Our STN: BL 125407/124

SUPPLEMENT APPROVAL
August 14, 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:

Please refer to your supplement to your Biologics License Application (BLA) received November 17, 2025, submitted under section 351(a) of the Public Health Service Act (PHS Act) for HPC-Cord Blood.

We also refer to our supplement approval letter dated March 19, 2026, which contained the following error:

> The absence of labeling information to be submitted after approval.

This replacement approval letter incorporates the correction of the error. The effective approval date will remain March 19, 2026, the date of the original supplement approval letter.

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.

LABELING

We hereby approve the draft content of labeling Package Insert submitted under amendment 124, November 17, 2025.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the final content of labeling (21 CFR 601.14) in Structured Product Labeling (SPL) format via the FDA automated drug registration and listing system, (eLIST) as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the Package Insert submitted on

November 17, 2025. Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As* at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

ADVERTISING AND PROMOTIONAL LABELING

You may submit two draft copies of the proposed introductory advertising and promotional labeling with Form FDA 2253 to the Advertising and Promotional Labeling Branch at the following address:

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Ave.
WO71–G112
Silver Spring, MD 20993-0002

You must submit copies of your final advertising and promotional labeling at the time of initial dissemination or publication, accompanied by Form FDA 2253 (21 CFR 601.12(f)(4)).

All promotional claims must be consistent with and not contrary to approved labeling. You should not make a comparative promotional claim or claim of superiority over other products unless you have substantial evidence or substantial clinical experience to support such claims (21 CFR 202.1(e)(6)).

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