DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
1401 Rockville Pike
Rockville MD 20852-1448

July 23, 1999

Frank H. Valone, M.D.
Vice President, Medical and Regulatory Affairs
Dendreon Corporation
3005 First Avenue
Seattle, WA 98102

Re:	BP 97-0003
Product:	DACS™SC
Filed:	October 14, 1997
Amended:	See appended list

Dear Dr. Valone:

The Center for Biologics Evaluation and Research (CBER) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the DACS™SC. This device is indicated for processing autologous mobilized peripheral blood progenitor cells (PBPC) collected by leukapheresis to reduce RBC, platelets and granulocytes in the final PBPC product. We are pleased to inform you that the PMA is approved subject to the conditions described below and the "Conditions of Approval" (enclosed here and previously communicated to you in a letter dated January 20, 1999). You may begin commercial distribution of the device upon receipt of this letter.

The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act. FDA has also determined that to ensure the safe and effective use of the device that the device is further restricted within the meaning of section 520(e) under the authority of section 515(d)(1)(B)(ii) insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the act.

Approval is contingent on meeting the "Conditions of Approval" (enclosed). In addition, you must perform and submit a report on the study agreed to in your letter of July 21, 1999.

In that letter you agreed to perform a post-marketing study to evaluate efficacy of the cell washing procedure using standard cell transfer bags and a "closed" centrifuge device, Dendreon's Wash Container. The objectives of this study are: 1) to determine the recovery of TNC and CD34+ cells following the cell separation and wash procedure using both commercially available transfer bags and Dendreon's Wash Container; 2) to determine the percent viability of the cells following the cell

separation and wash procedure using both cell transfer bags and Dendreon's Wash Container; 3) to evaluate the sterility of the product following the cell separation procedure using both cell transfer bags and Dendreon's Wash Container; 4) to calculate residual BDS60 present following the cell washing procedure using both cell transfer bags and Dendreon's Wash Container.

This study will be performed using apheresis products from G-CSF mobilized subjects and processed according to the procedures described in the DACS™SC package insert. Five mobilized apheresis products will be processed; additional mobilized apheresis products may be evaluated if the standard error is large. The need for additional samples and the number of additional samples will be determined following review by the FDA of the data from the first five subjects. Triplicate samples will be utilized for the CD34+ cell counts and the total nucleated cell counts.

Expiration dating for the Buoyant Density Solution (BDS60) has been established and approved at 30 months when stored at 20-25°C. The dating period for the tubing sets and Separation Container have been established and approved at 24 months when stored at ambient temperature. This is to advise you that the protocols you used to establish these expiration dating periods are considered approved protocols for the purpose of extending the expiration dating as provided by 21 CFR 814.39(a)(8).

CBER will publish a notice of its decision to approve your PMA in the FEDERAL REGISTER. The notice will state that a summary of the safety and effectiveness data upon which the approval is based is available to the public upon request. Within 30 days of publication of the notice of approval in the FEDERAL REGISTER, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the Federal Food, Drug, and Cosmetic Act (the act).

Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

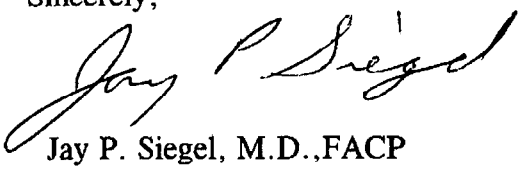
You are reminded that as soon as possible, and before commercial distribution of your device, that you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

Document Control Center (HFM-99)
Center for Biologics Evaluation and Research
Food and Drug Administration
1401 Rockville Pike
Rockville, Maryland 20852-1448

If you have any questions concerning this approval order, please contact Terrye G. Zaremba at (301) 827-5103.

Sincerely,



Jay P. Siegel, M.D.,FACP
Director
Office of Therapeutics
Research and Review
Center for Biologics
Evaluation and Research

Enclosure