

**Date:** April 12, 2007  
**To:** CBER Complicheck  
**Subject:** Request for Compliance Check for original BLA submission

**Request Type:** Original

**Reviewer:** Keith Wonnacott, OCTGT/DCGT, HFM 715, 301-827-5151

**CSO:** Lori Tull

**Application number:** STN 125197/0

**Application Type:** BLA

**Application Due Date:** 5/15/07

**Description:** Sipuleucel-T (Provenge) for the treatment of men with asymptomatic, metastatic, androgen independent prostate cancer

**Applicant:** Dendreon Corporation

**Address:** 3005 First Avenue, Seattle, WA 98121

**Manufacturing Locations:**

**ESTABLISHMENT INFORMATION:**

**Commercial Manufacturing Facilities and Testing Labs**

**sipuleucel-T**

Dendreon Corporation  
220 East Hanover Ave.  
Morris Plains, NJ 07950  
Manufacture of sipuleucel-T  
QC Testing  
Final Product Release  
Packaging and Shipping  
Raw Materials Release

**PA2024** [REDACTED] **Component**

Dendreon Corporation  
3005 First Avenue  
Seattle, WA 98121  
FEI: 3000204836  
[REDACTED] Testing  
[REDACTED] Testing

Diosynth RTP, Inc.  
101 J. Morris Commons  
Lane  
Morrisville, NC 27560

CFN: 1063385

b(4)

b(4)

b(4)

Testing

In-Process Testing

b(4)

**PA2024** b(4) **Component**

Dendreon Corporation

3005 First Avenue

Seattle, WA 98121

FEI: 3000204836

b(4)

Testing

Release Testing

b(4)

Testing

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