

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
Center for Biologics Evaluation and Research

MEMORANDUM

TELECONFERENCE SUMMARY

DATE: December 14, 2006

TIME: 4:00 PM to 4:30 PM

SPONSOR: Dendreon Corporation

PRODUCT: Sipuleucel-T

TO: File STN 125197/0

FROM: Gang Wang, Ph.D., CBER/OCBQ/DMPQ/MRB II, HFM-675

PARTICIPANTS: CBER: Gang Wang, Mary Padgett, Keith Wonnacott, Thomas Finn,
Dendreon: Liz Smith, Mary Coon, Andy Scherer, Nicole Provost,
Heidi Hagen, Connie Spooner

SUBJECT: To inform Dendreon that CBER will perform pre-licensed inspection (PLI) at sponsor's New Jersey manufacturing site on February 12 to February 16, 2007.

The following items were discussed during the telecon:

- We called Dendreon to inform them that CBER will conduct a PLI at their New Jersey manufacturing site on February 12 to February 16, 2007. The inspection team will include Mary Padgett, Gang Wang, Keith Wonnacott and Thomas Finn at this time. We will also invite District Office to participate the inspection.
- Ms. Padgett requested the information on risk assessment be submitted as part of BLA for review, and Dendreon agreed to submit as an amendment.
- We asked sponsor to provide hotel information around the area.
- Dendreon asked whether CBER will inspect their contract manufacturing facilities, and we responded that we will inform other firms if we decide to conduct inspections on other firms.

- Dr. Wonnacott told the sponsor that he wanted to look at basically all manufacturing procedures from receiving apheresis to final products. He also wanted to look at their test/analytical procedures and methods for the manufacturing of the products. He also told the sponsor that the information on changeover procedures, manufacturing history, excursions, batch records should also be ready for inspection.
- Dendreon informed CBER that they have applied FEI.
- We told Dendreon that we will provide them a list of detailed information request that we wish to have ready during the inspection in the next telecon as the inspection date approaches.
- We have agreed to have another telecon at sometime in January 2007.