

**From:** Dev, Vikram J  
**Sent:** Wednesday, June 26, 2002 2:26 PM  
**To:** Geller, Wayne  
**Cc:** Brecher, Martin; Oldham, Alex; Melville, Margaret G; Bassin, Lawrence G; Wayne, Chace  
**Subject:** FW: Proposed revision of decision on Wt Gain CDS wording

Wayne  
All systems go! Please amend the JD and send it along to GPI through the normal channels to amend the weight gain information in the Seroquel CDS.  
Thanks  
Vikram

-----Original Message-----

**From:** Brecher, Martin  
**Sent:** Wednesday, June 26, 2002 2:00 PM  
**To:** Dev, Vikram J  
**Subject:** RE: Proposed revision of decision on Wt Gain CDS wording

Vikram,  
I delayed responding in order to make sure the wording is OK with the UK. I heard today that the wording is fine. Lets get on with it.  
Thanks for your help.  
Martin

-----Original Message-----

**From:** Dev, Vikram J  
**Sent:** Friday, June 21, 2002 3:39 PM  
**To:** Melville, Margaret G; Brecher, Martin  
**Cc:** Oldham, Alex; Bassin, Lawrence G; Geller, Wayne  
**Subject:** RE: Proposed revision of decision on Wt Gain CDS wording

Meg  
Thank you for your kind words. It was a joint effort with Wayne. Wayne will amend the JD, however, we have still to get an OK from Martin.  
Have a great weekend.  
Vikram

-----Original Message-----

**From:** Melville, Margaret G  
**Sent:** Friday, June 21, 2002 3:36 PM  
**To:** Dev, Vikram J; Brecher, Martin  
**Cc:** Oldham, Alex; Bassin, Lawrence G; Geller, Wayne  
**Subject:** RE: Proposed revision of decision on Wt Gain CDS wording

Vikram,

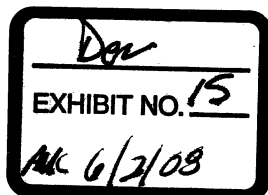
The wording is perfect. Thank you so much for resolving this issue. There are many on the team who will thank you.

I assume the JD will be amended and then we in Regulatory can take it forward to a CDS/Labeling change?

Best Regards,

Margaret (Meg) Melville  
Seroquel Global Regulatory Affairs Director  
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REDACTED



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-----Original Message-----

**From:** Dev, Vikram J  
**Sent:** Friday, June 21, 2002 2:59 PM  
**To:** Melville, Margaret G; Brecher, Martin  
**Cc:** Oldham, Alex; Bassin, Lawrence G; Geller, Wayne  
**Subject:** Proposed revision of decision on Wt Gain CDS wording

Meg and Martin

Following your telephone message to Larry and myself, I have proposed the following wording for addressing the weight gain amendment in the Seroquel CDS. This proposal has been accepted by Larry and Wayne and I read it out to Alex who phoned me this morning (after UK and USA lost the soccer!!). If acceptable to you both, this will only mean a minor tweak in the Justification document and this issue will not need to come back to SERM for the zillionth time.

I look forward to hearing from you both. I have tried my best to accommodate the truth, data and keep marketing happy.

Best wishes

Vikram

### **1.1 Possible adverse reactions**

Treatment with SEROQUEL may be associated with mild asthenia, dry mouth, rhinitis, dyspepsia or constipation. Somnolence may occur, usually during the first two weeks of treatment, which generally resolves with the continued administration of SEROQUEL.

#### **Very rarely hypersensitivity including angioedema has been reported.**

As with other antipsychotics, SEROQUEL may also be associated with limited-weight gain. This occurs predominantly during the early weeks of treatment.