

T910.15: First Committee Meeting Agenda/Summary

Application 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

Meeting date & time: January 5, 2017, 11:00 am until 12:00 pm

Committee Chair: Wayne Hicks, PhD

Meeting Recorder: Lorraine Wood, MS, MLS (ASCP)

Attendees:

Discipline	Name [with credentials (not title)]	Attended meeting?
Regulatory Project Manager (RPM)	Lorraine Wood, MS, MLS	Y
Chair	Wayne Hicks, PhD	Y
Clinical Reviewer	Charles Maplethorpe, MD	Y
CMC Reviewer	Wayne Hicks, PhD	Y
	Michael (Brad) Strader, PhD	Y
	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
	Chunrong Cheng, PhD	Y
Postmarketing Safety Epidemiological Reviewer	Shaokui Wei	Y
OCBQ/APLB Reviewer	Alpita Papat	Y
OCBQ/BIMO Reviewer	Christine Drabick	Y
OCBQ/DBSQC or OVRP/LIB Reviewer	Hyesuk Kong	Y
	Noel Baichoo	Y
	Varsha Garnepudi	Y
	Karen Smith	Y

Discipline	Name [with credentials (not title)]	Attended meeting?
	Sean Younker	
Other Attendee(s)	Iliana Valencia, MS Sondag Kelly, MS Salim Haddad, MD Abdu Alayash, PhD Anthony Lorenzo Orijei Illoh, MD CBER eMRP Support Staff	Y Y Y Y Y Y Y

Discussion Summary:

1. *Ensure that all Review Committee Members are appropriately assigned (including whether any consult reviewers are needed), they have received the appropriate documents or electronic links, and they have a clear understanding of their review responsibilities.
All review committee members are appropriately assigned.*
2. *Review and confirm the review schedule, including the review clock, i.e., standard or priority review. Attach review schedule to meeting summary, include monthly meetings if appropriate.
Review schedule confirmed. This application will be reviewed on the standard 12 month review schedule.*
3. *Confirm that the application is compliant with 21 CFR 601.2 for BLAs and 21 CFR 314.101 for NDAs
This application is compliant with 21 CFR 601.2 for Biologic License Applications (BLAs)*
4. *Confirm whether the product falls within the PDUFA Program, if a PDUFA product.
This product falls within the PDUFA Program.*
5. *Review all future meeting dates, e.g., Mid-Cycle, Late-Cycle.
Tentative Meeting dates were sent to the review committee and are populated in eMRP.*
6. *Review/confirm if Orphan Drug designation was granted.
Orphan Drug designation was not granted for this application.*
7. *Review/confirm if PREA is triggered and discuss the timeframe for scheduling a PeRC meeting. For Supplements, determine if the Supplement triggers PREA or if it is in response to an outstanding PREA PMR, and, if so, discuss the timeframe for scheduling a PeRC meeting.*

This application was granted a waiver according to the Agreed iPSP submitted with the application. PeRC meeting will be scheduled after mid cycle

8. *Document if an Advisory Committee Meeting is likely and review the appropriate Advisory Committee Meeting schedule for a potential date. If an Advisory Committee Meeting will likely not be needed, include the rationale/reasons in the meeting summary.
This application will not need to be reviewed by an Advisory Committee.*
9. *Document any potential issues found in the early review, categorized by discipline, including identification of data sets submitted incorrectly, use of data standards, problems encountered opening data tables or absent data sets, etc. If not completed during the meeting, document that "Any potential issues should be identified by Day 45 of the review."
No potential review issues identified at this time.*
10. *Document whether pre-license or pre-approval inspections are necessary. If not completed during the meeting, document that "the need for pre-license or pre-approval inspections will be determined by day 45 of the review."
The need for pre-approval inspection will be determined by day 45 of review.*
11. *Discuss whether BIMO inspection(s) will be required. If not completed during the meeting, document that "need for BIMO inspection(s) will be determined by Day 45 of the review."
There will be no BIMO inspections for this BLA since the submission is based on a literature search and review.*
12. *Identify activities to be completed before the Filing Meeting.
Each reviewer is expected to complete a draft version of the filing checklist prior to the filing meeting*
13. *Confirm meeting date for Filing Meeting and discuss expectations for the Filing Meeting. The filing meeting is currently scheduled for January 25, 2017. Each reviewer is expected to complete a draft version of the filing checklist prior to the meeting.*