substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, “Environmental Impacts: Policies and Procedures” prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

1. The authority citation for 14 CFR part 71 continues to read as follows:


§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11C, Airspace Designations and Reporting Points, dated August 13, 2018, and effective September 15, 2018, is amended as follows:

Paragraph 5000 Class D Airspace.

* * * * *

ASO MS D Meridian, MS [Amended]

Joe Williams NOLF, MS (Lat. 32°47′56″ N, long. 89°50′50″ W)

That airspace extending upward from the surface to and including 3,000 feet MSL within a 4.2-mile radius of Joe Williams NOLF. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.

ASO MS D Meridian, MS [Amended]

Key Field, MS (Lat. 32°19′57″ N, long. 88°45′07″ W)

That airspace extending upward from the surface to and including 2,800 feet MSL within a 4.5-mile radius of Key Field. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.

ASO MS D Meridian, MS [Amended]

NAS Meridian/McCain Field, MS (Lat. 32°33′13″ N, long. 88°33′19″ W)

That airspace extending upward from 700 feet above the surface within a 7-mile radius of Key Field, and within 1 mile each side of the 009° bearing from Key Field extending from the 7-mile radius of Key Field to 12.5 miles north of Key Field; and within 3.4 miles each side of the 009° bearing from the Key Field: RWY 19–LOC extending from the 7-mile radius of Key Field to 11.1 miles north of the Key Field: RWY 19–LOC, and within 2 miles each side of the 044° bearing from Key Field extending from the 7-mile radius of Key Field to 11.6 miles northeast of Key Field, and within 3.6 miles each side of the Meridian VORTAC 141° radial extending from the 4.5-mile radius of Key Field to 13.9 miles southeast of the Meridian VORTAC, and within 1 mile each side of the 189° bearing from Key Field extending from the 7-mile radius of Key Field to 12.6 miles south of Key Field, and within 3.4 miles each side of the 189° bearing from the Key Field: RWY 01–LOC extending from the 7-mile radius of Key Field to 11.2 miles south of the Key Field: RWY 01–LOC, and within 1.5 miles each side of the Meridian VORTAC 311° radial extending from the 7-mile radius of Key Field to 14.3 miles northwest of the Meridian VORTAC, and within a 6.7-mile radius of Joe Williams NOLF, and within a 7.8-mile radius of NAS Meridian/McCain Field, and within 6.7 miles each side of a line from Joe Williams NOLF to NAS Meridian/ McCain Field.

Issued in Fort Worth, Texas, on September 4, 2019.

Steve Szukala,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2019–19543 Filed 9–10–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 15

[Docket No. FDA–2019–N–3631]

Use of Fecal Microbiota for Transplantation to Treat Clostridium difficile Infection Not Responsive to Standard Therapies; Public Hearing; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing a public hearing to obtain input on the use of fecal microbiota for transplantation (FMT) to treat Clostridium difficile infection not responsive to standard therapies. FDA will consider scientific data and other information from the public hearing as we continue to consider ways to support the development of FMT to treat C.
Infection Not Responsive to Standard Therapies.

I. Background and Purpose of the Public Hearing

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

FMT administered to treat C. difficile infection meets the definition of a biological product, as defined in section 351(i) of the Public Health Service (PHS) Act (42 U.S.C. 262(i)), and the definition of a drug within the meaning of section 201(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)). As a biological product, FMT is subject to the licensing requirements set forth in section 351 of the PHS Act. FDA has received public comments from some stakeholders suggesting that FMT might be regulated as a human cell, tissue, and cellular and tissue-based product (HCT/P; see 21 CFR part 1271). FMT is a live biotherapeutic product composed of microorganisms. Microorganisms are not human cells or tissues and do not meet the definition of HCT/P (see 21 CFR 1271.3(d)). The hearing will not
include discussions about these comments.

In the Federal Register of July 18, 2013 (78 FR 42965), following a public workshop, held on May 2 and 3, 2013, entitled “Fecal Microbiota for Transplantation,” FDA announced the availability of a 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” (July 2013 Guidance) (available at: https://www.fda.gov/media/96440/download). The July 2013 Guidance, which is still in effect, informed members of the medical and scientific communities and other interested persons that we intend to exercise enforcement discretion regarding the investigational new drug (IND) requirements for the use of FMT to treat C. difficile infection not responding to standard therapies, provided that the treating physician obtains adequate consent from the patient or his or her legally authorized representative for the use of FMT products. The guidance states that consent should include, at a minimum, a statement that the use of FMT products to treat C. difficile is investigational and a discussion of its potential risks.

In the Federal Register of February 26, 2014 (79 FR 10814), we announced 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” (March 2014 Draft Guidance). The March 2014 Draft Guidance informed members of the medical and scientific communities and other interested persons that we intended to exercise enforcement discretion regarding the IND requirements for the use of FMT to treat C. difficile infection not responding to standard therapies, provided: (1) The licensed healthcare provider treating the patient obtains adequate consent from the patient or his or her legally authorized representative for use of the FMT product; (2) The FMT product is obtained from a donor known to either the patient or the licensed healthcare provider treating the patient; and (3) The stool donor and stool are qualified by screening and testing performed under the direction of the licensed healthcare provider for the purpose of providing the FMT product to treat the patient. FDA received many public comments in favor of patient access to FMT to treat C. difficile, including access to FMT products from stool banks, but objecting to the provision that the donor be known to the patient or the treating licensed healthcare provider.

After considering the comments on the March 2014 Draft Guidance, in the Federal Register of March 1, 2016 (81 FR 10632), FDA announced the availability of a revised 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” (March 2016 Draft Guidance) (available at: https://www.fda.gov/media/96562/download). The March 2016 Draft Guidance replaced the March 2014 Draft Guidance and proposed to revise our policy with regard to patient access to FMT product. We noted that centralized manufacturing in stool banks presents safety concerns related to the use of FMT from a limited number of donors administered to multiple patients. Therefore, we stated that FDA does not intend to extend enforcement discretion with respect to the IND requirements applicable to stool banks distributing FMT products. We stated that the sponsor’s compliance with the IND requirements would help to ensure that the stool donor and stool are appropriately qualified by screening and testing and that centralized processing of FMT adheres to appropriate current good manufacturing conditions. FDA received many public comments on this draft guidance, and we are continuing to evaluate our enforcement policy.

The purpose of this public hearing is to obtain public input on the state of the science regarding FMT to treat C. difficile infection not responsive to standard therapies, including the available clinical evidence for safety and effectiveness of FMT for this use and to understand better the impact of FDA’s enforcement policy on product development.

II. Issues for Consideration and Request for Data and Information

FDA would like input from stakeholders, including patients, clinicians, research scientists, industry, healthcare providers, and stool banks. We encourage public comments and presentations at the public hearing. If submitting comments, data, and information to the docket, please identify available references for the data and information, as well as the general category area and specific question listed below.

As noted above, fecal microbiota collected from healthy individuals are being investigated for use in the treatment of C. difficile infection. 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 profiles of this intervention have not yet been fully evaluated in controlled clinical trials. To inform FDA’s understanding of the current scientific status of FMT, especially as it relates to the use of FMT to treat C. difficile infection not responsive to standard therapies, we are interested in obtaining information, including data and studies, from all stakeholders, including patients, clinicians, research scientists, industry, healthcare providers and stool banks on the following topics:

1. Clinical Evidence of Effectiveness

• What is the strength of the evidence for the use of FMT to treat C. difficile infection not responsive to standard therapies?

• Please identify any published data from rigorously conducted randomized controlled (placebo or non-FMT standard of care comparator) trials that support the use of FMT for:
  ○ Prevention of recurrent C. difficile infection.
  ○ Treatment of refractory C. difficile infection.

2. Safety Evaluation

• What is the strength of evidence for the safety of FMT in patients with C. difficile infection not responsive to standard therapies?

• Has meaningful safety information been collected under FDA’s enforcement policy? How can any deficiencies in safety data collection be remedied?

• Are there particular safety issues FDA should consider regarding these products (e.g., donor screening/mixing donations)?

3. Impact of FDA’s current Enforcement Policy on FMT Product Development

• What impact has FDA’s enforcement policy had on recruitment and ability to conduct clinical trials to assess safety and effectiveness of FMT for C. difficile infection not responsive to standard therapies?

• Can specific examples be cited?

• How can any negative impacts be remedied?

• How does the existing availability of FMT affect the incentives for, and the feasibility of, FMT drug-development programs?

• The use of FMT is addressed in some treatment guidelines (Infectious
Diseases Society of Amorica and American Gastroenterological Association). What impact has this had on patient recruitment and conduct of clinical trials?

4. Future and Path Forward

- What additional scientific information is needed to determine the safety and effectiveness of FMT for C. difficile infection not responsive to standard therapies?
- How generalizable are the existing safety and effectiveness data on use of a specific FMT product for C. difficile infection not responsive to standard therapies to other FMT products for C. difficile infection not responsive to standard therapies?

III. Participating in the Public Hearing

Registration and Requests to Speak and for Formal Oral Presentations: The FDA Conference Center at the White Oak location is a Federal facility with security procedures and limited seating. Attendance will be free. An agenda for the hearing and any other background materials will be made available on October 25, 2019, at https://www.fda.gov/vaccines-blood-biologics/news-events-biologics/workshops-meetings-conferences-biologics. If you need special accommodations because of a disability, please contact Sherri Revell or Loni Warren Henderson at 240–402–8010 at least 7 days before the hearing.

For those interested in speaking at the hearing or presenting at the hearing with a formal oral presentation, please register at https://www.eventbrite.com/e/use-of-fecal-microbiota-for-transplantation-to-treat-clostridium-difficile-infection-not-responsive-tickets-63906239282 as “In-person presenter.” Speaker and presenter registrations are due October 8, 2019.

FDA will try to accommodate all persons who wish to make a formal oral presentation. Formal oral presenters may use an accompanying slide deck. Individuals wishing to present should identify their name, which stakeholder group they represent (e.g., patient, clinician, research scientist, industry, stool bank), and the number of the specific question, or questions, they wish to address. FDA will consider this information in organizing the agenda. Individuals and organizations with common interests should consider consolidating or coordinating their presentations and request time for a joint presentation. Individual organizations are limited to a single presentation slot. FDA will notify registered presenters of their scheduled presentation times on October 21, 2019. The time allotted for each presentation will depend on the number of individuals who wish to speak. If registered presenters are using an accompanying slide deck, those presenters must submit an electronic copy of their presentation (PowerPoint or PDF) to CBERPublicEvents@fda.hhs.gov on or before October 28, 2019. Persons registered to present are encouraged to arrive at the hearing room early and check in at the onsite registration table to confirm their designated presentation time. Actual presentation times, however, may vary based on how the hearing progresses in real time.

In-person attendance: For those who would like to attend in-person, but who are not making a formal presentation, please register at https://www.eventbrite.com/e/use-of-fecal-microbiota-for-transplantation-to-treat-clostridium-difficile-infection-not-responsive-tickets-63906239282 as “In-person attendee—no participation.” Seating is limited, and early registration is recommended to allow for broad participation.

Streaming Webcast of the Public Hearing: For those unable to attend in person, FDA will provide a live webcast of the hearing. Please register at https://www.eventbrite.com/e/use-of-fecal-microbiota-for-transplantation-to-treat-clostridium-difficile-infection-not-responsive-tickets-63906239282 as “online (webcast only).”


Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at https://www.fda.gov/vaccines-blood-biologics/news-events-biologics/workshops-meetings-conferences-biologics and https://www.regulations.gov. It may be viewed at the Dockets Management Staff (see ADDRESSES).

IV. Notification of Hearing Under 21 CFR Part 15

The Commissioner of Food and Drugs is announcing that the public hearing will be held in accordance with part 15 (21 CFR part 15). The hearing will be conducted by a presiding officer, who will be accompanied by FDA senior management officials. Under §15.30(f) (21 CFR 15.30(f)), the hearing is informal and the rules of evidence do not apply. No participant may interrupt the presentation of another participant. Only the presiding officer and panel members may question any person during or at the conclusion of each presentation. Public hearings under part 15 are subject to FDA’s policy and procedures for electronic media coverage of FDA’s public administrative proceedings (21 CFR part 10, subpart C).

Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA’s public administrative proceedings, including presentations by participants. Persons attending FDA’s public hearings are advised that the Agency is not responsible for providing access to electrical outlets.

The hearing will be transcribed as stipulated in §15.30(b) (see section III of this document). To the extent that the conditions for the hearing, as described in this notification, conflict with any provisions set out in part 15, this notification acts as a waiver of those provisions as specified in §15.30(h).


Lowell J. Schiller,
Principal Associate Commissioner for Policy.
[FR Doc. 2019–19643 Filed 9–10–19; 8:45 am]
BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52


Approval and Promulgation of Air Quality Implementation Plans; District of Columbia; Reasonably Available Control Technology State Implementation Plan for Nitrogen Oxides Under the 2008 Ozone National Ambient Air Quality Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a state implementation plan (SIP) revision submitted by the District of Columbia. This revision pertains to reasonably available control technology (RACT) requirements for nitrogen oxides (NOx) under the 2008 8-hour ozone national ambient air quality standard (2008 ozone NAAQS). The District of Columbia’s submittal for the NOx RACT