AGENDA

BLOOD PRODUCTS ADVISORY COMMITTEE

85th Meeting – November 3-4, 2005
Gaithersburg Holiday Inn
2 Montgomery Village Avenue
Gaithersburg, MD 20877

Thursday, November 3, 2005

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

8:10 a.m. Committee Updates

- **West Nile Virus Update – Hira Nakhasi, Ph.D., OBRR, FDA and Theresa Smith, M.D., M.P.H., CDC (15')**
- **Draft Guidance on NAT for HIV-1 and HCV: Testing, Product Disposition, and Donor Deferral and Re-entry – Paul Mied, Ph.D., OBRR, FDA (10')**
- **Summary of the TSEAC meeting held on October 31, 2005 – David Asher, M.D., OBRR, FDA (10')**
- **Summary of the DHHS Advisory Committee on Blood Safety and Availability – Jerry Holmberg, Ph.D., Executive Secretary, Advisory Committee on Blood Safety and Availability (10')**
- **Re-entry of Donors Deferred Based on anti-HBc Test Results – Gerardo Kaplan, Ph.D., OBRR, FDA and Susan Stramer, Ph.D., American Red Cross(10')**

9:00 a.m. O*pen Committee Discussion*

9:45 a.m. Break

10:00 a.m.

I. Approaches to Over-the-Counter (OTC) Home-Use HIV Test Kits

A. Introduction and Questions to the Committee – Elliot Cowan, Ph.D., OBRR, FDA (20')

B. Proposal for an OTC Home-Use HIV Test Kit – Sue Sutton-Jones, M.S., OraSure Technologies (20')

C. Changes in HIV Testing Practices and Counseling Recommendations – Bernard Branson, M.D., CDC (30')

D. Role of Quality Systems for Diagnostic Tests – Devery Howerton, Ph.D., CDC (30')

E. Psychological/Social Issues Associated with HIV Testing

and OTC Home-Use HIV Tests – Joseph Inungu, M.D., M.P.H., Dr.P.H., Central Michigan University (30')

F. Human Factors in OTC Testing – Arleen Pinkos, OIVD, CDRH, FDA (20')

12:30 p.m. Open Committee Discussion

1:00 p.m. LUNCH

2:00 p.m. Open Public Hearing

3:45 p.m. Break

4:00 p.m. Questions to the Committee and Committee Discussion

5:30 p.m. Adjournment

Friday, November 4, 2005

8:00 a.m. Information - Serious Adverse Events Following Falsely Elevated Glucose Measurements Resulting from Administration of an IGIV Product Containing Maltose – Ann Gaines, Ph.D., OBE, FDA, L. Ross Pierce, M.D., OBRR, FDA, and Patricia Bernhardt, B.S., MT(ASCP), OIVD/CDRH, FDA and Discussion (60')

9:00 a.m. Questions to the Speakers

9:30 a.m.

II. Heterogeneity of Commercial Alpha-1-Proteinase Inhibitor (Human) Products – Implications for Longer-Term Safety and Efficacy

A. Introduction and Questions to the Committee – Andrew Shrake, Ph.D., OBRR, FDA (10')

B. Observations on Marketed alpha-1-Proteinase Inhibitor Products – Ewa Marszal, Ph.D., OBRR, FDA (10')

C. Identification and Possible Implications of a Human Plasma Purified Anodal Variant of Alpha-1-Antitrypsin – Mark Brantly, M.D., Alpha-1-Foundation (15')

D. Characterization of Aralast® Compared to Other A1PI Preparations - Hans Peter Schwarz, M.D, Baxter Healthcare (15')

E. Safety Reporting for Alpha-1-PI products – Tina Khoie, M.D., M.P.H., OBE, FDA (10')

F. Post-Marketing Study Commitments for Licensed Alpha-1 PI Products - Rationale – L. Ross Pierce, M.D., OBRR, FDA (10')

G. Licensed Therapeutic Protein Products with Known Structural Modifications - Andrew Chang, Ph.D., OBRR, FDA, and Kurt Brorson, Ph.D., CDER, FDA (20')

11:00 a.m. Open Public Hearing

11:30 a.m. Break

11:45 a.m. Committee Discussion

12:45 p.m. Adjournment