

**TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES  
ADVISORY COMMITTEE MEETING**

**February 12 and 13, 2004**

**Issue Summary, Topic #4-D**

**Current CDER Approaches to Minimizing the Risk of TSE Agents in Drugs**

Staff from the Center for Drugs Evaluation and Research (CDER) will update the Transmissible Spongiform Encephalopathies Advisory Committee (TSEAC) on policies and procedures currently in place to minimize the risk of TSE transmission from drugs and biologics that contain or may have been exposed to bovine components during the manufacturing process.

Background

CDER has jurisdiction over a wide variety of injectable, oral, and topical medicinal products. Many of these drugs and most biologics either contain or were exposed to bovine components at some time during manufacturing process. Because there is no ante-mortem diagnostic test for the infectious TSE agent in pre-symptomatic animals, since 1992 and in line with a number of letters to the pharmaceutical industry, CDER has adopted policies that are as comprehensive as possible to ensure that the TSE agent does not enter into regulated drug products. These policies, applied throughout the regulatory review process, are developed based on the current scientific knowledge as well as guidance from FDA Advisory Committees. They have been disseminated to industry, to the medical community and the general public through direct interaction at meetings, or by letters, general and specific product guidance, and Federal Register Notices.

These policies and procedures include:

- ?? Require manufacturers to source bovine materials from non-BSE risk countries
- ?? Encourage manufacturers to seek non-mammalian alternatives for certain materials
- ?? Encourage studies of TSE agent inactivation or clearance by manufacturers
- ?? Continue the evaluation of import risk evaluation criteria
- ?? Continue evaluation of the risks associated with components for drug and therapeutic biologics
- ?? Encourage the use of dedicated facilities
- ?? Develop and support research programs to address relevant TSE issues

CDER continues to evaluate its BSE policies and procedures, as new scientific information becomes known.