

MEMORANDUM

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

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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