



Our STN: BL 125644/0/30

RESUBMISSION ACKNOWLEDGEMENT

January 3, 2018

Bio Products Laboratory Limited
Attention: Mary Ann Lamb, PhD.
Bio Products Laboratory USA Inc.
302 East Pettigrew Street
Suite C – 190
Durham, NC 27701

Dear Dr. Lamb:

We have received your December 15, 2017, resubmission to your Biologics License Application (BLA) for Human Albumin Solution (HAS) 5% and 25% on December 18, 2017.

The resubmission contains CMC and facility information that you submitted in response to our August 25, 2017, complete response letter.

We consider this a complete, class 2 response to our action letter. Therefore, the action due date is June 19, 2018.

If you have any questions, please contact the Regulatory Project Manager, Kelly Abraham, at (301) 796-0765.

Sincerely,

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