7-7-09

DRAFT AGENDA

BLOOD PRODUCTS ADVISORY COMMITTEE
95th Meeting, July 20-21, 2009

Hilton Washington DC North/Gaithersburg
620 Perry Parkway, Gaithersburg, MD 20877

Monday, July 20, 2009

8:00 a.m. Opening Remarks, Frederick P. Siegal, M.D., Medical Director, Comprehensive HIV Center, Saint Vincent's Catholic Medical Centers, New York, NY, Chairperson, BPAC

Statement of Conflicts of Interest, Announcements

8:15 a.m. Topic I. Strategies to Demonstrate Effectiveness of New Coral Snake Antivenoms

A. Introduction, Hon-Sum Ko, M.D., DH, OBRR, FDA (20')

B. Coral Snake Envenomation: Pathogenesis, Clinical Effects, Morbidity and Mortality and Distribution, Craig Kitchens, M.D., University of Florida (30')

C. Challenges for Clinical Trials, Steve Borron, M.D., South Texas Poison Center (30')

D. Animal Models and Surrogate Markers for Coral Snake Envenomation, Alejandro Alagon, M.D., Ph.D., Autonomous National University of Mexico (30')

E. Summary of January 2009 NIH Conference on Coral Snake Antivenoms, Steven Seifert, M.D., University of New Mexico School of Medicine, New Mexico Poison and Drug Information Center

F. FDA Statistical Considerations, Jessica Kim, Ph.D., OBE, FDA (10')

10:30 a.m. Break

10:45 a.m. Open Public Hearing

11:15 a.m. Open Committee Discussion

G. Questions for the Committee

H. Committee Discussion

12:00 p.m. Lunch

1:00 p.m. Topic II. Clinical and Surrogate Endpoints for Evaluating Efficacy of Alpha-1 Proteinase Inhibitor (Human) Augmentation Therapy

A. Introduction, L. Ross Pierce, M.D., DH, OBRR, FDA (10')

B. AAT Deficiency: Natural History and Pathogenesis, Kenneth Chapman, M.D., MSc, University of Toronto (25')

C. Review of Epidemiological Studies Using Augmentation Therapy and Serum AAT Levels as a

Surrogate Endpoint to Evaluate Efficacy of Augmentation Therapy, Robert Sandhaus, M.D., National Jewish Health (35')

D. Inhalation Therapy for Emphysema due to AAT Deficiency, Mark Brantly, M.D., University of Florida (30')

E. Trial Design Considerations for Clinically Meaningful Endpoint Trials in AAT Deficiency, L. Ross Pierce, M.D., DH, OBRR, FDA (20')

F. QCT and Disease Progression in AAT Deficiency: Results of EXACTLE and Danish-Dutch Studies, Asger Dirksen, M.D., M.S., Gentofte Hospital, University of Copenhagen (30')

3:30 p.m. Break

3:45 p.m. Open Public Hearing

5:00 p.m. Open Committee Discussion

E. Questions for the Committee

F. Committee Discussion

6:00 p.m. Adjournment

Tuesday, July 21, 2009

9:00 a.m. Opening Remarks, Frederick P. Siegal, M.D., Medical Director, Comprehensive HIV Center, Saint Vincent's Catholic Medical Centers, New York, NY, Chairperson, BPAC

Recognition of Retiring Members, Statement of Conflicts of Interest

9:15 a.m. Committee Updates

- Summary of the April 30-May 1, 2009 Meeting of the DHHS Advisory Committee on Blood Safety and Availability, Richard Henry, Advisory Committee on Blood Safety and Availability (15')

- Summary of the June 12, 2009 Meeting of the Transmissible Spongiform Encephalopathies Advisory Committee, David Asher, M.D., DETTD, OBRR, FDA (15')

- 2009 A/H1N1 Influenza Update, Joseph Bresee, M.D., Chief, Epidemiology and Prevention Branch, Influenza Division, CDC and Louis Katz, M.D., Mississippi Valley Regional Blood Center (30')

10:15 a.m. Break

10:30 a.m. Topic III: Informational Session: Hemovigilance

A. Pilot Hemovigilance Module of the National Healthcare Safety Network, William Bower, M.D., CDC (25')

B. FDA's Sentinel Initiative and CBER's Analytic Epidemiology Branch, Robert P. Wise, M.D., M.P.H., OBE, FDA (20')

11:30 a.m. Open Public Hearing

12:00 p.m. Adjournment