

**From:** Wood, Lorraine  
**Sent:** Wednesday, April 26, 2017 12:32 PM  
**To:** MaryAnn Lamb <MaryAnn.Lamb@bpl-us.com>  
**Subject:** Information Request for BLA 125644: Response Requested by Monday May 1, 2017  
**Importance:** High

Dear Dr. Lamb,

We are reviewing your submission for BLA 125644 Human Albumin Solution (HAS) 5% and 25% and we request the following information to continue our review:

1. You stated in this BLA that Steps (b) (4) in support for the manufacture of the Drug Substance for HAS 5% and 25% are conducted using the same equipment and processing rooms as used for the manufacture of Gammaplex, which is a US licensed product (BL125329). Also, you indicated that filling equipment used for the filling of Gammaplex, will be used for the filling of Drug Product for HAS 5% and 25%. However, you did not specify in this application if floor diagrams; personnel, material, equipment and waste flow pattern diagrams; facilities, utilities (HVAC and Water Systems), Environmental Monitoring (EM) and water monitoring programs, equipment used for cleaning, sterilization and depyrogenation of components; computer systems; in addition, to manufacturing and control processes; in-process, cleaning, contamination, cross-contamination, containment and segregation controls; raw materials, filters and components in support for the manufacture of HAS 5% and 25% Drug Substance and Drug Product; as well, the container/closure system for the Drug Product are the same as currently used for other US licensed products. Please corroborate if the mentioned items are the same as currently used for other US licensed products. Please clarify if there is any change in any of the mentioned in support for the manufacture of the Drug Substance and Drug Product for HAS 5% and 25%.

Please respond to this request by Monday May 1, 2017.

Thank you  
Lorraine

**Lorraine D. Wood, MS, MLS(ASCP)<sup>CM</sup>**  
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