

Application Type	Original Application
STN	125644/0
Applicant	Bio Products Laboratory
Established Name	Human Albumin Solution (HAS) 5% and 25%
Proposed Indication(s)	Hypovolemia, Ascites, Burns, Nephrotic Syndrome, Acute Respiratory Distress Syndrome, Cardiopulmonary Bypass
CBER Received Date	December 9, 2016 (original submission) December 15, 2017 (resubmission)
PDUFA Goal Date	June 19, 2018
Product Office	OBRR/DBCD
Priority Review	No
Reviewer's Office	OBE/DB/TEB
Reviewer Name(s)	Linye Song, Ph.D., Staff Fellow
Supervisory Concurrence	Chunrong Cheng, Ph.D., Mathematical Statistician
	Boguang Zhen, Ph.D., Branch Chief
	John Scott, Ph.D., Acting Division Director
Committee Chair	Wayne Hicks, Ph.D.
Clinical Reviewer(s)	Charles M. Maplethorpe M.D., Ph.D.
Project Manager	Lorraine D. Wood

Conclusions and Recommendations

Bio Products Laboratory (BPL) originally submitted a Biologics License Application (BLA) on December 9, 2016 for their Albumin (Human) product, Albuminex®, prepared in 5% and 25% solutions. FDA issued a Complete Response (CR) letter on August 25, 2017, mainly due to Chemistry, Manufacturing, and Controls (CMC) issues. The applicant's response and resubmission were received on December 15, 2017.

In a pre-BLA meeting (CRMTS #9311) held in 2014, it was decided that licensure could be based on literature review only. Since no clinical studies have been conducted in this submission, I performed a statistical review of the studies from the literature submitted by the applicant and found no statistical issues with this application. I agree with Dr. Maplethorpe's assessments documented in the Clinical Review memo.