

T 910.16: FILING 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 25, 2017, 1:00 pm until 2:00 pm

Committee Chair: Wayne Hicks, PhD

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

Background:

Table 1: Review Committee and Discipline Filing Decision Summary

Discipline/Organization	Name [with credentials (not title)]	Attended meeting	Fileable	RTF	Deficiencies Identified
Regulatory Project Manager (RPM)	Lorraine Wood, MS, MLS	Y	Y		X
Chair	Wayne Hicks, PhD	Y	Y		
Division Director/Deputy	Orieji Illoh, MD		Y		
Office Director/Deputy	Jay Epstein, MD	N	N / A		
Clinical Reviewer	Charles Maplethorpe, MD	Y	Y		
Toxicology Reviewer	Jin Hyen Baek, PhD	Y	Y		
CMC Reviewer	Wayne Hicks, PhD Michael (Brad) Strader, PhD Tigist Kassa, PhD	Y Y	Y Y		
OCBQ/DMPQ RPM	Amanda Trayer	Y	Y		
OCBQ/DMPQ Reviewer	Priscilla Pastrana, PhD	Y	Y		X

Discipline/Organization	Name [with credentials (not title)]	Attended meeting	Fileable	RTF	Deficiencies Identified
OCBQ/DMPQ/PRB Reviewer	Cheryl Hulme	Y	Y		
OCBQ/APLB Reviewer	Alpita Popat PharmD, MBA	Y	Y		
OCBQ/BIMO Reviewer	Christine Drabick	Y	Y		
OCBQ/DBSQC or OVRR/LIB Reviewer	Hyesuk Kong	Y	Y		
	Noel Baichoo	Y	Y		
	Varsha Garnepudi	Y	Y		
	Karen Smith	Y	Y		
	Sean Younker	Y	Y		
Statistical Reviewer of clinical data	LinYE Song, PhD Chunrong Cheng, PhD	Y	Y Y		
Postmarketing Safety Epidemiological/Pharmacology vigilance Reviewer	Shaokui wei	Y			
Other Attendee(s)	Wendy Paul, md John Eltermann William McCormick Lisa Stockbridge				

REGULATORY CONCLUSIONS / DEFICIENCIES

1. Does the application, on its face, appear to be suitable for filing or is the application unsuitable for filing and will require a RTF letter? *This application is suitable for filing. The application is fileable.*
2. If fileable, list any substantive deficiencies or issues that have significant impact on the ability to complete the review or approve the application:
 1. *The application lacks organizational elements. For example:*
 - a. *There is no Table of Contents that outlines the sections of your submission.*
 - b. *There is no Introduction Section that outlines the facility, manufacturing steps and equipment that are used for the manufacture of other US license products; in addition, to those manufacturing steps and equipment that are new and applicable to the manufacture of Human Albumin Solution 5% and 25% for Infusion.*

- c. FDA forms 3674, 3454, and Debarment certification were not included.*
- 2. The application appears to contain contradictory and incomplete information. For example:*
 - a. There are no facility diagrams that illustrate the area classification and differential pressure of the rooms used for the manufacture of Human Albumin Solution 5% and 25% for Infusion.*
 - b. There is no narrative of the controls to prevent contamination, cross-contamination and mix-ups. For example:*
 - i. There is no narrative of the containment, segregation, change-over and line clearance controls; as well, in-process controls implemented in your facility for the manufacture of plasma derived products;*
 - ii. There is no narrative of the controls implemented for the manufacture of products using non-US plasma in shared areas and equipment approved for the manufacture of US licensed products;*
 - iii. There is no description of the general equipment design used for the manufacture of plasma derived products;*
 - iv. There is no narrative of the cleaning and disinfection processes of the areas and equipment used for the manufacture of plasma derived products.*
 - c. The application does not contain a description of other products manufactured. For example:*
 - i. There is no list of dedicated, share and disposable (single-use) equipment used for the manufacture and packaging of US licensed products and for other markets;*
 - ii. There is no list of equipment that use automated systems;*
 - iii. There is no list of rooms used for the manufacture and packaging of US licensed products and other markets.*
 - iv. There is no list of existing and new equipment used for the manufacture and packaging of Human Albumin Solution 5% and 25% for Infusion.*

- d. *The application does not contain a narrative of the incoming procedure for the plasma and materials used for the manufacture of Human Albumin Solution 5% and 25% for Infusion.*
- e. *The application does not contain a manufacturing and packaging flow chart that illustrates each manufacturing and packaging step.*
- f. *The application does not contain a list and copies of the procedures used for the manufacture and packaging of Human Albumin Solution 5% and 25% for Infusion lot.*
- g. *The application does not contain copies from the batch records of Human Albumin Solution 5% and 25% for Infusion lots manufactured.*
- h. *The application does not contain a narrative of the shipping process from the plasma collection sites to the manufacturing facility.*
- i. *The application does not contain a narrative of the equipment used for the manufacture and packaging processes for Human Albumin Solution 5% and 25% for Infusion.*
- j. *The application does not contain a narrative of the vial inspection, labeling and packaging processes for Human Albumin Solution 5% and 25% for Infusion.*
- k. *The application does not contain a narrative of the aseptic filling simulation program in their facility for the manufacture of plasma derived products.*
- l. *The application does not contain summary reports of the aseptic filling simulation studies in support for the filling of Human Albumin Solution 5% and 25% for Infusion.*
- m. *The application does not contain summary reports of the Performance Qualification studies for the equipment used for washing, sterilization and depyrogenation of components in support for the manufacture of Human Albumin Solution 5% and 25% for Infusion.*
- n. *The application does not contain summary reports of the Performance Qualification studies for the process equipment used for the manufacture and packaging of Human Albumin Solution 5% and 25% for Infusion.*
- o. *The application does not contain summary reports of the Process Validation and Cleaning Validation studies in support for Human Albumin Solution 5% and 25% for Infusion.*

- p. The application does not contain summary report of the Container Closure Integrity Test (CCIT) in support for Human Albumin Solution 5% and 25% for Infusion.*
- q. The application does not contain a narrative of water and Heating, Ventilating, Air Conditioning (HVAC) systems. For example:*
 - i. There is no narrative of these systems;*
 - ii. There is no narrative of changes done in these systems in support for the manufacture of Human Albumin Solution 5% and 25% for Infusion;*
 - iii. There is no narrative that describe the Environmental and Water Monitoring Programs with their acceptance criteria;*
 - iv. There are no Environmental and Water Monitoring Results in support for the manufacture of Human Albumin Solution 5% and 25% for Infusion;*
 - v. There are summary reports of the Qualification studies done in these systems in support for the manufacture of Human Albumin Solution 5% and 25% for Infusion.*
- r. The application does not contain a narrative of facility systems (for example, facility/alarm monitoring system). For example:*
 - i. There is no narrative of changes done in these systems in support for the manufacture of Human Albumin Solution 5% and 25% for Infusion;*
 - ii. There are summary reports of the Qualification studies done in these systems in support for the manufacture of Human Albumin Solution 5% and 25% for Infusion.*

3. If RTF, list any substantive deficiencies or issues that would make this application unsuitable for filing:

N/A

FILING MEETING DISCUSSION, IF FILED:

4. Indicate any comments on the status of the proprietary name review (PNR).

The Property Name Review Request was not submitted with the application. Bio Products Laboratories will send an Information Request to submit the PNR request as an amendment to the application.

5. Indicate whether the product sh/would be subject to lot release, surveillance, or exempt from lot release. Verify sample availability.

This product will be subject to surveillance.

6. Confirm review schedule of this application.

This application will be reviewed on the standard 12 month review schedule.

7. Indicate the decision regarding the need for an Advisory Committee

This application doesn't need to be reviewed by an Advisory Committee

8. Indicate whether the submission triggers PREA; if yes, a PeRC meeting is needed. *This submission triggers PREA. An Agreed iPSP with a request for a waiver is included in the application. This application will be scheduled for PeRC review after mid-cycle.*

9. Is a comprehensive and readily located list of all clinical sites included or referenced in the application? *There are no clinical studies associated with this application. Only literature was provided for clinical.*

10. Is a comprehensive and readily located list of all manufacturing facilities included or referenced in the application? *Yes manufacturing facilities are listed in the application.*

11. Indicate any updates since the First Committee Meeting on pre-license inspection, pre-approval inspection, or BIMO sites requiring inspections (Is the establishment(s) ready for inspection?)

There will be no BIMO inspections for this BLA since the submission is based on a literature search and review.

12. If the application is affected by the Application Integrity Policy (AIP), has the division made a recommendation regarding whether or not an exception to the AIP should be granted to permit review based on medical necessity or public health significance? *This application is not affected by the Application Integrity Policy (AIP).*

13. Is the product an Original Biological Product or a New Molecular Entity (NME) for an NDA? *No*

FOR APPLICATIONS IN THE PDUFA PROGRAM (NME NDAs/Original BLAs), IF FILED

14. Confirm that any late submission components were submitted within 30 days. List any late submission components that arrived after 30 days. *No late submission components were submitted to the application.*

15. Was the application otherwise complete upon submission, including those applications where there were no agreements regarding late submission components? The application was missing several FDA forms:

A. FDA Form 3674 with authorized signature

B. Financial disclosure forms FDA 3454 and or 3455 included with authorized signature per 21 CFR 54.4(a)(1) and (3)

C. Debarment Certification form.

ADMINISTRATIVE DETAILS, IF FILED:

16. Review the Milestone Schedule and indicate if there are any issues with the schedule. Note: This is a confirmation to capture any changes made since the First Committee Meeting. There are no issues with the milestone schedule. *The internal mid cycle meeting is scheduled for May 24, 2017.*