

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DMB

Application No.	4-17-00
Application Date	4-18-00
Certifier	SNK/BE

Food and Drug Administration

[Docket No. 97N-0497]

**Request for Proposed Standards for Unrelated Allogeneic Peripheral and Placental/
Umbilical Cord Blood Hematopoietic Stem/Progenitor Cell Products; Reopening of
Comment Period**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening for 90 days the comment period for the notice requesting the submission of proposed product standards for unrelated allogeneic peripheral and placental/umbilical cord blood hematopoietic stem/progenitor cells. The notice was published in the **Federal Register** of January 20, 1998 (63 FR 2985). FDA is taking this action in response to a request for an extension and to allow interested parties additional time for review and to submit comments on proposed product standards.

DATES: Submit written comments by *[insert date 90 days after date of publication in the Federal Register]*.

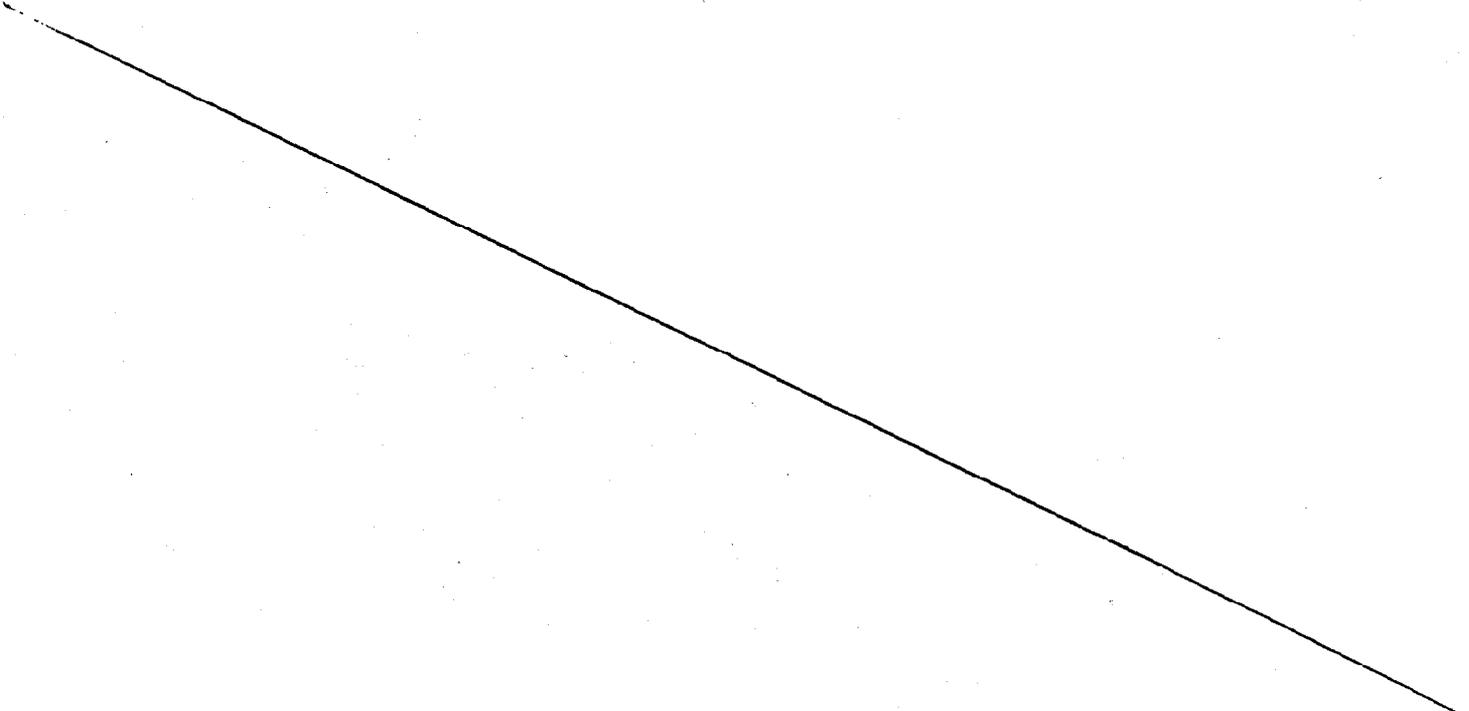
ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Valerie A. Butler, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 20, 1998 (63 FR 2985), FDA published a notice requesting proposed product standards intended to ensure the safety and effectiveness of minimally manipulated hematopoietic stem/progenitor cells derived from peripheral

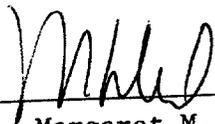
and cord blood for unrelated allogeneic use. Interested persons were given until January 20, 2000, to submit written comments. On January 18, 2000, a comment requesting that the agency extend the comment period was submitted to the docket. The comment noted that comprehensive standards that cover all aspects of cord blood banking have been drafted. However, additional editing and final review is required before submission to the docket. FDA finds it appropriate to reopen the comment period to permit interested persons additional time to submit proposed product standards intended to ensure the safety and effectiveness of minimally manipulated hematopoietic stem/progenitor cells derived from peripheral and cord blood for unrelated allogeneic use. Therefore the agency is reopening the comment period for an additional 90 days, until *[insert date 90 days after date of publication in the **Federal Register**]*, to allow the public more time to submit proposed product standards.

Interested persons may submit to the Dockets Management Branch (address above) written comments on proposing product standards intended to ensure the safety and effectiveness of minimally manipulated hematopoietic stem/progenitor cells derived from peripheral and cord blood for unrelated allogeneic use by *[insert date 90 days after date of publication in the **Federal Register**]*. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments are to be identified with the docket number found in the brackets in the heading



of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 4-10-00
April 10, 2000



Margaret M. Dotzel
Acting Associate Commissioner for Policy

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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