DEPARTMENT OF HEALTH AND HUMAN SERVICES

DEC 06 1996

Monica Krieger, Ph.D.
CellPro, Incorporated
22215 26th Avenue SE
Bothell, Washington 98021

Re: BP-94-0001
Product: CEPRATE® SC Stem Cell Concentration System
Filed: January 3, 1994
Amended: June 6, 1994, August 2, 1995, January 15, 1996

Dear Dr. Krieger:

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 CEPRATE® SC Stem Cell Concentration System. This device is indicated for the processing of autologous bone marrow to obtain a CD34+ cell enriched population which is intended for hematopoietic support after myeloablative chemotherapy. We are pleased to inform you that the PMA is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed). 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), (1) insofar as the labeling specify the requirements that apply to the training of practitioners who may use the device as approved in this order and (2) insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the act.

The expiration dating period for the anti-human CD34 biotinylated monoclonal antibody (murine) has been established and approved at 18 months when stored at -70°C. The expiration dating period for all other components of the CEPRATE SC Disposables Kit has been established and approved at 12 months when said components are stored at the appropriate temperatures as designated below. The Avidin column, the Precolumn, and the liter of sterile, non-pyrogenic RPMI 1640 Cell Culture Medium must be stored at 2 - 8°C. The Kit also includes one Tubing Set, one 40 micron Pall® SQ40S Blood Filter, and three liters of sterile, non-pyrogenic phosphate buffered saline which are to be stored at 15 - 30°C.

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-585)
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 Keith Webber, Ph.D. at (301) 594-5660.

Sincerely yours,

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