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

07-May-2007 15:20

To barbara.e.arning@gsk.com
cc "Bender, William" <William.Bender2@fda.hhs.gov>
Subject RE: FW: Adult suicidality letter

Hi Barbara,
Please replace the previous warning section with the new language we provided to in the Class labeling letter signed on may 9, 2007.

Best Regards,
Rimmy

Renmeet Grewal, Pharm.D., LCDR USPHS
Regulatory Project Manager
Division of Psychiatry Products
Center For Drug Evaluation and Research, FDA
Office of Drug Evaluation I
Ph: (301) 796-1080
Email: renmeet.grewal@fda.hhs.gov
Fax: (301) 796-9838

From: barbara.e.arning@gsk.com [mailto:barbara.e.arning@gsk.com]
Sent: Monday, May 07, 2007 2:33 PM
To: Grewal, Renmeet
Subject: Re: FW: Adult suicidality letter

Hi Rimmy,
can I please ask for one clarification?
Does FDA intend for Paxil and Paxil CR to keep the Paxil specific paragraph on young adults that we added in April 2006 in the label in addition to the class labeling provided below or do you ask us to replace the complete warning section on this topic by the new class labeling?

This is the section I am referring to:
Young adults, especially those with MDD, may be at increased risk for suicidal behavior during treatment with paroxetine. An analysis of placebo-controlled trials of adults with psychiatric disorders showed a higher frequency of suicidal behavior in young adults (prospectively defined as aged 18-24 years) treated with paroxetine compared with placebo (17/776 [2.19%] versus 5/542 [0.92%]), although this difference was not statistically significant. In the older age groups (aged 25-64 years and ≥65 years), no such increase was observed. In adults with MDD (all ages), there was a statistically significant increase in the frequency of suicidal behavior in patients treated with paroxetine compared with placebo (11/3,455 [0.32%] versus 1/1,978 [0.05%]); all of the events were suicide attempts. However, the majority of these attempts for

paroxetine (8 of 11) were in younger adults aged 18-30 years. These MDD data suggest that the higher frequency observed in the younger adult population across psychiatric disorders may extend beyond the age of 24.

Looking forward to hear from you and thanks a lot.

Barbara E. Arning M.D., RAC
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Cancer Immunotherapeutics
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Mail code: RN0210

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

02-May-2007 10:42

To barbara.e.arning@gsk.com
cc
Subject FW: Adult suicidality letter

Hi Barbara,
I just wanted to make sure you received a copy of this.

-Rimmy

Renmeet Grewal, Pharm.D., LCDR USPHS
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From: Grewal, Renmeet
Sent: Wednesday, May 02, 2007 9:40 AM
To: 'mary.e.martinson@gsk.com'
Subject: Adult suicidality letter

Dear Mary,
Please refer to the Advisory Committee meeting held on December 13, 2006 regarding adult suicidality data in antidepressants drugs. The Agency has come to a decision with final language for the prescriber labeling and Medication Guide (MG). Attached is a supplement request letter with the new language. We are requesting that sponsors submit revised prescriber labeling and MG, verbatim, as outlined in the attached letter within 30 days from today.

As for the Paxil letter, the Agency issued an approvable letter responding to your CBE letters.

Additionally, the Agency will be announcing these changes in the form of a Press Release later on today.

If you have any questions, please feel free to contact me.

Sincerely,
Rimmy

<<wellbutrin asl.pdf>> <<parnate asl.pdf>> <<paxil ae letter.pdf>>

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