

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

To barbara.e.arning@gsk.com

15-May-2007 15:14

cc

Subject RE: Adult suicidality letter, submission for Paxil NDA 20-03/S-053, Paxil CR NDA 20-936/S0-29 and Paxil Oral Suspension NDA 20-710/S-017

Hi Barbara,

Please submit your CBE application with your requests. We will be discussing all the sponsor's proposals during the last week of May. After we discuss everyone's proposal I will have a response to your questions.

Best Regards,
Rimmy

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From: barbara.e.arning@gsk.com [mailto:barbara.e.arning@gsk.com]

Sent: Friday, May 11, 2007 4:23 PM

To: Grewal, Renmeet

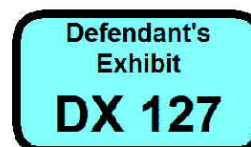
Subject: Adult suicidality letter, submission for Paxil NDA 20-03/S-053, Paxil CR NDA 20-936/S0-29 and Paxil Oral Suspension NDA 20-710/S-017

Dear Rimmy,

we are officially submitting the attached letter today via the electronic pathway:

- proposing to maintain the Paxil specific language within the new class labeling (changes are highlighted in color and strike through),
- asking for your rationale of your preference to rely on website and press release to inform the medical community about the recent changes,
- and asking for permission to post the link to your website on our product website and on gsk.com.

This email serves as an advanced notification for you.



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DX 127

As we are intending to make the requested label change within 30 days from date of your letter, could you please respond soon? I will touch base with you early next week. Thanks a lot and kind regards.

Barbara E. Arning M.D., RAC
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