



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-0001]

Science and Regulation of Live Microbiome-Based Products Used to Prevent, Treat, or Cure Diseases in Humans; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) Center for Biologics Evaluation and Research and the National Institutes of Health, National Institute of Allergy and Infectious Diseases (NIAID) are announcing a public workshop entitled “Science and Regulation of Live Microbiome-Based Products Used to Prevent, Treat, or Cure Diseases in Humans.” The purpose of the public workshop is to exchange information with the scientific community about the clinical, manufacturing, and regulatory considerations associated with live microbiome-based products, when administered to prevent, treat, or cure a disease or condition in humans. The public workshop will bring together government Agencies, academia, industry, and other stakeholders involved in research, development, and regulation of live microbiome-based products for such uses.

DATES: The public workshop will be held on September 17, 2018, from 9 a.m. to 5 p.m. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: The public workshop will be held at the NIAID Conference Center, 5601 Fishers Lane, Rm. 1D13, Rockville, MD 20852. Entrance for public workshop participants is through

the lobby, where routine security check procedures will be performed. For parking and security information, please refer to <https://www.niaid.nih.gov/about/visitor-information>.

FOR FURTHER INFORMATION CONTACT: Loni Warren Henderson or Sherri Revell, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 1118, Silver Spring, MD 20993, 240-402-8010, email: CBERPublicEvents@fda.hhs.gov (subject line: Live Microbiome-Based Products Workshop).

SUPPLEMENTARY INFORMATION:

I. Background

Live microbiome-based products used to prevent, treat, or cure a disease or condition in humans are biological products. There is increasing interest in the use of such products for the treatment and/or prevention of conditions such as necrotizing enterocolitis and diarrhea.

Historically, these products have presented with unique scientific and regulatory challenges.

II. Topics for Discussion at the Public Workshop

The topics for discussion at the public workshop include the clinical, manufacturing, and regulatory considerations for live microbiome-based products to prevent, treat, or cure a disease or condition in humans, and the objective is to provide a forum for the exchange of information and perspectives on these topics.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following website: <https://www.eventbrite.com/e/science-and-regulation-of-live-microbiome-based-products-used-to-prevent-treat-or-cure-diseases-in-tickets-44649072578>. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by August 28, 2018, midnight Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. There will be no onsite registration.

If you need special accommodations due to a disability, please contact Loni Warren Henderson or Sherri Revell no later than September 10, 2018 (See FOR FURTHER INFORMATION CONTACT).

Dated: August 13, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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