

## Mid-Cycle Meeting Summary

**Application type and number:**      **BLA 125644/0**

**Product name:**            **Human Albumin Solution (HAS) 5% and 25%**

**Proposed Indication:** **For the treatment of hypovolemia, burns, adult respiratory distress syndrome, cardiopulmonary bypass, liver cirrhosis and its complications; nephrotic syndrome, and ascites.**

**Applicant:** **Bio Products Laboratory Inc.**

**Meeting date & time:** **May 24, 2017 2:00 to 3:00 pm EDT**

**Committee Chair:** **Wayne Hicks, PhD**

**RPM:** **Lorraine Wood, MS, MLS(ASCP)<sup>CM</sup>**

**Attendees:**

<b>Discipline</b>	<b>Name [with credentials (not title)]</b>	<b>Attended meeting?</b>
Regulatory Project Manager (RPM)	Lorraine Wood, MS, MLS (ASCP) <sup>CM</sup>	Y
Chair	Wayne Hicks, PhD	Y
Clinical Reviewer	Charles Maplethorpe, MD	Y
CMC Reviewer	Wayne Hicks, PhD Michael (Brad) Strader, PhD Tigist Kassa, PhD	Y
Toxicology Reviewer	Jin Hyen Baek, PhD	Y
OCBQ/DMPQ RPM	Amanda Trayer	Y
OCBQ/DMPQ Reviewer	Priscilla Pastrana, PhD	Y
OCBQ/DMPQ/PRB Reviewer	Cheryl Hulme	Y
Statistical Reviewer of clinical data	LinYE Song, PhD	Y
Postmarketing Safety Epidemiological Reviewer	Shaokui Wei	
OCBQ/APLB Reviewer	Alpita Popat, PharmD, MBA	Y
OCBQ/DBSQC or OVRRLIB Reviewer	Hyesuk Kong Noel Baichoo Varsha Garnepudi Karen Smith Sean Younker	Y
Other Attendee(s)	Nicole Verdun, MD Orieji Illoh, MD Wendy Paul, MD Sonday Kelly, MS RAC, PMP Iliana Valencia, MS, MCPM	Y

Discipline	Name [with credentials (not title)]	Attended meeting?
	Laurie Norwood Jay Eltermann	

## Discussion Summary:

### Report and Discuss:

1. Reviewer Reports.  
*CMC*  
*Facilities*  
*DBSQC*  
*Pharm-Tox*  
*Clinical*  
*Biostatistics*
2. For PDUFA V Program submissions, indicate whether discipline review letters will be issued. There will not be any discipline review letters issues.
3. If the application will be discussed at an Advisory Committee (AC), review potential issues for presentation. *This application will not be discussed at an Advisory Committee*
4. Determine whether Postmarketing Requirements (PMRs), Postmarketing Commitments (PMCs), or a Risk Evaluation Mitigation Strategy (REMS) are needed. Not ready to be discussed at this time.
5. National Drug Code (NDC) assignments to product/packaging (excludes devices).  
*Currently in progress*
6. Proper naming convention. *Currently in progress*
7. Status of inspections (GMP, BiMo, GLP) including issues identified that could prevent approval and the establishment inspection report (EIR). *BiMO inspections cannot be conducted due to the submission being based on literature reviews.*

### Review

8. Major target and milestone dates from RMS/BLA. Discuss pending dates of targets and milestones (e.g. Late-Cycle meeting, Advisory Committee, labeling discussion).  
  
*Mid-Cycle Communication- June 7, 2017 (Tentative)*  
*Proprietary Name Review- July 12, 2017*  
*Late Cycle Meeting- August 24, 2017 (Tentative)*  
*Labeling Target- November 9, 2017*  
*PMC Study Target- November 9, 2017*
9. Establish a labeling review plan and agree on future labeling meeting activities. *Labeling review has will begin in July 2017.*

### Confirm, as applicable

10. Components Information Table was obtained and notification was sent to the Data Abstraction Team (DAT) if discrepancies were found per *SOPP 8401.5: Processing Animal, Biological, Chemical Component Information Submitted in Marketing Applications and Supplements*. If not complete, indicate date it will be completed. *N/A*
11. New facility information is included in the application, requiring implementation of regulatory job aid *JA 910.01: Facility Data Entry*. If not complete, indicate date it will be completed. *N/A*
12. Status of decisions regarding lot release requirements, such as submitting samples and test protocols and the lot release testing plan. *The Lot Release Protocol template was received on May 15, 2017 and is being circulated for review. There is no in support testing for this submission. The testing plan is currently being drafted.*
13. Unique ingredient identifier (UNII) code process has been initiated. See regulatory job aid *JA 900.01: Unique Ingredient Identifier (UNII) Code* for additional information. *Unique ingredient identifier will be requested.*
14. PeRC presentation date is set, and the clinical reviewer has addressed waiver/deferral/assessment of the PREA decision. *The meeting with PeRC is scheduled for Wednesday May 31, 2017. The required pediatric documents were completed and submitted to PeRC on May 17, 2017.*