QUESTIONS FOR THE COMMITTEE

1. Compared to the risk of transmission of variant CJD by blood transfusion, is there a significant risk of transmission of vCJD from human cells, tissues, and cellular and tissue-based products that are transplanted, implanted, infused, or transferred?

   --What are the relative risks for different cells and tissues?

2. The committee has previously assessed the risk of transmission of vCJD by blood, and has made recommendations accordingly. Based upon the committee's assessment of the risk of transmission of vCJD by human cells and tissue, and considering the potential impact on supply, should FDA recommend donor deferral criteria for possible exposure to the BSE agent?

   A. If no, are there additional data that should be gathered that might alter this decision?
   B. If yes, what deferral criteria should FDA recommend:

      i. Exclusion only for certain types of cells and tissues (which ones?)
      ii. UK only? UK and France? Other BSE countries (which ones?)
      iii. Time period of exposure—limit to 1980-1996
      iv. Duration of exposure—limit to 6 months cumulative exposure?

3. If a deferral policy were to be put into place, how can information about the donor's risk factors for CJD and vCJD be obtained—is a donor medical history interview required?

   --Currently, several states permit the recovery of corneas under legislative consent, whereby an interview with the next of kin may not take place. Should FDA require an interview for <u>all</u> cornea donors?