

September 12, 2003  
Reference No. SMAL03001

Linda Smallwood, Ph.D  
Executive Secretary  
Blood Products Advisory Committee  
Food & Drug Administration CBER  
1401 Rockville Pike HFM350  
Rockville, MD 20857

**VIA EMAIL**

RE: Background material for BPAC for PPTA's Presentation on West Nile Virus (WNV)

Dear Dr. Smallwood,

Please provide the attached documents to the BPAC as background for PPTA's presentation on September 18, 2003. These documents do not contain proprietary information and may be disclosed to the public. The purpose of the background material is to update the BPAC on interactions between PPTA and CBER since the March 2003 BPAC discussion of WNV and risk to plasma therapeutic products. PPTA's presentation on September 18, 2003, will primarily focus on the results of a study designed to test viral loads in manufacturing pools configured from plasma collected from high prevalence geographic areas during the height of the 2002 epidemic.

Additionally, we have attached a July 25, 2003, document issued by The European Agency for the Evaluation of Medicinal Products entitled, "CPMP Position Statement on West Nile Virus and Plasma-Derived Medicinal Products." The CPMP Statement supports the model virus concept for validation as effective for WNV. PPTA supports harmonization of regulatory policy, when appropriate, for plasma therapeutic products as they are used globally for patients with chronic, life-threatening diseases.

Sincerely,

Mary Gustafson  
Senior Director, Global Regulatory Policy

Attachments: PNAB03027 (Summary of West Nile Virus meeting with FDA)  
CBER0301 (PPTA-FDA WNV Working Meeting Overview)  
CBER0302 (NAT Screening Presentation)  
CBER0303 (Risk Assessment Presentation)  
WNV (CPMP Statement on WNV)