4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0001]

Pre-Clinical Evaluation of Red Blood Cells for Transfusion; 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 "Pre-Clinical Evaluation of Red Blood Cells for Transfusion." The purpose of the public workshop is to discuss new methodologies for pre-clinical evaluation of the safety and efficacy of red blood cell transfusion products. The workshop has been planned in partnership with the National Heart, Lung, and Blood Institute; National Institutes of Health (NIH); the Department of Defense; and the Office of the Assistant Secretary for Health, 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 October 6, 2016, from 8 a.m. to 5 p.m. and on October 7 from 9 a.m. to 1 p.m. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: The public workshop will be held at the Ruth Kirschstein Auditorium, Natcher Conference Center, Bldg. 45, National Institutes of Health Campus, 9000 Rockville Pike, Bethesda, MD 20892. The 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: Matthew Morrison, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 3128, Silver Spring, MD 20993, 240-402-8126, Matthew.D.Morrison@fda.hhs.gov. For questions email: CBERPublicEvents@fda.hhs.gov (Subject line: Red Blood Cell (RBC) Workshop).

SUPPLEMENTARY INFORMATION: The purpose of the public workshop is to discuss new methodologies for pre-clinical evaluation of the safety and efficacy of red blood cell transfusion products including potential identification of biomarkers measurable during red cell storage that could predict the in vivo functionality of transfused red blood cells. The first day of the workshop will include presentations and panel discussions on the following topics: 1) Overview of red blood cells for transfusion; 2) methods for determining the suitability of red blood cells for transfusion; 3) new methods for detecting red blood cell processing and storage legions; and 4) the use of animal models of oxygen delivery as markers of red blood cell safety and efficacy in the acute bleeding and trauma resuscitation settings.

The second day of the workshop will include presentations and panel discussions on the potential mechanisms of red blood cell transfusion-associated toxicity and a summary of all workshop panel discussions, identified gaps, and future directions.

Registration: Please visit the following Web site to register for the workshop by September 23, 2016: https://www.eventbrite.com/e/pre-clinical-evaluation-of-red-blood-cells-for-transfusion-registration-25813463765. There is no registration fee for the public workshop.

Early registration is recommended because seating is limited. Registration on the day of the public workshop will be provided on a space available basis beginning at 7:30 a.m.

If you need special accommodations due to a disability, please contact Matthew Morrison (see FOR FURTHER INFORMATION CONTACT) at least 7 days in advance.

Transcripts: Please be advised that as soon as possible after a transcript of this public workshop is available, it will be accessible at: http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/ucm507890.htm.

Dated: July 13, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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