4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-0811]

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; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "Enforcement Policy Regarding Investigational New Drug Requirements for Use of Fecal Microbiota for Transplantation to Treat Clostridium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. This draft guidance informs members of the medical and scientific community and other interested persons that we intend to exercise enforcement discretion regarding the investigational new drug (IND) requirements for the use of fecal microbiota for transplantation (FMT) to treat C. difficile infection not responding to standard therapies, provided the licensed health care provider treating the patient obtains adequate informed consent from the patient or his or her legally authorized representative for use of the FMT products, the stool is obtained from a donor known to either the patient or the licensed health care provider treating the patient, and the 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 This draft guidance, when finalized, is intended to supersede the guidance document entitled "Enforcement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 July 2013 (July 2013 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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. 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: 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.

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