

FOOD AND DRUG ADMINISTRATION

Center for Biologics Evaluation and Research

24th Meeting of the Transmissible Spongiform Encephalopathies Advisory Committee

FDA Fishers Lane Building
5630 Fishers Lane, Room 1066
Rockville, Maryland
March 14, 2013

DRAFT AGENDA

Thursday, March 14, 2013

8:00 a.m.	Call to Order and Opening Remarks Introduction of Committee Recognition of Retiring Members Conflict of Interest Statement	Linda Detweiler, D.V.M Acting Chair, TSEAC Bryan Emery, LCDR Designated Federal Officer, TSEAC
Topic I:	Preliminary Results from FDA's Quantitative Risk Assessment of the vCJD Risks Potentially Associated with the Transfusion of Red Blood Cells in the U.S.	
8:15 a.m.	Overview of FDA's Risk Assessment Approaches for Potential vCJD Risks in Blood and Blood Products	Steven Anderson, Ph.D., MPP OBE, FDA (20')
8:35 a.m.	Variant CJD (vCJD): UK and Worldwide Situation and Transfusion Medicine Epidemiological Review of UK: Interim Results	Prof. Robert G. Will, CJD RSU, Edinburgh (30')
9:05 a.m.	Bovine Spongiform Encephalopathy (BSE) Surveillance Program Update	Sylvia Kreindel, DVM, MPH USDA, APHIS (20')
9:25 a.m.	Possible Prevalence of Latent vCJD Infection in the UK: Final Results of 2 nd Appendix PrP ^{TSE} Survey	Prof. Noel Gill (30') Health Protection Agency, UK
9:55 a.m.	Break (20')	
10:15 a.m.	vCJD and Transfusion of Blood Components: An Updated Risk Assessment for the UK	Dr. Peter Bennett (30') Public Health Directorate, UK
10:45 a.m.	Introduction to the FDA vCJD Risk Assessment for Red Blood Cells	Steven Anderson, Ph.D., MPP OBE, FDA (15')
11:00 a.m.	FDA vCJD RBC Risk Model: Model Assumptions and Changes since Previous Assessments	Luisa Gregori, Ph.D. OBRR, FDA (30')
11:30 a.m.	Lunch	

FOOD AND DRUG ADMINISTRATION

Center for Biologics Evaluation and Research

24th Meeting of the Transmissible Spongiform Encephalopathies Advisory Committee

FDA Fishers Lane Building

5630 Fishers Lane, Room 1066

Rockville, Maryland

March 14, 2013

DRAFT AGENDA

- | | | |
|------------|---|--|
| 12:30 p.m. | FDA Assessment of Transfusion-Transmitted vCJD Risk for US Recipients of Red Blood Cells: Model, Risk Estimates, Sensitivity Analysis | Steven Anderson, Ph.D., MPP
OBE, FDA (60') |
| 1:30 p.m. | FDA Summary and Questions for the Committee | Steven Anderson, Ph.D. , MPP
OBE, FDA (10') |
| 1:40 p.m. | Open Public Hearing | |
| 2:40 p.m. | Open Committee Discussion Questions for the Committee | |
| 4:00 p.m. | Adjournment | |