



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

MEMORANDUM

Date: January 8, 2007

To: BLA Committee

From: Lori A. Tull, RAC

Subject: STN 125197/0 Filing Action

I have reviewed the Chemistry, Manufacturing and Controls including Facilities and Equipment section(s) of Dendreon's BLA (STN Number 125197/0) and find the application acceptable for filing.

Gang Wang, Ph.D., DMPQ