

<input type="checkbox"/> FDA Logo links to FDA home page	<input type="checkbox"/>	<input type="checkbox"/> Center for Biologics Evaluation and Research, U.S. Food and Drug Administration	<input type="checkbox"/>	<input type="checkbox"/> HHS Logo links to Department of Health and Human Services website
--	--------------------------	--	--------------------------	--

[FDA Home Page](#) | [CBER A-Z Index](#) | [CBER Search](#) | [Contact CBER](#) | [CBER Home Page](#)

CBER links to product areas

CBER links

Blood Products Advisory Committee

June 14-15, 2001 Meeting

Date and Time

The meeting will be held on June 14, 2001, 8:30 a.m. to 5:30 p.m.; and on June 15, 2001, 8:30 a.m. to 3:45 p.m.

Location

Gaithersburg Hilton, 620 Perry Parkway, Gaithersburg, MD 20877, 301-977-8900.

Contact Person

Linda A. Smallwood, Ph.D., 301-827-3514, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 19516. Please call the Information Line for up-to-date information on this meeting.

Agenda

On June 14, 2001, the following committee updates are tentatively scheduled: summary of the Public Health Service Advisory Committee on Blood Safety and Availability meeting, and current thinking: clinical trial design and performance standards for approval of rapid HIV tests. In the morning, the committee will hear presentations, discuss and make recommendations on re-entry for donors deferred because of human immunodeficiency virus (HIV) or hepatitis C virus (HCV) nucleic acid testing (NAT) or serological test results. In the afternoon, the committee will hear presentations, discuss and make recommendations on the Clinical Laboratory Improvement Act (CLIA) criteria for in vitro diagnostic tests: applicability of waivers to HIV rapid tests, and an informational presentation on the revision of the uniform donor history questionnaire. On June 15, 2001, the following updates are tentatively scheduled: summaries of the Department of Health and Human Services and the Office of Blood Research and Review, Center for Biologics Evaluation and Research, respectively, transmissible spongiform encephalopathy (TSE) and bovine spongiform encephalopathy (BSE) action plans. In the morning, the committee will hear an informational presentation, discuss and make recommendations on transfusion-related acute lung injury. In the afternoon, the committee will hear presentations on studies on leukoreduction

filtration failures.

Oral Presentations

Between approximately 10:15 and 10:45 a.m., 2:30 and 3:00 p.m., and 4:45 and 5:00 p.m. on June 14, 2001; and between 10:15 and 10:45 a.m., and 1:45 and 2:15 p.m. on June 15, 2001, oral presentations from the public will be scheduled. Those desiring to make formal oral presentations should notify the contact person before June 4, 2001.

Closed Committee Deliberations:

On June 15, 2001, from 3:15 to 3:45 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c) (6)). The committee will discuss reports of the review of individual research programs in the Division of Hematology, Office of Blood Research and Review, Center for Biologics Evaluation and Research.

Transfusion Related Acute Lung Injury (TRALI) Briefing Information:

[Introduction and Background \(CBER\)](#)

[TRALI \(CBER\)](#)

[TRALI \(Haemonetics\)](#)

[HLA Class II Antibodies \(Sacramento Blood Center\)](#)

Updated May 7, 2002

[CBER Home Page](#) | [CBER A-Z Index](#) | [CBER Search](#) | [Contact CBER](#)
[FDA Home Page](#) | [Search FDA Site](#) | [FDA A-Z Index](#) | [Contact FDA](#) | [Privacy](#) | [Accessibility](#) | [HHS](#)
[Home Page](#)

FDA / Center for Biologics Evaluation and Research