DRAFT AGENDA 02/4/04

FOOD AND DRUG ADMINISTRATION
TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES
ADVISORY COMMITTEE

February 12 & 13, 2004
Holiday Inn Silver Spring
8777 Georgia Avenue
Silver Spring, MD 20910

First Day, Thursday, February 12, 2004

8:00 a.m. Administrative Remarks (10')
8:10 Retirement awards for departing committee members
Dr. Jesse Goodman (not confirmed)(10')
Director, Center for Biologics Evaluation and Research (CBER)
8:20 Opening Remarks
FDA - Dr. Jesse Goodman (requested) (10')
Dr. Suzette Priola, TSEAC Chairperson (10')

8:40 **Topic # 1 – Informational presentations on risk of transfusion transmission of variant Creutzfeldt-Jakob Disease (vCJD)**

A. A presumptive transfusion-transmitted case of vCJD in the U.K. –
Dr. Robert Will, Consultant Neurologist
National CJD Surveillance Unit, (30')

B. Epidemiology of vCJD and CJD
1. Epidemiological approach: CJD Blood risk – Dr. James Sejvar, Division of Viral and Rickettsial Diseases, CDC (15')
2. Comparison of the transfusion risk for CJD vs. vCJD – Dr. Steve Anderson, FDA (15')
3. Canadian risk assessment: transfusion risk for vCJD – Dr. Susie ElSaadany, Center for Disease Prevention and Control, Health Canada (15')

C. Recent experimental studies in animals regarding TSE infectivity in blood and transfusion transmission of TSE's
1. Review of recent experiments in rodents and in sheep -
Dr. Robert Rohwer, Director Molecular Neurovirology Unit, VA Medical Center, Baltimore (45')
2. Review of recent experiments in non-human primates -
Dr. Paul Brown, Medical Director, Laboratory of
Central Nervous System Studies NIH (15')

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First Day, Thursday, February 12, 2004 (continued)

10:55 a.m. Break (20')
11:15 **Open Public Hearing** (30')
11:45 **Committee Discussion** (45')
12:30 Lunch

1:30 **Topic # 2 – Update on Bovine Spongiform Encephalopathy (BSE) in the United States**

A. Review of the reported case of BSE in Washington State
   1. Case Presentation and USDA Surveillance Program- Dr. Lisa Ferguson, USDA (15')
   2. Confirmation of BSE in the affected cow - Dr. Al Jenny, National Veterinary Services Laboratory, USDA (10')
   3. Food Safety Regulations for BSE – Dr. Mary Porretta, Regulations Development and Analysis Division Food Safety and Inspection Service, USDA (20')
   4. Status of the U.S. Feed Ban Dr. Stephen Sundlof, Director, Center for Veterinary Medicine (10')

2:25 p.m. **FDA Introduction to Topics #3 and #4 – Dr. David Asher, CBER (15')**

Topic #3 - Models for Risk-Based Sourcing of Bovine Materials in FDA-regulated medical products

A. New and proposed BSE-related USDA requirements - Dr. Lisa Ferguson, D.V.M. Senior Staff Veterinarian, U.S. Department of Agriculture (15')
B. Harvard Risk Analysis - Dr. Joshua Cohen, Senior Research Associate, Harvard Center for Risk Analysis (30')
C. Canadian and U.S. BSE Risk - Dr. Steven Anderson, FDA (20')
D. USDA Consultant Risk Assessment – (TBD)*??*

3:45 **Open Public Hearing** (30')
4:15 **Committee discussion** on factors to consider in risk-based sourcing models for bovine materials (75')
5:30 p.m. Adjourn for the day

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Second Day, Friday, February 13, 2004

8:00 a.m. Administrative Remarks

8:10 a.m. **Topic #4 - Minimizing risks of TSE agents in FDA-regulated medicinal products**

A. Current Safeguards for Blood Products
   a. Approach to products containing or exposed to bovine materials - Dr. Dorothy Scott, OBRR/CBER (15')
   b. Current blood donor deferrals and their impact - Dr. Alan Williams, OBRR/CBER (15')
B. Minimizing the Risks of TSE Agents in Human Tissues - Dr. Melissa Greenwald, OCTGT, CBER (15')
C. The Use of Bovine-derived Products in the Manufacture of Vaccines and Allergenic Products - Dr. William Egan, OVRR, CBER (15')
D. Minimizing the Risk of TSE Agents in Drugs - Dr. Gerald Feldman, CDER (15')
E. Minimizing Risk of TSE Agents in Medical Devices - CDR Martha O'Lone, CDRH (15')
F. Food and Cosmetic Safety - Dr. Morris Potter, CFSAN (15')

10:10 Break

11:00 **Open Public Hearing**

12:00 Lunch

1:00 **Committee Discussion** of safeguards for FDA-regulated medicinal products in light of the recent case of presumptive transfusion-transmission of vCJD and the report of a BSE positive cow in the U.S.

3:00 p.m. Adjourn