4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-0001]

Bacteriophage Therapy: Scientific and Regulatory Issues; 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 are announcing a public workshop entitled "Bacteriophage Therapy: Scientific and Regulatory Issues." The purpose of the public workshop is to exchange information with the medical and scientific community about the regulatory and scientific issues associated with bacteriophage therapy.

DATES: The public workshop will be held on July 10, 2017, from 8:30 a.m. to 5 p.m. and July 11, 2017, from 8:30 a.m. to 3 p.m. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: The public workshop will be held at 5601 Fishers Lane, rm. 1D-13, 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 the registration Web site provided in section III of the SUPPLEMENTARY INFORMATION section.

FOR FURTHER INFORMATION CONTACT: James Ginther or Cynthia Whitmarsh, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 4122, Silver Spring, MD 20993, Ph. 240-402-8010, email: CBERPublicEvents@fda.hhs.gov (subject line: Bacteriophage Public Workshop).

SUPPLEMENTARY INFORMATION:

I. Background

Since their discovery approximately one hundred years ago, bacteriophages have been investigated as a way to treat bacterial infections. In much of the world, the discovery, development, and implementation of antibiotic therapies led to a loss of interest in bacteriophages as a means to fight infections. However, in recent years, interest in this form of treatment has resurged, fueled by the increasing prevalence of antibiotic-resistant bacteria.

II. Topics for Discussion at the Public Workshop

The public workshop will bring together government agencies, academia, industry, and other stakeholders involved in research, development, and regulation of bacteriophages intended for therapeutic use in humans. The aims of the workshop are to discuss the scientific and regulatory considerations for bacteriophage therapies and to provide a forum for the exchange of information and perspectives, with the ultimate goal of facilitating development and rigorous clinical assessment of bacteriophage therapy products.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following Web site: https://www.eventbrite.com/e/bacteriophage-therapy-public-workshop-tickets-32333252629. Persons interested in attending this public workshop must register online by June 29, 2017.

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. 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 disability, please contact James Ginther or Cynthia Whitmarsh no later than 7 days in advance of the workshop (see FOR FURTHER INFORMATION CONTACT).

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at https://www.regulations.gov. It may be viewed at the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. A link to the transcript will also be available on the Internet at: https://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/ucm544294.htm.

Dated: June 2, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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