DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Biologics Evaluation and Rese
1401 Rockville Pike
Rockville MD 20852-1448

AUG 2 0 2001

Carolyn D. Jones
AdvaMed
1200 G Street NW
Suite 400
Washington, DC 20005-3814

Docket No. 01D-0171

Dear Ms. Jones:

This letter is to provide you an update regarding your proposed guidance document "Guidance for Industry and CBER Reviewers: Guidance for the Content of Premarket Notifications for Automated Blood Cell Separators Used in the Collection of Peripheral Blood Hematopoietic Stem Cells," submitted by the Advanced Medical Technology Association's Blood Processing Working Group and filed with the Dockets Management Branch on March 29, 2001. You requested that FDA review the proposed guidance for consideration as an FDA approved guidance. Thank you for your interest in pursuing guidance in this area.

The Center for Biologics Evaluation and Research (CBER) intends to review your submission more fully. We may decide to make revisions to it and announce it in the Federal Register as a draft guidance document for public comment in the future. Until such a determination is made, we cannot establish a proposed date of issuance. If you have any questions, please contact Stephen Ripley, Regulations and Policy Staff at 301-827-6345.

Sincerely yours,

Diane Maloney

Diane Maloney
Associate Director for Policy

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