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

DRAFT AGENDA Open Session

10:40

Q&A

Welcome and Introduction of Committee 8:00 a.m. 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 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

Subcommittee meeting of the Blood Products Advisory Committee

Draft agenda (Continued)

10:50 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

Q and A (10')

11:45 Overview of the Research Program of the Division of Blood Applications

Alan Williams, Ph.D., Director DBA

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.