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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

Use of Radiolabeled Platelets for Assessment of In Vivo Viability of Platelet Products; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled "Use of Radiolabeled Platelets for Assessment of the In Vivo Viability of Platelet Products". The goal of the workshop is to orient the transfusion community to a new approach for assessing the quality of platelet products through radiolabeling studies in healthy human volunteers.

Date and Time: The public workshop will be held on May 3, 2004, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at Lister Hill Auditorium, Building 38A, National Institutes of Health, 8600 Rockville Pike, Bethesda, MD 20894.

Contact Person: Joseph Wilczek, Center for Biologics Evaluation and Research (HFM-302), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6129, FAX: 301-827-2843, e-mail: wilczek@cber.fda.gov.

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number) to the contact person by April 23, 2004. Early registration is recommended because seating is limited to 176

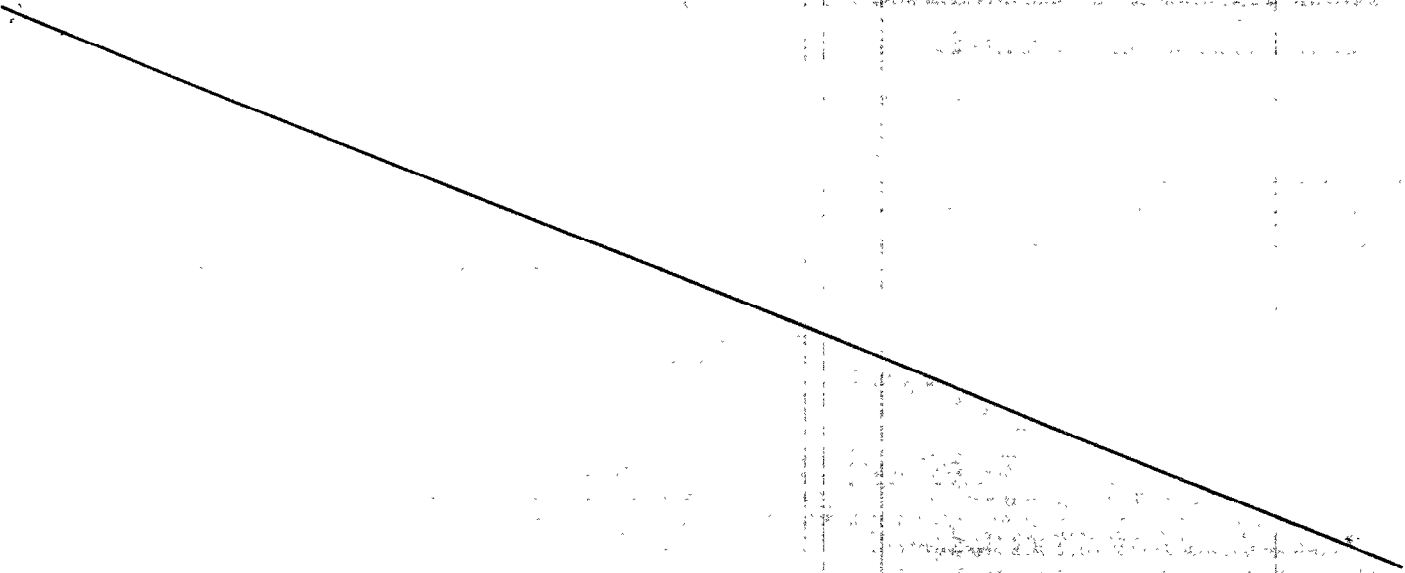
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participants. Registration will be done on a space available basis on the day of the workshop, beginning at 7:15 a.m. There is no registration fee.

If you need special accommodations due to a disability, please contact Joseph Wilczek (see *Contact Person*) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: FDA, in co-sponsorship with the Hitchcock Foundation, is sponsoring a public workshop on the development of a new standard for assessing the in vivo quality of platelet products through radiolabeling studies. The workshop objectives are to review current methods in radiolabeling studies, to propose a new approach that will set the performance of fresh platelets as a gold standard, to present data on application of a new standard, and to discuss the development of a novel experimental protocol. The public workshop agenda is posted on FDA's Internet at <http://www.fda.gov/cber/meetings/radioplt0504.htm>.

Transcripts: Transcripts of the workshop may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page. In addition, the transcript will be placed on FDA's Internet at <http://www.fda.gov/cber/minutes/workshop-min.htm>.



Dated: 4.2.04

April 2, 2004.

Jeffrey Shuren

Jeffrey Shuren,
Assistant Commissioner for Policy.

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