHEDULE FOR FY 2014

Fee category	Fee rates for FY 2014
Initial BPD	$216,910
Annual BPD	216,910
Reactivation	433,820
Applications [1]	
Requiring clinical data	2,169,100
Not requiring clinical data	1,084,550
Supplement requiring clinical data	1,084,550
Establishment	554,600
Product	104,060

[1] Under section 744H(a)(2)(A) of the FD&C Act, if a sponsor that submits a biosimilar biological product application has previously paid initial BPD fees, annual BPD fees, and/or reactivation fees for the product that is the subject of the application, the fee for the application is reduced by the cumulative amount of these previously paid fees.

IV. Fee Payment Options and Procedures

A. Initial BPD, Reactivation, Application, and Supplement Fees

The fees established in the new fee schedule are effective October 1, 2013. The initial BPD fee for a product is due when the sponsor submits an IND that FDA determines is intended to support a biosimilar biological product application for the product, or within 5 calendar days after FDA grants the first BPD meeting for the product, whichever occurs first. For sponsors who have discontinued participation in the BPD Program, a reactivation fee will be due when the sponsor submits an IND for an investigation that FDA determines is intended to support a biosimilar biological product application, or within 5 calendar days after FDA grants the sponsor's request for a BPD meeting for a product, whichever occurs first.

The application or supplement fee for a biosimilar biological product is due upon submission of the application or supplement.

To make a payment of the initial BPD, reactivation, supplement, or application fee, you must complete the Biosimilar User Fee Cover Sheet, available on FDA's Web site (*http://www.fda.gov/ForIndustry/UserFees/BiosimilarUserFeeActBsUFA/default.htm*) starting October 1, 2013, and generate a user fee identification (ID) number. Payment must be made in U.S. currency by electronic check, check, bank draft, U.S. postal money order, or wire transfer.

FDA has partnered with the U.S. Department of the Treasury to use Pay.gov, a Web-based payment application, for online electronic payment. The Pay.gov feature is available on FDA's Web site after completing the Biosimilar User Fee Cover Sheet and generating the user fee ID number.

Please include the user fee ID number on your check, bank draft, or postal money order, and make it payable to the order of the Food and Drug Administration. Your payment can be mailed to: Food and Drug Administration, P.O. Box 979108, St. Louis, MO 63197–9000. If checks are to be sent by a courier that requests a street address, the courier can deliver the checks to: U.S. Bank, Attention: Government Lockbox 979108, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This U.S. Bank address is for courier delivery only.) Please make sure that the FDA post office box number (P.O. Box 979108) is written on the check, bank draft, or postal money order.

If paying by wire transfer, please reference your unique user fee ID number when completing your transfer. The originating financial institution may charge a wire transfer fee. Please ask your financial institution about the fee and include it with your payment to ensure that your fee is fully paid. The account information is as follows: New York Federal Reserve Bank, U.S. Department of Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No.: 75060099, Routing No.: 021030004, SWIFT: FRNYUS33, Beneficiary: FDA, 1350 Piccard Dr., Rockville, MD, 20850.

The tax identification number of FDA is 53–0196965.

B. Annual BPD, Establishment, and Product Fees

FDA will issue invoices for annual BPD, biosimilar biological product establishment, and biosimilar biological product fees under the new fee schedule in August 2013. Payment instructions will be included in the invoices. Payment will be due on October 1, 2013. FDA will issue invoices in November 2014 for any annual BPD, products and establishments subject to fees for FY 2014 that qualify for fee assessments after the August 2013 billing.

Dated: July 29, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–18621 Filed 8–1–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0010]

Cooperative Agreement to Support the Food and Agriculture Organization

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its intention to receive and consider a single source application for award of a cooperative agreement in fiscal year 2013 to the Food and Agriculture Organization (FAO) of the United Nations to support global strategies that address food safety and public health.

The goal of this collaborative project between FDA and FAO is to contribute to the knowledge base and development of food safety systems globally due to the increasingly diverse and complex food supply. The project is also designed to enhance and broaden FDA's ability to address global food safety and public health issues associated with food as well as provide opportunities to leverage additional resources of other countries. The collaborative project will also support the FDA's implementation of the FDA Food Safety Modernization Act (FSMA), including FDA's International Food Safety Capacity Building Plan, which emphasizes the concept of preventing food safety-related problems before they occur and the importance of establishing strong relationships and mutual support among all stakeholders, including multilateral organizations, to improve worldwide food safety. In addition, the collaborative project will support food safety, nutrition, and public health programs that align with FDA's mission.

DATES: Important dates are as follows:

1. The application due date is September 1, 2013.

2. The anticipated start date is September 2013.

3. The expiration date is September 2, 2013.

ADDRESSES: Submit electronic applications to: *http://www.grants.gov.* For more information, see section III of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: *Scientific/Programmatic Contact:* Julie Moss, Center for Food Safety and Applied Nutrition (HFS–550), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2031, *Julie.moss@fda.hhs.gov. Grants Management Contact:* Gladys

Melendez, Office of Acquisitions and Grant Services (HFA 500), Food and Drug Administration, 5630 Fishers Lane, rm. 2032, Rockville, MD 20857, 301–827–7175, *gladys.bohler@fda.hhs.gov.*

For more information on this funding opportunity announcement (FOA) and to obtain detailed requirements, please refer to the full FOA located at *www.fda.gov/food/newsevents/default.htm.*

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

93.103 RFA–FD–13–037

A. Background

An intergovernmental organization, FAO has 191 Member Nations, two associate members, and one member organization (the European Union). Achieving food security for all is at the heart of FAO's efforts—to make sure people have regular access to enough high-quality food to lead active, healthy lives. FAO's mandate is to raise levels of nutrition, improve agricultural productivity, better the lives of rural populations, and contribute to the growth of the world economy. FAO's activities comprise four main areas:

Putting information within reach: FAO serves as a knowledge network. The organization uses the expertise of its staff—agronomists, foresters, fisheries and livestock specialists, nutritionists, social scientists, economists, statisticians and other professionals—to collect, analyze, and disseminate data that aid development.

Sharing policy expertise: FAO lends its years of experience to member countries in devising agricultural policy, supporting planning, drafting effective legislation, and creating national strategies to achieve rural development and hunger alleviation goals.

Providing a meeting place for nations: As a neutral forum, experts from around the globe convene at headquarters or in field offices to forge agreements on major food and agriculture issues.

Bringing knowledge to the field: FAO provides the technical know-how and mobilizes and manages millions of dollars provided by industrialized countries, development banks, and other sources to make sure the projects achieve their goals.

Capacity Development is a core function highlighted in FAO's new strategic framework. Member Countries place strong emphasis on FAO enhancing delivery in this area as they recently approved the Corporate Strategy on Capacity Development. The Strategy was developed in consultation with Member Countries and all FAO units worldwide. Taking a corporate approach to Capacity Development allows FAO to learn from its collective efforts and to support Member Countries in their own Capacity Development activities. The new FAO Capacity Development framework will guide FAO staff and their partners in analyzing capacities in Member Countries and identifying the appropriate intervention(s) for fostering sustainable development.

FAO supports Member Countries in developing their capacities to effectively manage food safety and quality as a key step to safeguarding the health and well-being of people as well as to accessing domestic, regional, and international markets. Capacity Development in Food Safety and Quality is the process through which relevant stakeholders from farm to table (including government agencies, food enterprises, academia, and consumers) are able to better perform their functions and to assume their responsibilities in ensuring safety and quality of food for domestic consumption and export.

For the Food Safety and Quality Unit (AGN) within FAO, its overall goal is to improve systems of food safety and quality management, based on scientific principles, that lead to reduced foodborne illness and support fair and transparent trade, thereby contributing to economic development, improved livelihoods, and food security. This unit:

1. Provides independent scientific advice on food safety and nutrition, which serves as the basis for international food standards.
2. Develops institutional and individual capacities for food control and food safety management in many countries, including the management of food safety emergencies.
3. Supports processes for the development of food safety policy frameworks.
4. Facilitates global access to information and encourages and supports the development of food safety/quality networks.

While the specific projects to be undertaken under this agreement will be determined following the agreement entering into force, examples of the types of food safety projects of interest to FDA that could be undertaken by the FAO include the following: Development of policy support tools to guide planning and investment in national food control systems; provision of technical advice for the development and improvement of integrated and modern food control systems; enhancement of effective participation in the work of the Codex Alimentarius Commission and other international fora; addressing emerging food safety issues; and development of technical tools and guides related to various technical and managerial aspects of food control. In addition to the aforementioned types of projects, FDA would also be interested in supporting nutrition projects through this Agreement. Examples of such projects include the FAO's Nutrition Education and Communication project focusing on professional education, as well as assistance with countries seeking to develop effective food-based dietary guidelines.

AGN also houses the secretariat of the Joint FAO/World Health Organization Codex Alimentarius Secretariat.

B. Research Objectives

With an increasingly diverse and complex global food supply, FDA's interest is to strengthen food safety systems globally to prevent food safety problems rather than merely reacting to problems after they occur. FDA recognizes that it can't do this alone. By working with other World Trade Organization member countries and partnering with the FAO, FDA can broaden the reach of food safety capacity building efforts.

This Cooperative Agreement will allow FDA to deepen its international food safety capacity building partnerships, provide a wider scope of impact than exists currently, and merge resources with other countries.

This cooperative agreement will provide support so that the FAO can meet the following projected milestones:

1. Contribute to the knowledge base and development of food safety systems due to the increasingly diverse and complex food supply.
2. Enhance and broaden FDA's ability to address global food safety and public health issues associated with food.
3. Provide opportunities to leverage additional resources of other countries.
4. Support FSMA and its International Food Safety Capacity Building Plan, which emphasizes the concept of preventing food safety-related problems before they occur and the importance of establishing strong relationships and mutual support among all stakeholders, including multilateral organizations, to improve worldwide food safety.
5. Support food safety, nutrition, and public health programs that align with FDA's mission.

C. Eligibility Information

Competition is limited to the FAO because, as a global organization with a

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. (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.* 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.

[FR Doc. 2013–18631 Filed 8–1–13; 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 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/GuidanceCompliance RegulatoryInformation/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