

Our STN: BL 125644/0

PROPRIETARY NAME ACCEPTABLE

Bio Products Laboratory
Attention: Dr. MaryAnn Lamb
Bio Products Laboratory USA, Inc.
302 East Pettigrew Street Suite C-190
Durham, NC 27701

Dear Dr Lamb:

We have reviewed your April 13, 2017, submission to your Biologics License Application (BLA) for Human Albumin Solution (HAS) 5% and 25%, requesting a proprietary name review for ALBUMINEX.

In consultation with Center for Biologics Evaluation and Research's Advertising and Promotional Labeling Branch (CBER/APLB), we conclude that, under the Federal Food, Drug, and Cosmetic Act and applicable regulations, ALBUMINEX is Acceptable.

If you have any questions, please contact the Regulatory Project Manager, Lorraine Wood at (240) 402-8439 or lorraine.wood@fda.hhs.gov.

Sincerely yours,

Orieji C. Illoh, MD
Director
Division of Blood Components and Devices
Office of Blood Research and Review
Center for Biologics Evaluation and Research