

From: Sweeney, Colleen
Sent: Wednesday, January 18, 2017 11:55 AM
To: Margaretten, Nadine (nadine_margaretten@merck.com)
Cc: Steele, Matthew; Khurana, Taruna
Subject: RE: carton and container labels
Importance: High

Dear Dr. Margaretten:

Please revise the carton and container labels to include the following:

1. As per [21 CFR 610.62 (b)] the point size for the proper name on the carton labels should be at least as prominent as the trade name.
2. The lateral barcodes are missing from the carton labels. Please revise to conform with [21 CFR 610.67].
3. Please ensure that all detachable labels have only the following information: NDC, Proprietary Name, Lot and Expiry date.
4. Please confirm whether you intend to print the lot and expiry dates onto the labels as indicated.

Please send these revisions as an amendment to your BLA.

Thank you.

Please submit this Final Study Report as an amendment to STN 125592/0.

Thank you.

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