

From: Abraham, Kelly
Sent: Tuesday, January 09, 2018 12:43 PM
To: 'MaryAnn Lamb' <MaryAnn.Lamb@bplgroup.com>
Cc: Valencia, Iliana <Iliana.Valencia@fda.hhs.gov>
Subject: Information Request for BL125644/0 - Please respond by February 2, 2018
Importance: High

Our Reference: BL 125644/0

Bio Products Laboratory
Attention: Mary Ann Lamb, PhD
January 9, 2018
Sent by email

Dear Dr. Lamb:

We are reviewing your December 18, 2017, Class 2 resubmission to BL125644/0 for Human Albumin Solution (HAS) 5% and 25%. We determined that the following information is necessary to continue our review:

1. Please provide a PVP (Pharmacovigilance Plan) for completeness of the submission.

The review of this submission is on-going and issues may be added, expanded upon, or modified as we continue to review this submission.

Please submit your response to this information request as an amendment to this file by February 2, 2018, referencing the date of this request. If you anticipate you will not be able to respond by this date, please contact me immediately so a new response date can be identified.

The action due date for this file is June 19, 2018.

If you have any questions, please contact me.

Sincerely,

Kelly Abraham, MPH, CPH
Lieutenant Commander, U.S. Public Health Service
Regulatory Project Manager
Center for Biologics Evaluation and Research
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