

(System Info - 232486 VALENTI ELIZABETH 04/05/2013 10:05:26 VALENTI)

From: Valenti, Elizabeth

Sent: Friday, April 05, 2013 9:46 AM

To: 'Greenfeder, Scott'

Cc: Rivers, Katie; Sweeney, Colleen; Valenti, Elizabeth

Subject: RE: Printing of the Proprietary Name on the Blister Packs for Launch Lots

Dear Scott,

Your proposal to print the blister packs, leaving a black space for the proprietary name, and then applying a sticker with the proprietary name appears acceptable for your launch lots. In your amendment, please address the sticker application procedures, the proper position and placement and how this will be ensured on each blister pack, adequate adhesion of the sticker, how the sticker will affect the tablets when applied to the blister pack and when the tablets are removed from the blister pack, etc.

However, as with all labeling, this is subject to review and not approved until the BLA is approved. The electronic markups will be reviewed during labeling negotiations and the actual product will be reviewed when it is submitted for lot release.

Betsy

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From: Greenfeder, Scott [<mailto:scott.greenfeder@merck.com>]

Sent: Wednesday, March 27, 2013 1:37 PM

To: Valenti, Elizabeth

Subject: RE: BLA 125,478 for MK-3641

Betsy,

Thanks again for helping to clarify the issue. I'm thinking a bit more about our potential mitigation of the issue and just wanted to pick your brain a little.

If we were to print the blister foils now with a blank space for the Trade Name and then apply a sticker to the blisters with the approved proprietary name prior to distribution would that be something viewed as acceptable?

Regards,
Scott

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