



Our STN: BL 125407/124

SUPPLEMENT APPROVAL

March 19, 2026

Duke University School of Medicine
Attention: Amanda Parrish, PhD, RAC
Carolinas Cord Blood Bank
2424 Erwin Road, Box 901
Durham, NC 27705

Dear Dr. Parrish:

We have approved your request received November 17, 2025, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for HPC, Cord Blood to add the AXP II System, manufactured by Thermogenesis, for automated processing of cord blood units (CBUs) at the Carolinas Cord Blood Bank.

We will include information contained in the above-referenced supplement in your BLA file.

Sincerely,

Melanie Eacho, PhD
Director
Division of Cell Therapy 1
Office of Cellular Therapy and Human Tissue
Office of Therapeutic Products
Center for Biologics Evaluation and Research