

From: Wood, Lorraine
Sent: Wednesday, June 06, 2018 10:06 AM
To: 'MaryAnn Lamb' <maryann.lamb@bplgroup.com>
Subject: BLA 125644 Suffix Selection and Format
Importance: High

Dear Mary Ann,

Please see the comments below regarding the suffix for the proper name for BLA 125644

We find the proper name, human albumin solution-kjda, conditionally acceptable for your proposed product. Should your 351(a) BLA be approved during this review cycle, human albumin solution-kjda, will be the proper name designated in the license, and you should revise your proposed labels and labeling accordingly. However, please be advised that if your application receives a completer response, the acceptability of your proposed suffix will be re-evaluated when you respond to the deficiencies. If we find your proposed proper name unacceptable upon our re-evaluation at that time, we will inform you of our finding.

The correct format for the proper name is “human albumin solution-kjda.” The strength should be written after the proper name. For example:

ALBUMINEX (human albumin solution-kjda) 5%
ALBUMINEX (human albumin solution-kjda) 25%

Please update the package insert and all labeling to reflect the suffix written in proper format. Please submit the labeling and package insert by COB Friday June 8, 2018.

Thank you
Lorraine

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