

**Subcommittee meeting of the
Blood Products Advisory Committee
for Office Site Visit Review of the
Office of Blood Research and Review
July 22, 2005**

AGENDA

Open Session

- 8:00 a.m.** Welcome and Introduction of Committee
OSV Chair
Conflict of Interest Statement
- 8:10** Introduction/Charge to Committee
Dr. Karen Midthun
Deputy Director, Center for Biologics Evaluation and Research
CBER Mission
CBER Program Structure
- 8:35** Overview of CBER Research Programs
Kathryn Carbone, M.D.
Associate Director for Research
- 8:55** Overview Office of Blood Research and Review (OBRR)
Jay S. Epstein, M.D. Director, OBRR
Office Mission and Structure
Regulatory Activities and Priorities
Research Program Introduction
- 9:20** Q & A for Deputy Director, CBER, Associate Director for Research, CBER &
Office Director, OBRR
- 9:30** **Break**
- 9:45** Overview of the Research Program of the Division of Blood Applications
Alan Williams, Ph.D., Director DBA
- 10:05** Q&A

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10:15 Overview of the Research Program of the Division of Emerging and Transfusion Transmitted Diseases
Hira L. Nakhasi, Ph.D., Director, DETTD
Scope/Mission/Regulatory Relevance/Public Health Impact
Division Research Program Structure & Research
Accomplishments
Regulatory and Product Contributions/Relevance/Expertise
Five-year Objectives

11:10 Q and A

11:20 Overview of the Research Program of the Division of Hematology
Basil Golding, M.D. Director, DH
Scope/Mission/Regulatory Relevance/Public Health Impact
Division Research Program Structure & Research Programs
Accomplishments
Regulatory and product contributions/relevance/expertise
Five-year Objectives

12:05 p.m. Q&A

12:15 **Open Public Hearing**

1:15 **Lunch**

Closed Session

2:15 p.m. **Discussion of Regulatory/Personnel Issues**

Introduction of CBER Panel and Questions to Panel by committee (Drs. Epstein, Nakhasi, Golding, Williams, Scott, Vostal, Alayash, Mied, Asher, Hewlett, Kaplan, Biswas, Cowan, Abbondanzo, Silverman, Lozier)

3:30 **Closed Executive Session of Committee**

4:45 **Oral Summary** (Deputy Director, Assoc. Dir. Research, CBER, Office Director and Division Directors, OBRR)

5:00 **Adjourn**

Presentation of finalized Sub-Committee Report at next full meeting of the Full Blood Products Advisory Committee and discussion/vote by full committee.

