DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Office of Compliance and Biologics Quality, CBER, FDA 1401 Rockville Pike, HFM-676 Rockville, MD 20852, Phone:301-827-3031	February 12 to February 16, 2007 FEI NUMBER

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: David Urdal, Ph.D., Chief Scientific Officer

FIRM NAME	STREET ADDRESS
Dendreon Corpration	220 East Hanover Ave.
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Morris Plains, NJ 07950	Cell Therapy Manufacturing Facility

THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS, AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT, CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

This was a pre-license inspection for sipuleucel-T, STN BL 125197/0.

1. There are no data to support the concurrent manufacturing of [redacted] lots within a clean room module. Process Validation Report QVD No. 50999 includes data from only one day of concurrent manufacturing of [redacted] lots in Module [redacted] and [redacted] lots from a second day. The commercial process as described in the Biologics License Application (BLA) specifies the use of [redacted] clean room modules, total of [redacted] workstations, [redacted] per station.

2. Insufficient personnel from the New Jersey manufacturing site were available to perform Aseptic Process Validation in Module [redacted] (QVD No. 51000). A New Jersey contract employee with no previous training in aseptic operations gowned in to participate in the aseptic simulation to support this validation study.

3. The quality control laboratory did not demonstrate adequate ability to maintain the chain of identity for the autologous product.

   a. No documented system is in place to track and manage the flow of the samples. There is also an inconsistent labeling system to maintain the chain of identity of the samples.

   b. The commercial system, as described in the BLA and presented during inspection, specifies the use of a bar code to maintain identity. The QC laboratory does not have the capacity to read the barcode, nor is it connected to the [redacted] database used throughout the rest of manufacturing. In addition, information sent from the QC laboratory to the manufacturing module does not contain a bar code.

4. During Day 0 processing on Tuesday, February 13, 2007, we observed that lot number [redacted] being processed at step [redacted] in workstation [redacted] was resuspended in [redacted] before being placed in the [redacted] According to Technical Report 30366, the validated time for holding [redacted]

5. SOPs 11058, Exception Reporting, and 11059, Investigations, contain no time frame for closing out reports.

6. Regarding SOP 10839, Change Control:

   a. There is no review of the Change Control Regulatory Impact Assessment (Form 60042) by the Regulatory Affairs group.

   b. Form 60042 is used to document the Change Control Review Board (CCRB) decisions but this is not stated in the SOP.

7. Regarding SOP 10047, Supplier, Contractor, and Vendor Audits:

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	/S/	Mary P. Padgett, CSO Gang Wang, Ph.D., Biologist Keith Wonnacott, Ph.D., Chief, Cellular Therapy Branch Thomas P. Finn, Ph.D., Microbiologist Helen B. Ricalde, CSO	February 16, 2007

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DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

a. An audit team is defined as including a "qualified auditor," however, there is no stipulation as to what qualification for auditing would entail.

b. It is actual practice that the audit report would be reviewed by Quality Systems personnel but this is not stated in the SOP.

8. There is no documentation to support the formulas used in the [redacted] spreadsheets, [redacted] Results, and In Process and Final Product [redacted] Results, used to generate sample analysis results.

9. There is no documentation that Senior Manufacturing Associate [redacted] has received cGMP training.

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	/S/	Mary P. Padgett, CSO Gang Wang, Ph.D., Biologist Keith Wonnacott, Ph.D., Chief, Cellular Therapy Branch Thomas P. Finn, Ph.D., Microbiologist Helen B. Ricalde, CSO	**February 16, 2007**