DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

May 9, 1996

TO MANUFACTURERS OF FDA-REGULATED DRUG/BIOLOGIC/DEVICE PRODUCTS:

As the media have widely reported, the British government announced on March 20, 1996, that new information had been gathered about bovine spongiform encephalopathy (BSE) in cattle that suggests a possible relationship between BSE and ten cases of a newly identified form of Creutzfeldt-Jakob disease (CJD), a similar fatal transmissible spongiform encephalopathy (TSE), in humans. To serve our mutual interest in protecting public health, the Food and Drug Administration (FDA) believes it is prudent to reiterate concerns we have previously expressed on this issue.

We strongly recommend you take whatever steps are necessary to assure yourselves and the public that, in the manufacture of FDA-regulated products intended for administration to humans, you are not using materials that have come from cattle born, raised, or slaughtered in countries where BSE is known to exist. FDA believes that immediate and concrete steps must be taken by manufacturers to reduce the potential risk of human exposure to, or transmission of, the infectious agent which causes BSE in cattle.

BSE is an infectious neurologic disorder of cattle and is prevalent in certain parts of the world. BSE has never been diagnosed in cattle in the United States. It is believed that the rapid spread of BSE in cattle in some countries, particularly Great Britain, was caused by the feeding of certain infected cattle and sheep tissues to cattle. While transmission of the causative agent of BSE to humans has not been definitively documented to date, inter-species transfer has been demonstrated (e.g., mice can be infected by exposure to infected bovine tissues). Recent developments in Great Britain raise serious questions regarding potential hazards of the use of animal tissues containing the causative agent of BSE.

The list of countries where BSE is known to exist is maintained by the U.S. Department of Agriculture (USDA) and codified in Title 9, Code of Federal Regulations, Part 94.18. A current list of these countries follows:

USDA LIST OF COUNTRIES WHERE BSE EXISTS
(Current as of May 1996)

Great Britain (including Northern Ireland and the Falklands)
Switzerland
France
Republic of Ireland
Oman
Portugal

A range of research projects into the exact nature of both the BSE agent and other TSE agents is ongoing. Available scientific information indicates that these agents are extremely resistant to inactivation by normal disinfection or sterilization procedures.

At a future date, we will contact you with guidance on how best to provide assurance that your products do not contain potentially BSE-infected materials.

If you need more information, please contact the following:

Yuan Yuan Chiu, Ph.D., 301 443-3510 (drug products)
Kiki Hellman, Ph.D., 301 443-7158 (medical devices)
Paul Richman, Ph.D., 301 827-3070 (biologics).

Thank you for your attention to and cooperation in this matter.

Sincerely yours,

Michael A. Friedman, M.D.
Deputy Commissioner for Operations