



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
1401 Rockville Pike
Rockville, MD 20852-1448

Our STN: BL 125197/0

January 11, 2007

Dendreon Corporation
Attention: Elizabeth C. Smith
Vice President of Regulatory Affairs
3005 First Avenue
Seattle, WA 98121

Dear Ms. Smith:

This letter is in regard to your biologics license application (BLA) submitted under section 351 of the Public Health Service Act.

We have completed an initial review of your application dated November 9, 2006 for Sipuleucel-T to determine its acceptability for filing. Under 21 CFR 601.2(a), we have filed your application today. The review goal date is May 15, 2007. This acknowledgment of filing does not mean that we have issued a license nor does it represent any evaluation of the adequacy of the data submitted.

At this time, we have not identified any potential review issues. Our filing review is only a preliminary review, and deficiencies may be identified during substantive review of your application. Following a review of the application, we shall advise you in writing of any action we have taken and request additional information if needed.

If you have any questions, please contact the Regulatory Project Manager, Lori Tull, at (301) 827-5102.

Sincerely yours,

Raj K. Puri, M.D., Ph.D.
Director
Division of Cellular and Gene Therapies
Office of Cellular, Tissue, and Gene Therapies
Center for Biologics Evaluation and Research