



To: Wayne Geller/HQ/Astra Merck  
cc: /G=Gerald/I=GL/S=Limp/OU=PHWILM/P=ZENECA/A=TMAILUK/C=GB  
From: Vikram Dev @ X400  
Date: 05/11/2000 09:51 AM  
Subject: FW: Response to FDA Seroquel letter

This message contains 1 attachment(s).

Message

Wayne  
FYI

Gerald

Please add Wayne Geller to this list. He will be taking over Seroquel from me in the near future.

Vikram

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From: Limp Gerald GL  
Sent: Thursday, May 11, 2000 9:13 AM  
To: Bache Ricky RA; Jones Martin AM - PHMS; Duffy Paul PA; Dev Vikram VJ; Mullen Jamie JA; Brecher Martin M; Rak Ihor IW; DeFeo Pat PA; Reece Stots SB  
Cc: Beamish Don DG; De Vriese Geert; McKenna Kevin K; Evans Yolanda YR  
Subject: Response to FDA Seroquel letter

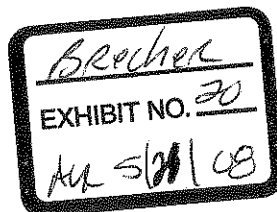
At yesterday's US Product Team meeting, I was actioned to pull together the responsible parties to address the FDA's inquiry regarding hyperglycemia and other related issues from the Seroquel experience (FDA letter attached).

Please note that this inquiry includes preclinical and clinical trial experience (NDA reports), postmarketing reports, and any exchange of correspondence with other regulatory authorities. They also suggest that we consider collaborating with organizations having large pools of treated patients (HMOs or VA databases).

FDA is seeking a complete and timely response within 3 months.

Please begin to develop a plan to address this inquiry from your area of responsibility. My AA Yolonda Evans will be seeking a time when we can discuss our plan of attack, perhaps via a teleconference or video. Perhaps we can touch on this topic at the joint global/US product team meeting next week at APA/Chicago; I think we still need to meet separately to agree on a plan and timeline, and assure we have adequate resources.

If you believe that additional staff should be pulled into this exercise, please feel free to share this note, and inform me of their participation.



AZSER07410458


If you wish any clarification from the FDA on the issues that they have raised, please let me know, and I can set up that interaction.

Thanks in advance for your assistance,

gerald

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From: Williamson Brian BK  
Sent: Tuesday, May 09, 2000 3:27 PM  
To: Rogers Anthony AF; Mullen Jamie JA; Rak Ihor IW; Reele Stots SB; Yeung Paul PP; Tugend Georgia GL; Cummins David DP; Orzolek Robert RJ; Rowell Sherry SL; Ulatowski Terrance TG; Baker Kendra; Brecher Martin M; Salazar-Grueso Edgar;  
McKenna Kevin K; Bache Ricky RA; Limp Gerald GL  
Subject: O:\pdfs to send\seroquel20 638 5 9 00.pdf

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 - seroquel.pdf

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