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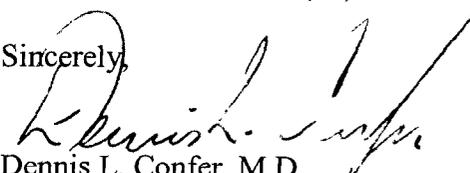
Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

December 20, 2002

The National Marrow Donor Program<sup>®</sup> (NMDP) appreciates the opportunity to provide comment to the Draft Guidance for Industry, "Preventive Measures to Reduce the Possibility of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Human Cells, Tissue, and Cellular and Tissue-Based Products (HCT/PS)", Docket number 02D-0266.

The attached comments are on behalf of the NMDP and its Network of Donor Centers (90), Apheresis Centers (83), Transplant Centers (149), and Cord Blood Banks (12).

Sincerely,

  
Dennis L. Confer, M.D.  
Chief Medical Officer

02D-0266

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#### IV. Recommendations For Donor Eligibility

The NMDP commends the agency's recognition that elimination of HCT/P donors from specific geographic areas could seriously jeopardize the ability for some HCT/P recipients to receive a transplant from a closely HLA-matched donor.

The NMDP agrees that HCT/P donors with risk factors as defined in IV, 3-8 should be permitted to provide HCT/P's in the allogeneic setting, because the risk for the transmission of CJD may be outweighed by the benefit of receiving a transplant from a closely HLA-matched donor. The NMDP currently defers donors with the risks factors as defined in IV, 1-3 due to the potential risk of donor to recipient transmission of CJD. At the present time, the NMDP would continue to defer donors with risk factors defined in IV, 1-3.

Note: The NMDP urges the agency not to define the specific wording requirements for the donor CJD screening questions. Rather, allow establishments to have the flexibility to develop a screening questionnaire, which has been validated to meet content and clarity requirements.

#### VI. Assessing The Impact Of These Recommendations On the HCT/P Supply

Unlike the blood industry, most HCT/P donors are not selected to provide actual products. Therefore, it is difficult to determine the impact the deferral of a HCT/P donor based on risk factors as defined in IV, 3-8. However, based upon the registries listed in Bone Marrow Donors Worldwide (BMDW), blanket deferral of donors from the countries defined in Appendix IX would result in removal of 3.2 million PBSC donors and 48,000 cord blood units from the total donor pools of 8 million PBSC and 123,000 cord blood donors.

In 2003, the NMDP projects importation of 120 HCT/P donor products, and 68 marrow products from the areas in Europe defined in Appendix IX. If the donors were screened according to the eligibility criteria IV, 3-8 and were identified as having these risks, we predict that most, if not all, of these products would be accepted by the transplant physicians and patients. The NMDP would consider these units as exception units requiring appropriate release documentation indicating the findings of the donor screening results.