

PUBLIC AGENDA

47-24 '01 OCT -3 P 1:23

FOOD AND DRUG ADMINISTRATION

**Joint meeting of the
TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES
ADVISORY COMMITTEE**

and the

**VACCINES AND RELATED BIOLOGICAL PRODUCTS
ADVISORY COMMITTEE**

Holiday Inn, Versailles Ballrooms I, II, and III

Bethesda, Maryland 208 14

July 27, 2000

Thursday, July 27, 2000 -

8:00 a.m. CLOSED SESSION

OPEN SESSION

- 9:00 a.m.** Administrative announcements
W. Freas, PhD, Executive Secretary, TSEAC, FDA
- 9:10** Welcome
Paul Brown, MD, Committee Chair
Harry Greenberg, MD, Co-Chair
- 9:15** Introduction
W. Egan, PhD, Acting Director OVRP, FDA
- 9:30** Overview of U.S. Vaccination Program
Walter Orenstein, MD
Director of National Immunization Program, CDC
- 9:45** BSE Overview
D. Asher, MD, FDA
- 10:00** Break
- 10:15** Studies of BSE Infectivity in Tissues of Cattle
Gerald Wells, BVetMed, FRCPath, DipLEVCVP, MRCVS
Consultant Veterinary Pathologist
Veterinary Laboratories Agency
New Haw, United Kingdom

This is the final Agenda

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AGENDA, JOINT MEETING OF TSEAC & VRBPAC (page 2)

- 10:45 a.m. Current Research Overview:
John Wilesmith, BVSc, MRCVS
Head of the Epidemiology Department
Veterinary Laboratories Agency
Weybridge, United Kingdom
- 11:10 European Union Presentation
Professor Jean-Hugues Trouvin and
Dr. Roland Dobbelaer
CPMP Biotechnology Working Party
EMA, London
- 11:40 Bacterial Vaccines: Overview of Manufacturing & Risk-Assessment
Willie Vann, PhD, OVR, CBER,
- 12:00 p.m. Viral Vaccines: Overview of Manufacturing & Risk-Assessment
Ira Berkower, OVR, CBER
- 12:20 Lunch
- 1:20 Manufacturers Comments/Presentations:
SmithKline Beecham Pharmaceuticals
Dr. Clare Kahn
V.P. North American Regulatory Affairs
- Dr. R. Bradley, CBE,**
Private BSE Consultant and formerly Head of Pathology,
Ministry of Agriculture, Fisheries and Food (MAFF, UK)
- 1:40 **Aventis Pasteur**
Dr. Jeffrey Almond
Senior Vice President, Research and Development
- 1:55 Comments from other Manufacturers
- 2:20 Open public hearing
- 3:20 Discussion/presentation of "Questions for the Committee"
- 5:30 Adjourn