

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

MEMORANDUM

TELECONFERENCE SUMMARY

DATE: February 1, 2007

TIME: 2:00 PM to 2:15 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, Helen Ricalde
Dendreon: Liz Smith, Mary Coon, Andy Scherer, Nicole Provost, Heidi Hagen, Connie Spooner

SUBJECT: To provide Dendreon a list of information request for the pre-licensed inspection at their New Jersey manufacturing site to be held on February 12 to February 16, 2007.

CBER has responded to an email telecon request by Dendreon on January 24, 2007 to discuss the manufacturing schedule and the list of requested documents for review on the first day of the inspection that was previously agreed upon at the telecon held between CBER and Dendreon dated December 14, 2006. During today's telecon, CBER has provided Dendreon the following information request that we wish to be ready during the inspection.

1. A 15 minute short presentation about the facility and the product;
2. Walk through the facility and manufacturing process;
3. Hard copies of BLA submission;
4. A copy of USP as a reference;
5. Detailed organizational chart;
6. Legible facility drawings/floor plans/equipment locations;
7. Manufacturing process flow;
8. Production schedules;
9. A list of SOPs used in manufacturing of Sipuleucel-T;

10. Summary of routine environmental monitoring data for all production areas for years 2005 – 2006, including monthly, quarterly, annually reports, excursions, trending, analysis, corrective actions, etc.
11. Summary report of pressure differentials/temperature/humidity monitoring data for manufacturing areas for year 2006.
12. A list of all lots/batches that Dendreon has manufactured to date, including the current status and those that have been discarded;
13. A list of deviations/out of specifications/change controls for Sipuleucel-T manufacturing;
14. Batch records;
15. All the validation records for clarification;
16. Records for aseptic processing validation (APV);
17. Records/logbooks for equipment usages/maintenance/cleaning, and room cleaning in manufacturing area, including daily, weekly, monthly;
18. Information on risk assessment;

For item 3, Dendreon says that they will provide electronic copies of BLA in laptops;

For item 12, it is clarified that the lots/batches are referred to those manufactured in Dendreon's New Jersey site. Dendreon also clarified that they have not manufactured any commercial product for clinical use in New Jersey site yet. Only the data on normal donor lots for conformance studies will be available.

CBER has asked the information on Dendreon's retention samples and their storage location at the New Jersey site.

Dendreon has agreed to provide the requested information and will facilitate the inspection.