U.S. Food and Drug Administration

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

"Getting More Information"

Because the following document was developed a number of years ago, the contact information is no longer accurate. If you wish to contact the agency with questions, please use the following:

Mail: Office of Surveillance and Biometrics (HFZ 510)
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Rockville, MD 20850

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April 28, 1987

FDA SAFERY ALERT
POSSIBLY CONTAMINATED DURA MATER

Dear Doctor:

This is to alert you to the potential risk of transmitting Creutzfeldt-Jakob Disease (CJD) to surgical patients through possibly contaminated batches of human dura mater transplant material, and to ask that you check your stocks for these batches. Note that although human dura mater is used principally to neurosurgery, it is also used in other procedures, including orthopedic, otologic, dental, urologic, gynecologic and cardiac surgery. Please forward this letter to the appropriate departments in your institution.

The material in question is an imported, commercially prepared dura mater of human origin, "LYODURA", processed by B. Braun Melsungen AG of the Federal Republic of Germany and distributed of Tri Hawk International of Montreal, Canada. The batches of concern were packaged in 1982, and can be identified by a first digit of "2" in their four-digit lot numbers . One of these lots, number 2105, has been associated with the first, identified case of CJD following use of a human dura mater graft, as reported by the Centers for Disease Controls (CDC) in the February 6, 1987, issue of Morbidity and Mortality weekly Report.

To diminish the risk of Transmitting CJD, a rare but lethal disease, we recommend that you dispose of all "LYDORA" from packages bearing lot numbers beginning with the digit "2" as well as unmarked pieces of this product that may remain in stock. We are also requesting that you or your staff report to us any other cases of CJD that may be associated with the use of human dura mater grafts.

To report cases, or for further information, please contact:

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Food and Drug Administration
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Because presently known procedures to sterilize human dura mater are not sufficient to completely inactivate the CJD agent, and because even the most stringent donor screening cannot exclude asymptomatic carries of CJD, the use of any human dura mater product carries some risk. The best method to minimize the risk is to screen donors adequately. Also, co-mingling materials from various donors during processing should be avoided. We strongly recommend that users of dura mater choose only pro ducts from known sources which retrieve, process and handle the material according to guidelines such as those of the American Association of Tissue Banks.

Sincerely yours,

John C. Villforth
Director
Center for Devices
And Radiological health