

From: Wood, Lorraine

Sent: Friday, May 04, 2018 2:04 PM

To: MaryAnn Lamb <MaryAnn.Lamb@bpl-us.com>

Subject: BLA 125644 Package Insert Labeling Edits: Response Requested by 5/8/18

Importance: High

Dear Mary Ann,

Attached is the WORD version of the changes suggested by the review committee for BLA 125644. The attached label is for the Albuminex 25% but should be applied to Albuminex 5% as well. If these changes are acceptable, please re-submit this updated package insert to STN 125644 after BPL have reviewed it and have taken responsibility for the following:

1. Correcting any spelling, grammar, usage, or formatting errors.
2. Correcting content, if there is a reason for making a change, in which case the reason should be stated.
3. Updating the Table of Contents
4. Updating (adding, deleting) the references in the reference section.
5. Make corresponding changes in the Albuminex 5% label, where appropriate.

Please submit the updated labels for Albuminex 5% and Albuminex 25% by COB Tuesday May 8, 2018.

Thank you
Lorraine

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