

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)^{CM}
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



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