

**MEMORANDUM**

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Public Health Service  
Food and Drug Administration  
Center for Biologics Evaluation and Research

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DATE April 11, 2007

FROM Bhanu Kannan, Bioresearch Monitoring Branch, HFM-664  
Division of Inspections and Surveillance  
Office of Compliance and Biologics Quality

THROUGH Patricia Holobaugh, Chief, Bioresearch Monitoring Branch, HFM-664

TO Ke Liu, M.D., HFM-755  
Keith Wonnacott, Ph.D., HFM-715  
Chairs, BLA Licensing Committee

***SUBJECT Summary of Bioresearch Monitoring Inspections***  
SPONSOR: Dendreon Coporation  
PRODUCT: Sipuleucel-T (APC8015-autologous antigen presenting  
cells loaded with prostate antigen PA2024)  
BLA: STN 125197/0

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