

**(System Info - 232483 VALENTI ELIZABETH 04/05/2013 09:59:16 VALENTI)**

**From:** Valenti, Elizabeth

**Sent:** Wednesday, April 03, 2013 4:36 PM

**To:** 'Greenfeder, Scott'

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

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

Dear Scott,

Please see the Guidance for Industry: Contents of a Complete Submission for the Evaluation of Proprietary Names

(<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm075068.pdf>).

A second PNR would not begin for an alternate name until the review of the first proprietary name is complete, if that first name is found unacceptable.

Regards,  
Betsy

*Elizabeth J. Valenti, MPH, RAC (U.S.), REHS/RS*

LCDR, USPHS

FDA/CBER/OVRR/DVRPA

1401 Rockville Pike

Mailstop HFM-481

Rockville, MD 20852

(301) 796-2640

[elizabeth.valenti@fda.hhs.gov](mailto:elizabeth.valenti@fda.hhs.gov)

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

**Sent:** Wednesday, April 03, 2013 10:04 AM

**To:** Valenti, Elizabeth

**Cc:** Rivers, Katie

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

Betsy, Katie,

We have been discussing additional ways to mitigate the blister issues with regard to the trade name. The PNR that we submitted contains only our 1<sup>st</sup> preferred name RAGWITEK. I am wondering if it is possible for use to also now submit one or two additional back up names for review. If this is a potential path forward can you please comment on how that may affect the current PNR review timeline.

Thanks for your help on this.

Regards,  
Scott

**Scott Greenfeder, Ph.D.**

Associate Director and Liaison  
Global Regulatory Affairs  
T: +1 732-594-1021  
Fax: +1 732-594-1030  
[scott.greenfeder@merck.com](mailto:scott.greenfeder@merck.com)

Merck Research Labs  
126 East Lincoln Ave.  
MS RY33-204  
Rahway, NJ 07065  
[www.merck.com](http://www.merck.com)