



MEMORANDUM

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Biologics Evaluation and

Research

To: File of STN 125197/0
Device: Laboratory Information Management System (LIMS)
Sponsor: Dendreon Corporation

From: Valerie Coleman, Software Reviewer, Devices Review Branch

Subject: BLA Software Review Memo

Through: Linda Weir, BECS Expert, Devices Review Branch
Teresita C. Mercado, Chief, Devices Review Branch

Background:

I performed the software consult review for Laboratory Information Management System (LIMS) from Dendreon Corporation. The submission consisted of a 100- page amendment from the firm labeled, 1.12, Amendment 32_LIMS Shipping Stability Shop Floor. This document was in response to issues discussed during CMC follow-up to the June 5, 2009 Type C Meeting and a document labeled Sipuleucel-T Test Sample Management Program.

Level of concern:

The software is a minor level of concern software.

Intended Use:

The LIMS system meets good manufacturing practices (GMP) requirements by providing functions such as sample tracking, user certification, full auditing, 21 CFR Part 11 compliance capabilities, reporting, sample scheduling and bar coding. Dendreon relies on the LIMS functionality to ensure that critical GMP data is audited. LIMS audit trail features use a combination of electronic records and sample tracking history. The combination of the LIMS built-in system security and the associated operating procedures ensure that only authorized users can access or modify the data.

Device Description:

Dendreon has implemented a Laboratory Information Management System (LIMS, --(b)(4)-- ----- for the management of data and test sample flow during Quality Control (QC) environmental monitoring and Sipuleucel-T release and stability testing. This system provides superior logistic tools for sample and data management, including minimizing the potential for transcription errors. The LIMS system features the following functions:

- Improved data analysis
- Data trending and reporting
- Improved ability to track and manage laboratory testing activities

- Barcode interfacing for rapid, error-free entry of chain of identity and sample identifiers, which can be used to track samples through the laboratory workflow

Items Reviewed:

- Level of concern
- Intended Use
- Summary of LIMS Validation
- Device Description
- Sipuleucel- T Test Sample Management Program
- IOQ Results for the Release and Stability Configuration Table 1