Draft Agenda: 3/11/2004

BLOOD PRODUCTS ADVISORY COMMITTEE
79th Meeting – March 18-19, 2004
Gaithersburg Holiday Inn, 2 Montgomery Village Avenue
Gaithersburg, MD 20877

Thursday, March 18, 2004

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

8:05 a.m. ***Open Committee Discussion***

I. Clinical Trials for Licensing Hepatitis B Immune Globulin Intravenous as Treatment to Prevent HBV Liver Disease Following Liver Transplantation in HBV+ Recipients (3.5 hrs)

A. Introduction and Background – Basil Golding, MD, Director, Division of Hematology, OBRR (15')

B. Presentation – Anna Lok, MD (70')

9:30 a.m. **OPEN PUBLIC HEARING**

10:00 a.m. **BREAK**

10:30 a.m. ***Open Committee Discussion***

C. FDA Current Thinking and Questions for the Committee

D. Committee Discussion and Recommendations

11:15 a.m. Committee Updates

- **Current Thinking on Variances to Address the Specificity Issues of Ortho HBsAg 3.0 Assays – Gerardo Kaplan, PhD (15')**
- **Summary of Meeting of PHS Advisory Committee on Blood Safety Availability – Jerry Holmberg, MD (15')**
- **Summary of Meeting of Transmissible Spongiform Encephalopathies Advisory Committee Meeting – David Asher, MD (15')**

- **Current Thinking on Draft Guidance for Nucleic Acid Testing (NAT) for HIV and HCV: Testing,**

Product Disposition, and Donor Deferral and Re-entry – Paul Mied, PhD (15')

- **Current Thinking on Final Guidance for Use of Nucleic Acid Testing (NAT) on Pooled and Individual Samples from Donors of Whole Blood and Blood Components to Adequately and Appropriately Reduce the Risk of Transmission of HIV-1 and HCV – Indira Hewlett, PhD (15')**

12:30 p.m. LUNCH

1:30 p.m. ***Open Committee Discussion***

II. Supplemental Testing for Human Immune Deficiency Virus (HIV) and Hepatitis C Virus (HCV) (3.5 hrs)

A. Introduction and Background – Robin Biswas, MD and Indira Hewlett, PhD, DETTD, OBRR, FDA

B. Performance of HIV and HCV Supplemental Assays

1. **Wendi Kuhnert, PhD, CDC – 15'**
2. **Susan Stramer, PhD, ARC – 20'**
3. **Michael Busch, MD, PhD, Blood Centers of the Pacific**

3:30 p.m. BREAK

3:45 p.m. OPEN PUBLIC HEARING

4:15 p.m. ***Open Committee Discussion***

C. Questions for the Committee

D. Committee Discussion and Recommendations

5:00 p.m. RECESS (8:00 a.m. Friday, March 19, 2004)

<u>Friday, March 19, 2004</u>

8:00 a.m. Open Committee Discussion (3.5 hrs)

III. FDA's Current Thinking on Product Standards, Quality Assurance, and Submission Requirements for

Platelets, Pheresis

A. Introduction and Background – Alan E. Williams, PhD, Director, Division of Blood Applications, OBRR

B. FDA Current Thinking: Product Standards, Quality Assurance and Submission Requirements - Sharyn Orton, PhD

C. Laboratory Evaluation of Platelet Components Submitted to CBER – Betsy Poindexter

D. Strategies for Quality Assurance Monitoring – Alan E. Williams, PhD

E. Blood Center Perspective on Plateletpheresis Quality Control – German Leparc, MD, Florida Blood Services

9:30 a.m. OPEN PUBLIC HEARING

10:00 a.m. BREAK

10:30 a.m. Open Committee Discussion

F. FDA Current Thinking and Questions for the Committee

G. Committee Discussion and Recommendations

11:30 a.m. LUNCH

12:30 p.m. Open Committee Discussion

IV. Review of Site Visit of the Laboratory of Hepatitis and Related Emerging Agents and the Laboratory of Bacterial, Parasitic, and Unconventional Agents, Division of Emerging and Transfusion Transmitted Diseases, OBRR, CBER

2:15 p.m. CLOSED SESSION

3:00 p.m. ADJOURNMENT