

(DRAFT)

FOOD AND DRUG ADMINISTRATION

**TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES
ADVISORY COMMITTEE**

Hilton Hotel
8727 Colesville Road
Silver Spring, MD 20910

DRAFT AGENDA (revised 10/4/04)

Thursday, October 14, 2004

- 8:00 a.m. Administrative Remarks,
William Freas, PhD, Executive Secretary
- 8:10 a.m. Opening Remarks
Suzette Priola, PhD, Acting Chairperson
Introduction
Dr. Jesse Goodman, Director,
Center for Biologics Evaluation and Research, FDA
Presentation of Plaques to Retiring Committee Members
Dr. Jesse Goodman
- 8:25 a.m. Informational Presentation #1: USDA BSE Licensed Tests and
Enhanced Surveillance Program (15 minutes), Lawrence Elsen,
DVM, USDA (confirmed)
- Informational Presentation #2: USDA Review of Worldwide BSE
Situation and USDA Responses (15 minutes), Lisa Ferguson,
DVM, USDA (confirmed)
- Informational Presentation #3: New CFSAN BSE-Food Safety
Rules (15 minutes), Rebecca Buckner, Ph.D., CFSAN/FDA
- Informational Presentation # 4: Update on Animal Feed
Rulemaking (15 minutes), Burt Pritchett, DVM, CVM
- 9:25 a.m. Questions for Presenters
- 9:35 a.m. **OPEN PUBLIC HEARING** (30 minutes)
- 10:05 Informational Presentation #5: Labeling Claims for TSE
Clearance Studies for Plasma Derivative Products (20 minutes),
Dorothy Scott, MD, OBRR, FDA (confirmed)

10:25

BREAK

10:45 a.m.

Topic – Presumptive Transfusion Transmissions of Variant CJD (vCJD): Consideration of Current FDA-Recommended Safeguards

- A. FDA Introduction (15 minutes), David Asher, MD, OBRR/FDA (confirmed)
- B. Presumptive Transfusion Transmission of vCJD (review of CJD and vCJD: UK and EU epidemiology, case reports, surveillance and projections, potential public health implications, and responses) (45 minutes), Professor Robert G. Will, MD, UK CJD Surveillance Unit (confirmed).
- C. Comparison of the Transfusion Risk for CJD vs. vCJD (10 minutes), Steven Anderson, PhD, OBE/FDA (confirmed)
- D. Leukoreduction and Its Failure to Remove Most Infectivity from Blood (15 minutes), Robert G. Rohwer, PhD (confirmed)

12:10 p.m.

Questions for Speakers

12:25

LUNCH

1:25

- E. Changes in Canadian CJD/vCJD Blood Safety Policies (not confirmed) (20 min), Dr. Peter Ganz, HealthCanada
- F. Current Safeguards for Blood Products Recommended by FDA (15 minutes), Dorothy Scott, MD, OBRR/CBER (confirmed)
- G. Possible Effects of Prior CJD-Related Blood Donor Deferrals on Blood Supply (30 minutes), Alan Williams, PhD, OBRR/CBER (confirmed)

2:30

Questions for Speakers

2:45

OPEN PUBLIC HEARING

3:15

BREAK

3:35

Question to the Committee

3:45

Committee Discussion and Vote

5:00

ADJOURN