

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hr)
Newborn Screening Programs	Set-up of ED3N Data Elements	18	1	40
	Ongoing transfer of ED3N Data Elements	53	365	1/60

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0811]

Enforcement Policy Regarding Investigational New Drug Requirements for Use of Fecal Microbiota for Transplantation To Treat *Clostridioides difficile* Infection Not Responsive to Standard Therapies; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a final guidance entitled “Enforcement Policy Regarding Investigational New Drug Requirements for Use of Fecal Microbiota for Transplantation to Treat *Clostridioides difficile* Infection Not Responsive to Standard Therapies; Guidance for Industry.” The guidance document informs members of the medical and scientific community and other interested persons notice that, at this time, we intend to exercise enforcement discretion with respect to the investigational new drug application (IND) requirements for the use of fecal microbiota for transplantation (FMT) to treat *Clostridioides difficile* (*C. difficile*) infection not responding to standard therapies under limited circumstances described in the guidance. The guidance announced in this notice finalizes the draft guidance entitled “Enforcement Policy Regarding Investigational New Drug Requirements for Use of Fecal Microbiota for Transplantation to Treat *Clostridium difficile*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 2016, and supersedes the guidance 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.

DATES: The announcement of the guidance is published in the **Federal Register** on November 29, 2022.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and

identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2013–D–0811 for “Enforcement Policy Regarding Investigational New Drug Requirements for Use of Fecal Microbiota for Transplantation to Treat *Clostridium difficile* Infection Not Responsive to Standard Therapies; Final Guidance for Industry.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 240-402-8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Phillip Kurs, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled “Enforcement Policy Regarding Investigational New Drug Requirements for Use of Fecal Microbiota for Transplantation to Treat *Clostridioides difficile* Infection Not Responsive to Standard Therapies; Guidance for Industry.” The guidance informs members of the medical and scientific community and other interested persons of our policy regarding the IND requirements for the use of FMT to treat *C. difficile* infection not responding to standard therapies. In light of the considerations described in the guidance, at this time, FDA intends to exercise enforcement discretion with respect to the applicable IND requirements when the FMT product is not obtained from a stool bank and where: (1) the licensed health care provider treating the patient obtains appropriate consent from the patient or his or her legally authorized representative for the use of FMT product. The consent should include, at a minimum, a statement that the use of

FMT products to treat *C. difficile* is investigational and a discussion of the product’s reasonably foreseeable risks; (2) 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 for treatment of the patient; and (3) the use of the FMT product does not raise reported safety concerns or potential significant safety concerns (e.g., concerns regarding inappropriate storage or handling or concerns regarding administration of product collected without appropriate screening or testing).

FDA has developed this policy to help facilitate access to FMT for patients with *C. difficile* infection not responding to standard therapies, while addressing and controlling the risks that centralized manufacturing in stool banks presents to individuals receiving such products. We have concluded this policy appropriately balances considerations regarding patient safety and facilitating access to unapproved FMT products for unmet medical needs. FDA will continue to work with sponsors who intend to submit INDs for use of FMT to treat *C. difficile* infection not responding to standard therapies.

In the **Federal Register** of March 1, 2016 (81 FR 10632), FDA announced the availability of the draft guidance 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 2016. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. In the **Federal Register** on September 11, 2019 (84 FR 47911), FDA announced a part 15 hearing on the Use of Fecal Microbiota for Transplantation to Treat *Clostridium difficile* Infection Not Responsive to Standard Therapies. The hearing was held on November 4, 2019. FDA considered input from stakeholders received as part of the hearing as the guidance was finalized. A summary of changes includes changes to make clear that situations where use of an FMT product raises reported safety concerns or potential significant safety concerns are outside the scope of this enforcement policy; clarification of the products that are the subject of the guidance; and other editorial changes to improve clarity. The guidance announced in this notice finalizes the draft guidance 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 2016, and supersedes the guidance 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.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on “Enforcement Policy Regarding Investigational New Drug Requirements for Use of Fecal Microbiota for Transplantation to Treat *Clostridioides difficile* Infection Not Responsive to Standard Therapies.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 312 have been approved under control number 0910-0014. The collections of information in 21 CFR part 50 have been approved under OMB control number 0910-0130.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: November 22, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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