

From: Wood, Lorraine
Sent: Monday, April 09, 2018 2:13 PM
To: 'MaryAnn Lamb' <MaryAnn.Lamb@bpl-us.com>
Subject: Incorrect Proprietary Name on Carton Labels for BLA 125644: Response Requested by 4/16/18
Importance: High

Dear Dr. Lamb,

The carton and container labels submitted to this BLA on 12/7/16 has the incorrect proprietary name on it. The cartons says “(b) (4)” but the proprietary name approved for this product is “**ALBUMINEX**”.

Please submit the carton and container labels with the proprietary name “ALBUMINEX” by Monday **April 16, 2018** so the review of the labeling can be completed on time.

Thanks
Lorraine

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