4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-4531]

Emerging Tick-Borne Diseases and Blood Safety; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop entitled "Emerging Tick-Borne Diseases and Blood Safety." The purpose of the public workshop is to discuss tick-borne pathogens that continue to emerge as threats to blood safety, the effectiveness of current and potential mitigation strategies, and the general approach to decision making on blood safety interventions. The workshop has been planned in partnership with AABB; America's Blood Centers; National Heart, Lung, and Blood Institute, National Institutes of Health (NIH); the U.S. Department of Defense; and the U.S. Department of Health and Human Services. The workshop will include presentations and panel discussions by experts from academic institutions, industry, and government agencies.

DATES: The public workshop will be held on April 6, 2017, from 8 a.m. to 5:30 p.m. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: The public workshop will be held at the Natcher Auditorium, Natcher Conference Center, Bldg. 45, National Institutes of Health Campus, 9000 Rockville Pike, Bethesda, MD 20892. Entrance for the public workshop participants (non-NIH employees) is through the NIH Gateway Center located adjacent to the Medical Center Metro, where routine security check procedures will be performed. Please visit the following Web site for NIH

campus location, parking, security, and travel information http://www.nih.gov/about/visitor/index.htm. Please visit the following Web site for information on the Natcher Conference Center: http://www.genome.gov/11007522.

FOR FURTHER INFORMATION CONTACT: Kimberly Jones or Pauline Cottrell, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 3128, Silver Spring, MD 20993, CBERPublicEvents@fda.hhs.gov. For questions email: CBERPublicEvents@fda.hhs.gov (Subject line: Tick-Borne Diseases and Blood Safety Workshop).

SUPPLEMENTARY INFORMATION:

I. Background

The purpose of the public workshop is to discuss tick-borne pathogens that continue to emerge as threats to blood safety, the effectiveness of current and potential mitigation strategies, and the general approach to decision making on blood safety interventions.

II. Topics for Discussion at the Public Workshop

The workshop will include presentations and panel discussions on the following topics: (1) Biology, epidemiology, and clinical burden of Anaplasma phagocytophilum (the etiologic agent of human granulocytic anaplasmosis) and other emerging tick-borne agents; (2) the performance characteristics of currently available diagnostic assays for agents of concern; (3) known and potential risks of transfusion transmission posed by emergent tick-borne agents; (4) current and potential mitigation strategies; and (5) considerations in decision making for safety interventions. The day will conclude with a roundtable discussion.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following Web site at: https://www.eventbrite.com/e/emerging-tick-borne-diseases-and-blood-safety-public-workshop-tickets-28654127266. 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 March 23, 2017. Early registration is recommended because seating is limited. If time and space permit, onsite registration on the day of the public workshop will be provided beginning at 7:30 a.m.

If you need special accommodations due to a disability, please contact Kimberly Jones or Pauline Cottrell by email sent to CBERPublicEvents@fda.hhs.gov at least 7 days in advance. Requests for sign language interpretation or Computer Aided Realtime Translation (CART)/captioning should be made 2 weeks in advance of the event, no later than March 23, 2017. A request for either interpreting or captioning is to be sent directly to the FDA Interpreting Services Staff email account: interpreting.services@oc.fda.gov.

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 (HFA-305) Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. A link to the transcript will also be available on the Internet at http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/ucm525485.htm.

Dated: December 30, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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