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of Cellular Therapy**

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April 19, 2004

Docket Management Branch (HFA-305)
Food and Drug Administration
Room 123
Rockville, MD 20857

Re: Docket No 97N-0497: Request for Proposed Standards for Unrelated
Allogeneic Peripheral and Placental Cord Blood Hematopoietic Progenitor-
Stem Cell Products Request for Comments

On July 1, 2000, the Foundation for the Accreditation of Cellular Therapy (FACT) responded to the Food and Drug Administration's request for comments on the proposed product standards published in the Federal Register on April 18, 2000.

The response included a copy of the First Edition of the FACT Standards for Hematopoietic Progenitor Cell Collection, Processing and Transplantation and the First Edition of the NETCORD-FACT International Standards for Cord Blood Collection, Processing, Testing, Banking, Selection and Release. In July 2001, the Second Edition of the NETCORD-FACT Cord Blood Standards was published. In March 2002, the Second Edition of the FACT Standards was published.

A copy of these current editions of Standards are enclosed for your review. As new editions are published, FACT will submit these documents for your consideration.

If you require any further information, please contact me at (402) 561-7557.

Sincerely,

Linda Miller, MPA
Administrative Director, FACT

97N-0497

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