

# CONTENTS

Blood Products Advisory Committee  
69<sup>th</sup> Meeting – June 14-15, 2001

Hilton - Gaithersburg, 620 Perry Parkway, Gaithersburg, MD 20877

TOPIC	DISCUSSION
	<b>Thursday, June 14, 2001</b>
<b>Committee Updates</b>	<ul style="list-style-type: none"> <li>• Meeting Summary on Blood Safety and Availability PHS Advisory Committee, April 19-20, 2001- Stephen Nightingale, M.D.</li> <li>• Current Thinking: Clinical Trial Design and Performance Standards for Approval of Rapid HIV Tests - Elliot Cowan, Ph.D.</li> <li>• Proposed FDA Scientific Workshops - Linda Smallwood, Ph.D.</li> </ul>
<b>I.</b>	<p><b>Re-entry for Donors Deferred Because of HIV or HCV NAT or Serological Test Results</b></p> <ul style="list-style-type: none"> <li>A. Introduction and Background – Paul A. Mied, Ph.D., DETTD, OBRR, CBER, FDA</li> <li>B. Presentation – Susan Stramer, Ph.D., American Red Cross</li> <li>C. Presentation – Michael Busch, M.D., Ph.D., The Blood Centers of the Pacific</li> <li>D. Presentation - Susan Galel, M.D., Stanford University</li> </ul>
<b>II.</b>	<p><b>CLIA Criteria for In Vitro Diagnostic Tests: Applicability of Waivers to HIV Rapid Tests</b></p> <ul style="list-style-type: none"> <li>A. Introduction and Background – Joseph Hackett, Ph.D., DCLED, ODE, CDRH, FDA</li> <li>B. Overview of Applicability of Draft CLIA Waiver Guidance to Rapid HIV Tests - Elliot Cowan, Ph., DETTD, OBRR, CBER, FDA</li> <li>C. Presentation – Judith Yost, Health Care Finance Administration</li> <li>D. Presentation - Thomas Hearn, M.D., Centers for Disease Control and Prevention</li> <li>E. Presentation - Ida Onorato, M. D., Centers for Disease Control and Prevention</li> </ul>
	<p><b>Centers of the World in Donor History Questionnaire – International Presentation</b></p> <ul style="list-style-type: none"> <li>A. Overview and Introduction – Alan Williams, Ph.D., DBA, OBRR, CBER, FDA</li> <li>B. Update on AABB Task Force Programs Presentation – Joy Fridley, M.D., American Red Cross</li> </ul>

	<b>Friday, June 15, 2001</b>
<b>Committee Updates</b>	<ul style="list-style-type: none"> <li>• <b>DHHS TSE/BSE Action Plan - Stephen Nightingale, M.D.</b></li> <li>• <b>OBRR TSE/BSE Action Plan - Mary Elizabeth Jacobs, Ph.D.</b></li> <li>• <b>Update on TSEAC Advisory Committee Meeting - June 28-29, 2001 - TBD</b></li> </ul>
<b>IV.</b>	<p><b>Transfusion-Related Acute Lung Injury - Informational Presentation</b></p> <ul style="list-style-type: none"> <li>A. Introduction and Background - Leslie Holness, M.D., DBA, OBRR, CBER, FDA, HHS</li> <li>B. Presentation - Mark Popovsky, M.D., Haemonetics</li> <li>C. Presentation - Patricia Kopko, M.D., Sacramento Blood Center</li> <li>D. Presentation - Lynn Boshkov, M.D., Oregon University</li> <li>E. Presentation - John Finlayson, Ph.D., IOD, OBRR, CBER, FDA</li> </ul>
<b>V.</b>	<p><b>Studies on Leukoreduction Filtration Failures</b></p> <ul style="list-style-type: none"> <li>A. Introduction and Background - Martin Ruta, J.D., Ph.D., IOD, OBRR, CBER, FDA</li> <li>B. Presentation - Constance Noguchi, Ph.D., NIH</li> <li>C. Presentation - American Red Cross</li> <li>D. Presentation - Ronald Gilcher, M.D., Oklahoma Blood Center</li> <li>E. Presentation - TBA- Gulf Coast Blood Bank</li> <li>F. Presentation - TBD- Canada</li> </ul>
<b>VI.</b>	<p><b>Report of the Intramural Site Visit of the Laboratory of Plasma Derivatives, Division of Hematology, OBRR, CBER, FDA</b></p> <ul style="list-style-type: none"> <li>A. Introduction and Overview <ul style="list-style-type: none"> <li>• Neil Goldman, Ph.D., Associate Director for Research, CBER</li> <li>• John Finlayson, Ph.D., Associate Director for Science, OBRR</li> <li>• Basil Golding, M.D., Chief, Lab. of Plasma Derivatives</li> </ul> </li> <li>B. Closed Committee Deliberations</li> </ul>