

**Dermatologic and Ophthalmic Drugs Advisory Committee**  
**March 17, 2003**  
**NDA# 21-414, Vitrase (hyaluronidase for intravitreal injection)**

**D R A F T**

Are additional analyses of the data needed to understand the safety or efficacy of Vitrase for the treatment of vitreous hemorrhage?

Are additional studies needed to establish the efficacy of this product?

Has sufficient evidence been submitted to support the efficacy of Vitrase for the treatment of vitreous hemorrhage?

Is there concern about the death rate observed in these studies?

What additional clinical studies would be helpful in further evaluating the potential benefits of Vitrase therapy?

Are there adverse experiences that are of particular concern for this product?

Does the committee recommend approval of Vitrase for the treatment of vitreous hemorrhage?