

MEMORANDUM

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

Date: February 12, 2010

To: Lori Tull, CSO, OCTGT/RMS
Thomas Finn, PhD, Chairperson, OCTGT/DCGT
Bindu George, MD, OCTGT/DCEPT

From: Catherine A. Miller, CSO
Advertising and Promotional Labeling Branch (APLB)

Through: Ele Ibarra-Pratt, RN, MPH
Branch Chief, APLB

Subject: Preliminary comments on draft container and patient-specific labels
Provenge (sipuleucel-T)
BLA STN 125197/0/34

Dendreon submitted a draft carton label on November 9, 2006, and product-specific and patient-specific container labels on October 30, 2009, to BLA STN 125197 for Provenge (sipuleucel-T). The product-specific and patient-specific labels directly adhere to the infusion bag. APLB offers the following comments on the draft labels.

Carton Label

The draft carton label is missing the following information:

- Proper name of the product
- Name, address, and license number of the manufacturer
- Lot number or other lot identification
- Expiration date
- Preservative used and its concentration or if no preservative is used and the absence of a preservative is a safety factor, the words “no preservative”
- Amount of product in the container
- Recommended storage temperature
- The words “Do not Freeze” as well as other instructions, such as “The product must remain within the insulated carton until the time of administration”, as needed
- Route of administration or reference to such directions in an enclosed circular
- Known sensitizing substances, or reference to an enclosed circular containing appropriate information, as needed
- Source of the product
- “No U.S. standard of potency”
- “Rx only”
- “FOR AUTOLOGOUS USE ONLY”
- “NOT EVALUATED FOR INFECTIOUS SUBSTANCES” unless appropriate screening and testing has been performed
- NDC barcode

Container Labels

The container labels are missing the NDC barcode and we recommend that one of the container labels include “The product must remain within the insulated carton until the time of administration.”

The above comments have been provided from a comprehension and promotion perspective. If you have any questions regarding this review please contact Catherine Miller, Consumer Safety Officer, at 301-827-3028.

Firm: Dendreon Corporation

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