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: Paul E. Levine, Jr., Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Guidance for Industry: Enforcement Policy Regarding Investigational New Drug Requirements for Use of Fecal Microbiota for Transplantation to Treat *Clostridium difficile* Infection Not Responsive to Standard Therapies,'' dated March 2014.

Fecal microbiota collected from healthy individuals are being investigated for use in the treatment of *C. difficile* infection that is not responsive to standard therapies. Published data suggest that the use of fecal microbiota to restore intestinal flora may be an effective therapy in the management of refractory *C. difficile* infection. However, the efficacy and safety profile of this intervention has not yet been fully evaluated in controlled clinical trials.

In the **Federal Register** of July 18, 2013 (78 FR 42965), FDA announced the availability of the July 2013 Guidance. At that time, FDA informed members of the medical and scientific community, and other interested persons that it intended to exercise enforcement discretion regarding these requirements provided that the physician treating the patient obtains adequate informed consent from the patient or his or her legally authorized representative for the use of FMT products. FDA received several comments on the guidance, all of which supported enforcement discretion with regard to the continued use of FMT products to treat *C. difficile* infection not responsive to standard therapies.

Since publishing the July 2013 Guidance, FDA has reviewed and intends to modify its enforcement discretion policy. In this draft guidance, FDA explains that it intends to exercise enforcement discretion regarding the IND requirements for the use of FMT to treat *C. difficile* infection not responding to standard therapies provided that: (1) The licensed health care provider treating the patient obtains adequate informed consent from the patient or his or her legally authorized representative for the use of FMT products; (2) the FMT product is obtained from a donor known to either the patient or the licensed health care provider treating the patient; and (3) the stool donor and stool are qualified by screening and testing performed under the direction of the licensed health care provider for the purpose of providing the FMT product to treat his or her patient. This policy does not extend to the use of an FMT product when the FMT product is manufactured from the stool of a donor who is not known by the patient and/or the licensed health care provider treating the patient, or the donor and donor stool are not qualified under the direction of the licensed health care provider. Furthermore, this policy does not extend to other uses of FMT. Data related to the use and study of FMT to treat diseases or conditions other than *C. difficile* infection are limited, and study of FMT for these other uses is not included in this enforcement policy.

FDA intends to exercise this discretion on an interim basis while the Agency further considers the matter, and continues to evaluate its enforcement policy. The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on this topic. 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 requirement of the applicable statutes and regulations.

II. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. 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 draft guidance at either *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: February 20, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–04095 Filed 2–25–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Food and Drug Administration/Xavier University Global Medical Device Conference

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public conference.

SUMMARY: The Food and Drug Administration (FDA) Cincinnati District, in cosponsorship with Xavier University, is announcing a public conference entitled ''FDA/Xavier University Global Medical Device Conference (MedCon).'' This 3-day public conference includes presentations from key FDA officials and industry experts with small group breakout sessions. The conference is intended for companies of all sizes and employees at all levels.

Dates and Times: The public conference will be held on May 7, 2014, from 8:30 a.m. to 5 p.m.; May 8, 2014, from 8:30 a.m. to 5 p.m.; and May 9, 2014, from 8:30 a.m. to 12:45 p.m.

Location: The public conference will be held on the campus of Xavier University, 3800 Victory Pkwy., Cincinnati, OH 45207, 513–745–3073 or 513–745–3020.

Contact Persons: For information regarding this notice: Gina Brackett, Food and Drug Administration, 6751 Steger Dr., Cincinnati, OH 45237, 513–679–2700, FAX: 513–679–2771, email: *gina.brackett@fda.hhs.gov.*

For information regarding the conference and registration: Marla Phillips, Xavier University, 3800 Victory Pkwy., Cincinnati, OH 45207, 513–745–3073, email: *phillipsm4@xavier.edu.*

Registration: There is a registration fee. The conference registration fees cover the cost of the presentations, training materials, receptions, breakfasts, and lunches for the 3 days of the conference. Early registration ends March 11, 2014. Advanced registration rates begin March 12, 2014. Standard registration rates begin April 9, 2014. There will be onsite registration. The cost of registration is as follows:

TABLE 1—REGISTRATION FEES [1]

Attendee Type	Early rate (through 3/11/14)	Advanced rate (3/12/14 to 4/8/14)	Standard rate (4/9/14 to 5/9/14)
Industry	$1,195	$1,495	$1,695
Small Business (<100 employees)	$900	$1,000	$1,200
Startup Manufacturer	$200	$250	$300
Academic	$200	$250	$300
FDA/Government Employee	Fee Waived	Fee Waived	Fee Waived.

[1] The following forms of payment will be accepted: American Express, Visa, Mastercard, and company checks.

To register online for the public conference, please visit the ''Registration'' link on the conference Web site at *http://www.XavierMedCon.com.* FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register.**

To register by mail, please send your name, title, firm name, address, telephone and fax numbers, email, and payment information for the fee to Xavier University, Attention: Mason Rick, 3800 Victory Parkway, Cincinnati, OH 45207. An email will be sent confirming your registration.

Attendees are responsible for their own accommodations. The conference headquarters hotel is the Cincinnati Hilton Netherlands Plaza, 35 West 5th Street, Cincinnati, OH, 45202, 513–421–9100. Special conference block rates are available through April 16, 2014. To make reservations online, please visit the ''Venue/Logistics'' link at *http://www.XavierMedCon.com.*

If you need special accommodations due to a disability, please contact Marla Phillips (see *Contact Persons*) at least 7 days in advance of the conference.

SUPPLEMENTARY INFORMATION: The public conference helps fulfill the Department of Health and Human Services and FDA's important mission to protect the public health. The conference will provide those engaged in FDA-regulated medical devices (for humans) with information on the following topics:

- Center for Devices and Radiological Health Future Vision and Strategy Keynote Address;
- European Union Regulations: New Regulations, Company Strategy, and Open Discussion Forum;
- How to Implement the Unique Device Identification Requirements;
- Update from the Office of Device Evaluation;
- FDA Regulation of Health Information Technology: Medical Apps, Cybersecurity, and ''the Cloud'';
- Managing Scientific and Regulatory Disagreement;
- Combination Products;
- FDA Inspectional Approach—Panel with current FDA investigators;
- Operationalizing Post-Market Surveillance;
- 510(k) Process;
- Risk Management;
- Purchasing Controls;
- Office of Compliance Update; and
- Strategic Thinking on Access in China.

FDA has made education of the drug and device manufacturing community a high priority to help ensure the quality of FDA-regulated drugs and devices. The conference helps to achieve objectives set forth in section 406 of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. 393), which includes working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. The conference also is consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121) by providing outreach activities by Government Agencies to small businesses.

Dated: February 20, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–04134 Filed 2–25–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; National Institute of Mental Health Recruitment and Milestone Reporting System

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on August 2, 2013, page 46994 and allowed 60-days for public comment. One public comment was received regarding human subjects research recruitment and retention and the perception of coercion. The recruitment and enrollment procedures proposed by a NIMH-funded clinical trial are reviewed and approved by an IRB of record, which has agreed to review human subject research projects in accordance with 45 CFR Part 46 and its Federal-wide Assurance. The IRB of record ensures that the possibility of coercion or undue influence is minimized, that an investigator seeks consent only under circumstances that provide the prospective subject/representative sufficient opportunity to consider whether or not to participate. To address these concerns, we plan to add a statement about human subject protections to the policy and add a link to the human subjects training on the policy Web page. The purpose of this notice is to allow an additional 30 days for public comment. The National Institute of Mental Health (NIMH), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: NIH Desk Officer.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments or request more information on the proposed project contact: Keisha Shropshire, NIMH Project Clearance Liaison, Science Policy and Evaluation Branch, OSPPC, NIMH, NIH, Neuroscience Center, 6001 Executive Boulevard, MSC 9667,