



Our STN: BL 125594/0

PROPRIETARY NAME ACCEPTANCE

Cleveland Cord Blood Center
Attention: Wouter Van't Hof, PhD
25001 Emery Road
Suite 150
Warrensville Heights, OH 44128

Dear Dr. Van't Hof:

We have reviewed your submission dated February 25, 2016 to your biologics license application (BLA) for HPC-Cord Blood requesting a proprietary name review.

In consultation with CBER's Advertising and Promotional Labeling Branch (APLB) we conclude that under the Federal Food, Drug, and Cosmetic Act and applicable regulations, your proposed proprietary name, CLEVECORD, is acceptable at this time.

If you have any questions, please contact the Regulatory Project Manager, Lori Tull, at (240) 402-8361.

Sincerely yours,

Raj K. Puri, MD, PhD
Director
Division of Cellular and Gene Therapies
Center for Biologics Evaluation and Research