The New York
Firefighters Skin Bank
525 East 68th Street • NY, NY 10021
Tel: (212) 746-7546 Fax: (212) 746-8177

Docket ## 02D-0266

January 22, 2003

1641

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket # 02D-0266

Dear Sir or Madam:

This is in response to the FDA's draft "Guidance for Industry: Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD and Variant Creutzfeldt-Jakob Disease (vCJD) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)".

As a Skin Bank Director, I agree with the concern of potential transmission of prion disease through tissue and believe in a risk based approach in screening donors, but the exclusions in these guidelines will eliminate the majority of tissue donors and pose additional public health concerns.

Please accept my following comments regarding donor eligibility:

IV Recommendations for Donor Eligibility

2. Has been diagnosed with dementia or any degenerative or demyelinating disease of the central nervous system (CNS) or other neurological disease of unknown etiology; (HCT/Ps from donors with dementia confirmed by gross and microscopic examination of the brain to be caused by cerebrovascular accident, brain tumor, head trauma, or toxic/metabolic dementia and who are confirmed not to have evidence of TSE on microscopic examination of the brain may be acceptable based on an evaluation by the Medical Director.)

This exclusion would require all potential cardiovascular accident, traumas and brain tumor donors to have an autopsy. Although most trauma victims do have an autopsy most do not have brain tissue microscopics. This exclusion will have paramount effects on tissue availability. It is more appropriate and feasible for a clinical decision by a licensed physician be made regarding the differential diagnosis of dementia. Medical Directors should be able to determine etiology on clinical grounds with supporting documentation. Each bank should be expected to set clinical guidelines and review case by case, always excluding the donor with dementia of unknown etiology.

02D-0266 C19

8. Has injected bovine insulin since 1980, unless you can confirm that the product was not manufactured after 1980 from cattle in the U.K.

This information will be impossible to obtain. While some families are familiar with current drugs their loved one had been taking, they will not remember the drug taken 20 years prior. This exclusion would eliminate all long-term diabetics.

Thank you for this opportunity.

Sincerely,

Nancy Gallo, RN, MPH
Administrative Director

Cc: Roger W. Yurt, MD, Medical Director
William T. Greene, VP