

"Grewal, Renmeet" <Renmeet.Grewal@fda.hhs.gov>

22-Jun-2007 11:56

To barbara.e.aming@gsk.com

cc "Bender, William" <William.Bender2@fda.hhs.gov>, "Saini, Sonny"  
<sonny.saini@fda.hhs.gov>

Subject Adult suicidality email

Hi Barbara,  
I received your voicemail as well as email earlier this morning.

As for your first question, the Agency has reviewed your proposed changes, and we do not believe that your product specific analysis should be included in the class labeling revisions since the labeling is targeted at the class of drugs. If you would like to discuss this matter further, please submit a formal meeting request.

As for your second question, please respond by email that you accept the changes and also send in a word version of the labeling via email. We will then send an approval letter since you have accepted the changes.

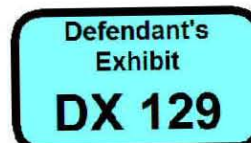
Thanks  
Rimmy

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