

From: Wood, Lorraine
Sent: Tuesday, April 17, 2018 1:51 PM
To: 'MaryAnn Lamb' <MaryAnn.Lamb@bpl-us.com>
Subject: Name Suffix Request for BLA 125644: Response Requested by May 1 2018
Importance: High

Dear Dr. Lamb,

According to the attached FDA Guidance Document ***Nonproprietary Naming of Biological Products***, applicants for products submitted for a Biologics License Application (BLA) should propose a suffix to their biological product proper name composed of four lowercase letters, for use as the distinguishing identifier included in the proper name designated by the FDA at the time of licensure. Applicants should submit up to 10 proposed suffixes as described in section VI of the Guidance document.

Please submit the proposed suffixes for Human Albumin Solution (HAS) 5% and 25% as an amendment to BLA 125644 by May 1, 2018. Please review the attach guidance document for more information and contact me if you have any questions.

Thank you
Lorraine

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