

**From:** Wood, Lorraine  
**Sent:** Monday, June 04, 2018 1:09 PM  
**To:** 'MaryAnn Lamb' <MaryAnn.Lamb@bpl-us.com>  
**Subject:** BLA 125644 Container Labeling Changes  
**Importance:** High

Dear MaryAnn,

Please see message below regarding the container labels and make the recommended changes and submit to the file as soon as possible as the action due date for this file is June 19, 2018.

We reviewed the container label that was included in the most recent submission (125644/0.40). Per 21 CFR 610.62, the proper name of the product on the package label shall be placed above any trademark or trade name identifying the product and symmetrically arranged with respect to other printing on the label. We would recommend moving the trade name to be below the proper name on the container label similar to the package labeling.

Please let me know if you have any questions.

Thank you  
Lorraine

**Lorraine D. Wood, MS, MLS(ASCP)<sup>CM</sup>**  
*Regulatory Project Manager*

Center for Biologics Evaluation and Research  
Office of Blood Research and Review  
U.S. Food and Drug Administration  
Tel: 240-402-8439  
[lorraine.wood@fda.hhs.gov](mailto:lorraine.wood@fda.hhs.gov)



THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please notify the sender immediately by e-mail or phone.