

draft PUBLIC AGENDA as of July 20, 2000

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 20814
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
- 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 a.m. Studies of BSE Infectivity in Tissues of Cattle
 Gerald Wells, BVetMed, FRCPath, Dipl.EVCP, MRCVS
 Consultant Veterinary Pathologist
 Veterinary Laboratories Agency
 New Haw, United Kingdom

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 p.m. **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