DRAFT AGENDA

TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES ADVISORY COMMITTEE

Holiday Inn Gaithersburg,
Gaithersburg, MD 20879
September 18-19, 2006

Monday, September 18, 2006

8:30 a.m. Administrative Remarks, TSEAC Executive Secretary

8:40 a.m. Opening Remarks, Glen Telling, Ph.D. Chairperson, TSEAC

8:45 a.m. Committee Updates

- US and worldwide BSE (20') (L. Ferguson, DVM, USDA)
- vCJD epidemiology and transfusion-transmission (15') (D. Scott, M.D., FDA)
- Blood and plasma donor deferral for transfusion in France since 1980: Guidance (10') (A. Williams, Ph.D., FDA)
- Critical factors influencing prion decontamination using sodium hydroxide – PPTA Collaborative study (20') (K.Cai, Ph.D, PPTA, Talecris Biotherapeutics)

9:50 a.m. Break

10:05 a.m. Topic I. Experimental Clearance of Transmissible Spongiform Encephalopathy Infectivity in Plasma-derived FVIII Products

A. TSE clearance studies for pdFVIII: Study methods and clearance levels (D. Scott, M.D., FDA) (30')

10:35 a.m. B. Human Prions: Clearance and Plasma Lipoproteins (J. Safar, M.D., University of California, San Francisco (25')

11:00 a.m. C Industry TSE clearance studies for pdFVIII (T. Kreil, Ph.D., PPTA, Baxter Bioscience (30')

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11:30 a.m. Open Public Hearing

12:00 p.m. Lunch

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Monday, September 18, 2006 (Continued)

1:00 p.m. Open Committee Discussion

Questions for the Committee

Committee Discussion and Recommendations

2:30 p.m. Break

2:45 p.m. Committee Updates

- Status of FDA's Initiative on Communication of the Potential Exposure to vCJD risk from an investigational product, plasma derived Factor XI that was manufactured from UK donor plasma (15') (M. Weinstein, Ph.D., FDA)

- Summary of World Health Organization Consultation on distribution of infectivity in tissues of animals and humans with transmissible spongiform encephalopathies (20') (D. Asher, M.D., FDA)

3:30 p.m. Open Public Hearing

4:00 p.m. Adjourn

Tuesday, September 19, 2006

8:00 a.m. Topic II. Possible Criteria for Approval of a Donor Screening Test for vCJD

A. Donor Screening Test Issues: Sensitivity, specificity, and confirmatory testing (30') (P. Piccardo, M.D., FDA)

B. Algorithm for approval of human TSE tests in Europe (Marc Turner, MBChB, PhD, FRCP, FRCPath,University of Edinburgh) (30')

C. Available reference materials (P. Minor, Ph.D., NIBSC) (30')

9:30 a.m. Break

9:50 a.m. Research Updates from Test Developers

A. Raeber, M.D. (Prionics) (10')
C. Soto, Ph.D. (University of Texas) (10')

S. Wilson, Ph.D. (Microsens Biotechnologies) (10')
H. Perron, Ph.D. (bioMerieux) (10')
K. Lohman, Ph.D. (Adlyfe) (10')
D. Peretz, MSc., DSc. (Chiron) (10')
J. Safar, M.D. (University of California, San Francisco)(10')

11:10 a.m. Questions for presenters from Committee

11:25 a.m. Open Public Hearing

11:45 p.m. Open Committee Discussion

Summary of FDA Proposed Requirements and Questions for Committee (P. Piccardo, M.D.)

Committee Discussion and Recommendations

1:00 p.m. Adjournment