

**TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES ADVISORY COMMITTEE  
VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE**

**JULY 27, 2000**

**CHARGE**

The TSEAC and VRBPAC are requested to consider appropriate precautions to be taken with regard to the use of bovine-derived materials in the manufacture of vaccines when those materials are obtained from countries in which BSE is known to exist or from countries where the USDA has been unable to assure the FDA that BSE does not exist. The committees are also asked to consider the potential risks and possible actions to be taken with regard to licensed or investigational vaccine products that may be affected.

**QUESTIONS**

1. Please discuss the potential risk presented by the use of bovine-derived materials, sourced from Europe (including the UK), in currently licensed vaccines. In this discussion, please comment on the various risk estimates that have been presented to the Committee. In this discussion, please include:

- a) Preparation of bacterial and viral master and working seeds; preparation of master and working cell banks (e.g., use of calf serum, fetal calf serum).
- b) Fermentation process (e.g., use of bovine-derived media)
- c) Formulation of the final products (e.g., use of gelatin, etc.)

Additionally, in this discussion, please include risk assessments for bovine materials sourced, at different times, from different European countries (e.g., UK, Germany, France).

2. The following item pertains to currently licensed US vaccines that contain bovine-derived material obtained from Europe (including the UK).

Please discuss those circumstances, if any, under which FDA should take specific regulatory action regarding these vaccines. Some examples of regulatory actions which are available to the FDA include product recall, modification of the package insert, and/or issuance of a "Dear Doctor/Health Care Provider" letter.

3. The following item pertains to investigational (non-US licensed) vaccines that contain bovine-derived material obtained from Europe (including the UK). This includes certain investigational vaccines (used under IND) that contain currently-US licensed vaccines as components (such as components of a new investigational combination vaccine). In addition, this includes the "usual" investigational vaccines without previously US licensed components.

Please discuss those circumstances, if any, under which FDA should take specific regulatory action regarding these investigational vaccines, such as stopping a clinical trial (pending an acceptable remedy of the product) or modification of the informed consent form.