DRAFT AGENDA 6/20/2005

BLOOD PRODUCTS ADVISORY COMMITTEE

83nd Meeting – July 21, 2005
Gaithersburg Holiday Inn, 2 Montgomery Village Avenue
Gaithersburg, MD 20877

Thursday, July 21, 2005

8:00 a.m. Welcome, Statement of Conflict of Interest, Announcements

8:10 a.m. Committee Updates

- **Summary of May 2005 Meeting of the DHHS Advisory Committee on Blood Safety and Availability – Jerry Holmberg, PhD, Executive Secretary, Advisory Committee on Blood Safety and Availability (10')**

- **Disseminated intravascular coagulation associated with acute hemoglobinemia following anti-D IGIV administration for idiopathic thrombocytopenic purpura – Ann Gaines, FDA (15')**

- **Update on Safety of Albumin – Laurence Landow, M.D., FDA (5')**

- **Summary of June 2005 Workshop on Biological Therapeutics for Rare Plasma Protein Disorders – Mark Weinstein, Ph.D., FDA (10')**

- **Summary of July 2005 Workshop on Leukoreduction- Alan Williams, Ph.D., FDA (10')**

- **Update on West Nile Virus Guidance – Alan Williams, PhD, FDA (10')**

9:30 a.m. O*pen Committee Discussion*

I. Management of Donors and Units that Test Positive for Hepatitis B Virus (HBV) DNA by Nucleic Acid Tests (NAT)

A. Introduction and Background – Robin Biswas, MD, OBRR, FDA (15')
B. Roche – Tom Clement (10')
C. National Genetics Institute – Dr. Richard Smith (10')

10:15 a.m. BREAK

10:30 a.m. OPEN PUBLIC HEARING

11:00 a.m. *Open Committee Discussion*
D. FDA Perspective and Questions for the Committee
E. Committee Discussion and Recommendations

12:00 p.m. LUNCH

1:00 p.m.

II. Scientific Basis for Review of Varicella Zoster Immune Globulin

A. Background – Dorothy Scott, M.D., FDA (10')
B. VZIG manufacture, potency testing, and current supply status – D. Ambrosino, M.D., MPHBL (15')
C. Varicella Zoster Disease, Indications for VZIG – P. La Russa, M.D., Columbia University (30')
D. VZIG licensure history and clinical trials (FDA, Scott or Ko) (15')
E. ACIP Recommendations for VZIG use – Mona Marin, M.D., CDC (10')
F. Vaccine trials, correlates of protection, implications for donors of IGIV – Philip Krause, M.D., FDA (10')

2:30 p.m. OPEN PUBLIC HEARING

3:00 p.m. ***Open Committee Discussion***
G. FDA Perspective and Questions for the Committee
H. Committee Discussion and Recommendations

3:45 p.m. Break

4:00 p.m.

III. Dextran 1 Pre-treatment For Safe Use of Dextran 40/70

A. Introduction and Background – Lawrence Landow, M.D., FDA (10')
B. Swedish Studies With Dextran 1 – Ljungstrom M.D.(25')

5:00 p.m. OPEN PUBLIC HEARING

5:30 p.m. ***Open Committee Discussion***
D. FDA Perspective and Questions for the Committee
E. Committee Discussion and Recommendations

6:30 p.m. Adjournment