DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: March 19, 2003

From: Director, Office of Compliance, CDRH, HFZ-300

Subject: TSE/BSE Letter to Manufacturers of FDA-Regulated Medical Devices Containing Animal Tissue Products or Components

To:

As of March 3, 2003, the CDRH January 3, 2003, TSE letter to "Manufacturers of FDA-Regulated Medical Devices Containing Animal Tissue Products or Components" has been mailed to 25,000 medical device industry firms. These firms include manufacturers, contract sterilizers, importers and repackagers. The letter serves as a very important reminder to the medical device industry of the recommendations in our CDRH 1998 Guidance designed to minimize the risk of TSE transmission via medical device use. It clarifies information needed in pre-submissions of devices which either contain or are exposed to animal-derived materials during manufacturing. In addition, the letter indicates that FDA investigators may be evaluating the adequacy of procedures and effectiveness of their implementation during any inspection of the manufacturing facility.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN - 3 2003

To: Manufacturers of FDA-Regulated Medical Devices Containing Animal Tissue Products or Components

We wish to call your attention to FDA's current recommendations pertaining to animal-derived medical devices intended to minimize risk of Tissue Spongiform Encephalopathy (TSE) to users. On November 6, 1998, the Center for Devices and Radiological Health (CDRH) issued a guidance for FDA reviewers and industry titled "Medical Devices Containing Materials Derived From Animal Sources (except for In Vitro diagnostic devices)." The purpose of this document was to clarify the information needed in Pre-submissions (IDE, PMA, 510(k)) for medical devices which either contain or are exposed to animal-derived materials during manufacturing.

This guidance is applicable to all medical devices (except In Vitro diagnostic devices) which either contain or are exposed to animal-derived materials during manufacturing. All animal species (e.g., human, bovine, ovine, porcine, chicken, fish, etc.) are included.

FDA investigators may be evaluating the adequacy of your procedures and the effectiveness of implementation during any inspection of your manufacturing facility.

A copy of this guidance is available on the worldwide web/CDRH home page at http://www.fda.gov/cdrh/ode/88.html or CDRH facts-on-demand at 1-800-899-0381 or 301-827-0111. Specify number 2206 when prompted for the document shelf number. For questions regarding the use or interpretation of this guidance, contact Kiki B. Hellman, Ph.D., at 301-443-7158 or Karen F. Warburton, at 301-594-1744.

The most current information on BSE and related diseases can be accessed on the United States Department of Agriculture (USDA) website at www.aphis.usda.gov/oa/bse.

Sincerely yours,

David W. Feigal, Jr., M.D., M.P.H.
Director
Center for Devices and
Radiological Health