

(DRAFT)

**FOOD AND DRUG ADMINISTRATION
TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES
ADVISORY COMMITTEE**

Holiday Inn, Ballroom 2
2 Montgomery Village Avenue
Gaithersburg, MD 20879
February 20, 2003

DRAFT AGENDA (revised 2/14/03)

Thursday, February 20, 2003

OPEN SESSION

- 8:00 a.m. Administrative Remarks,
William Freas, Ph.D., Executive Secretary
- 8:10 a.m. Presentation of Plaques to Former Members
Lester Crawford, D.V.M., Ph.D.
Deputy Commissioner, FDA
- 8:20 a.m. Opening Remarks
Suzette Priola, Ph.D., Acting Chairperson
- 8:25 a.m. Update #1: Implementation vCJD Guidance - Blood Supply
after Implementation of European Donor Deferral
- Overview of Blood Supply Monitoring (25 minutes)
Alan Williams, Director, Division of Blood Applications,
OBRR, FDA
- Blood Supply Monitoring
DHHS: Capt. Lawrence McMurtry
Acting Executive Secretary, DHHS Advisory
Committee on Blood Safety and Availability
ABC: Celso Bianco, M.D.
Executive Vice President, ABC
ARC: Peter L. Page, M.D.
Senior Medical Officer, ARCBS-BHQ
NYBC: Robert Jones, M.D.
President, New York Blood Center
AABB: Kay Gregory, MS, MT(ASCP)SBB
Director Regulatory Affairs, AABB

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Thursday, February 20, 2003 (Continued)

- 9:55 a.m. Questions for Presenters
- 10:10a.m **OPEN PUBLIC HEARING** (20 minutes)
- 10:30 a.m. **BREAK**
- 10:45 a.m. Update #2: BSE Epidemiology and Food Chain Controls
 David Asher, M.D., OBRR, FDA
- 11:15 a.m. Topic #1: Consideration of Labeling Claims for Transmissible
 Spongiform Encephalopathy (TSE) Agent Clearance in Plasma
 Derivatives
- Introduction
 Dorothy Scott, M.D., OBRR, FDA
- Virus Removal from Blood Products: Validation, Label Claims
and Possible Paradigm for Removal of TSE Agents
 Mahmood Farshid, Ph.D., OBRR, FDA (15 minutes)
- TSE Agent Clearance Issues (15 minutes)
 Dorothy Scott, M.D., OBRR, FDA
- Risk Analysis for TSE and Plasma Derivatives
 Steven Anderson, Ph.D., OBE, FDA (30 min)
- European Perspective on TSE Agent Clearance in Plasma
Derivatives
 Sol Ruiz, Ph.D., Division of Biologicals and
 Biotechnology, Spanish Medicines Agency (20 minutes)
- 12:45 p.m. **LUNCH**
- 1:45 p.m. Committee Discussion
- 2:05 p.m. TSE Clearance Studies – Scientific Presentations from Industry
 Confirmed by PPTA:

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Thursday, February 20, 2003 (Continued)

3:35 p.m.	OPEN PUBLIC HEARING
4:15 p.m.	BREAK
4:30 p.m.	Questions to the Committee
4:35 p.m.	Committee Discussion and Vote
5:35 p.m.	ADJOURN