

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

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Testing

Release Testing

b(4)

Testing

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