DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA/CBER/OCBQ/DMPQ 1401 Rockville Pike, HFM-670 Rockville, MD 20852 Phone: 301-827-3031 Industry Information: www.fda.gov/oc/industry	January 25 - 29, 2010
	FEI NUMBER 3005890060

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: David L. Urdal, Sr. Vice President & Chief Scientific Officer

FIRM NAME	STREET ADDRESS
Dendreon Corporation	220 East Hanover Ave.
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Morris Plains, NJ 07950	Cellular Therapy Product 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 (I) (WE) OBSERVED:

1. The SOP-11020: Workstation Clearance and Change Over is deficient in that it does not require QA involvement for verifying and releasing the workstation after completion of the previous lot and prior to initiation of the next lot.

2. Environmental monitoring for (b)(4) conducted during the manufacturing processes is inadequate in that the (b)(4) inside the Class (b)(4) within the Class (b)(4) cleanroom are not monitored throughout the entire manufacturing process.

3. The current cleaning procedures used in the cleanroom have not been qualified.

EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
/S/	Gang Wang, Ph.D., Biologist (Lead) Randa Melhem, Ph.D., CSO Barbara W. Limazyk, CSO Thomas Finn, Ph.D., Microbiologist Steven Oh, Ph.D., Microbiologist	January 29, 2010

SEE REVERSE OF THIS PAGE

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or

2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."