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Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New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 The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 240-402-8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Gretchen Opper, 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 draft 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." The draft guidance document provides members of the medical and scientific community and other interested persons with notice that, when finalized, we intend to exercise enforcement discretion under limited conditions, regarding the IND requirements for the use of FMT to treat *C. difficile* infection not responding to standard therapies. FDA intends to exercise this discretion, provided that: (1) The licensed health care provider treating the patient obtains adequate consent from the patient or his or her legally authorized representative for the use of FMT products. 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 its reasonably foreseeable risks; (2) the FMT product is not obtained from a stool bank; 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 for treatment of the patient.

FDA has developed this policy to assure that patients with *C. difficile* infection not responding to standard therapies may have access to this treatment, while addressing and controlling the risks that centralized manufacturing in stool banks presents to subjects. FDA intends for this to be an interim policy, while the Agency develops a comprehensive approach for the study and use of FMT products under IND.

A stool bank is defined, for the purpose of this guidance, as an establishment that collects, prepares, and stores FMT product for distribution to other establishments, health care providers, or other entities for use in patient therapy or clinical research. An establishment that collects or prepares FMT products solely under the direction of licensed health care providers for the purpose of treating their patients (e.g., a hospital laboratory) is not considered to be a stool bank under this guidance.

In the draft guidance, FDA provides that the stool bank sponsor may request a waiver of certain IND regulations relating to the obligations of investigators and subinvestigators (e.g., certain sections of the Statement of Investigator Form FDA 1572 that may not be applicable to FMT provided to the health care provider to treat their patients) (21 CFR 312.10). FDA is requesting comments on which IND regulations are appropriate to waive. In particular, FDA is requesting comments on the requirement for institutional review board review of the use of FMT to treat patients with *C. difficile* infection not responding to standard therapies when the FMT is provided by a stool bank (21 CFR 312.23(a)(1)(iv) and 21 CFR 312.66).

In the draft guidance, FDA proposes a revised policy with regard to patient access to FMT. The provision that the donor be known either to the patient or to the treating licensed health care provider, a concept that was used in the March 2014 draft guidance, was subject to difficulties in interpretation, and the revised approach more accurately reflects our intent to mitigate risk, based on the number of patients exposed to a particular donor or manufacturing practice rather than the risk inherent from any one donor. Although FDA acknowledges that directed donations present different risks than stool bank donations, the number of persons exposed through a directed donation will be limited. FDA also requests comments on this revised policy. The draft guidance replaces the draft guidance of the same title, dated March 2014 and, when finalized, is intended to

supersede the document of the same title, dated July 2013.

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 the current thinking of FDA on "Enforcement Policy Regarding Investigational New Drug Requirements for Use of Fecal Microbiota for Transplantation to Treat *Clostridium 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

The draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910-0014. The collections of information in 21 CFR part 50 have been approved under OMB control number 0910-0755.

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 23, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-04372 Filed 2-29-16; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Designation of a Class of Employees for Addition to the Special Exposure Cohort

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention, Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HHS gives notice of a decision to designate a class of employees from the Battelle Laboratories—King Avenue site in

Columbus, Ohio, as an addition to the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000.

FOR FURTHER INFORMATION CONTACT:

Stuart L. Hinnefeld, Director, Division of Compensation Analysis and Support, NIOSH, 1090 Tusculum Avenue, MS C-46, Cincinnati, OH 45226-1938, Telephone 1-877-222-7570.

Information requests can also be submitted by email to DCAS@CDC.GOV.

SUPPLEMENTARY INFORMATION: On February 18, 2016, as provided for under 42 U.S.C. 7384l(14)(C), the Secretary of HHS designated the following class of employees as an addition to the SEC:

All Atomic Weapons Employees who worked at the facility owned by the Battelle Laboratories at the King Avenue site in Columbus, Ohio, during the period from July 1, 1956, through December 31, 1970, for a number of work days aggregating at least 250 work days, occurring either solely under this employment, or in combination with work days within the parameters established for one or more other classes of employees included in the Special Exposure Cohort.

This designation will become effective on March 19, 2016, unless Congress provides otherwise prior to the effective date. After this effective date, HHS will publish a notice in the **Federal Register** reporting the addition of this class to the SEC or the result of any provision by Congress regarding the decision by HHS to add the class to the SEC.

Authority: 42 U.S.C. 7384q(b). 42 U.S.C. 7384l(14)(C).

John Howard,

Director, National Institute for Occupational Safety and Health.

[FR Doc. 2016-04415 Filed 2-29-16; 8:45 am]

BILLING CODE 4163-19-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Request for Information on Updates to the ONC Voluntary Personal Health Record Model Privacy Notice

AGENCY: Office of the National Coordinator for Health Information Technology, Department of Health and Human Services.

ACTION: Notice with comment; request for information.

SUMMARY: The Office of the National Coordinator for Health Information Technology (ONC) seeks comments on the scope and content of the voluntary

Personal Health Record Model Privacy Notice (MPN) developed by ONC and published in 2011. In response to stakeholder requests for an electronic means to inform consumers about how health technology products store, use, and share health information (especially products of health technology developers not covered by the Health Insurance Portability and Accountability Act of 1996, Pub. L. 104-191), we have initiated a process to update the MPN to better align with the current consumer health technology landscape.

DATES: To be assured consideration, electronic comments must be received at one of the addresses provided below, no later than 5 p.m. on April 15, 2016.

ADDRESSES: You may submit comments, identified by MPN RFI, by either of the following two methods (please do not submit duplicate comments).

- **ONC Web site:** Follow the instructions for submitting comments. Attachments should be in Microsoft Word, Microsoft Excel, or Adobe PDF; however, we prefer Microsoft Word. <https://www.healthit.gov/policy-researchers-implementers/personal-health-record-phr-model-privacy-notice>.
- **Email:** ONCMPN@hhs.gov.

FOR FURTHER INFORMATION CONTACT:

Maya Uppaluru or Michael Lipinski, 202-690-7151.

SUPPLEMENTARY INFORMATION: In June 2008, the Office of the National Coordinator for Health Information Technology (ONC) began a multi-phase and iterative project to develop an easy-to-understand, voluntary Personal Health Record (PHR) Model Privacy Notice (MPN) that any PHR company could adopt to communicate its information practices to its users. Developed in collaboration with the Federal Trade Commission (FTC), the project's goals were two-fold: (1) Increase consumers' awareness of PHR companies' information practices; and (2) empower consumers by providing them with an easy way to compare the information practices of two or more PHR companies. The MPN was designed to enable PHR companies to easily enter their information practices and produce a notice to allow consumers to quickly learn and understand privacy and security policies and information practices, compare PHR company practices, and make informed decisions. Similar to the Food and Drug Administration's Nutrition Facts Label, this approach did not mandate specific policies, but rather was meant to encourage user-friendly transparency of a company's existing practices.

The MPN has two sections: (1) The "Release" section; and (2) the "Secure" section. Both sections of the MPN include model language that informs consumers about how a PHR company is using an individual's health information. The current MPN can be found here, *but we note that* it is no longer available for use. Additional background on the MPN can be found at: <https://www.healthit.gov/policy-researchers-implementers/personal-health-record-phr-model-privacy-notice>.

Since the development of the MPN, the consumer health technology landscape has greatly evolved. More consumers are now able to electronically access their health information than ever before. Not only are consumers interacting with their clinical and claims data (often collected and maintained by health care providers and health plans regulated under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (*i.e.*, "covered entities")), but they are also interacting with fitness and wellness data from devices offered by health technology developers that may not be regulated by HIPAA. In general, HIPAA regulations govern how covered entities and their business associates maintain, access, use and disclose individually identifiable health information and protected health information, otherwise known as "PHI".¹ Specifically, the HIPAA regulations include requirements for: keeping information private in the Privacy Rule,² which also includes notifying individuals about how their PHI can be accessed, used, and disclosed;³ adopting administrative, technical and physical safeguards to secure electronic PHI;⁴ and mandating notice to affected individuals when a breach of PHI occurs.⁵ Health technology developers that may not be covered by HIPAA are often called "non-covered entities" or "NCEs."

Health technology developers make available a diverse array of products, including mobile apps, wearable devices, and sensors, and often display notices of their privacy and information practices to consumers. These developers may be subject to other federal laws, including the FTC Act's prohibition on unfair or deceptive acts or practices,⁶ and the FTC's Health

¹ 45 CFR 160.103.

² 45 CFR 164.501 *et seq.*

³ 45 CFR 164.520; see also Office of Civil Rights Model Notices of Privacy Practices: <http://www.hhs.gov/hipaa/for-professionals/privacy/guidance/model-notices-privacy-practices/>.

⁴ 45 CFR 164.301 *et seq.*

⁵ 45 CFR 164.400-414.

⁶ 15 U.S.C. 45(a) (Section 5 of the FTC Act).