

From: Khurana, Taruna
Sent: Monday, June 20, 2016 8:37 AM
To: 'Margaretten, Nadine'
Cc: Sweeney, Colleen; Steele, Matthew
Subject: RE: Status, HDM BLA 125592: revised mockup for blister for CBER review

Thank you Nadine,

Please provide revised mock up for carton label for review.

Taruna

Taruna Khurana, Ph.D.
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From: Margaretten, Nadine [mailto:nadine_margaretten@merck.com]
Sent: Friday, June 17, 2016 11:13 AM
To: Khurana, Taruna
Cc: Sweeney, Colleen; Steele, Matthew
Subject: RE: Status, HDM BLA 125592: revised mockup for blister for CBER review

Dear Taruna, thank you very much for the feedback on the blister! I will inform the team to expect comments on the carton. The team has an updated mockup on the carton which we can provide as it might be helpful to you.

Best regards, Nadine

From: Khurana, Taruna [<mailto:Taruna.Khurana@fda.hhs.gov>]
Sent: Friday, June 17, 2016 10:27 AM
To: Margaretten, Nadine
Cc: Sweeney, Colleen; Steele, Matthew
Subject: RE: Status, HDM BLA 125592: revised mockup for blister for CBER review

Hello Nadine,

The revised mockup blister label reflecting all the changes as suggested by the Agency is acceptable.

Your carton label query is under discussion and any comments and issues will be communicated.

Thank you
Taruna

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