Barbara E Arning/PharmRD

05-Apr-2006 17:20

To gujralr@cder.fda.gov, Renmeet.Gujral@fda.hhs.gov

cc david@cder.fda.gov, paul.david@fda.hhs.gov, thomas.laughren@fda.hhs.gov, James E Murray/PharmRD/GSK@GSK

Subject GSK Paroxetine Adult Suicidality Analysis (MDD and non-MDD) -FDA Submission of April 5, 2006

Dear Rimmy,
This e-mail is intended to alert you of an official electronic submission, submitted today, containing results of a GSK-conducted analysis of suicidality from paroxetine clinical studies in adults which we believe justifies a labeling revision and a Dear Healthcare Provider letter which we wish to discuss with you via teleconference in advance of a Changes Being Effected labeling supplement.

Referring to our submission from March 8, 2006 which provided results of the adult MDD paroxetine analysis, we have now updated these results with the results from the non-MDD suicidality analysis of adult paroxetine studies. We are providing a cover letter, an updated briefing document containing MDD and non-MDD data, draft revision highlighted proposed package insert and a draft Dear Healthcare Professional letter. As you can see in the cover letter, we are asking for a teleconference to discuss the proposed label change with the Division in advance of a CBE labeling supplement as well as Agency agreement with the content of a Dear Healthcare Provider letter.
I will be in contact with you to determine if the Agency can accommodate our request for teleconference.
For convenience I am attaching the documents that are part of the separate electronic submission.
Kind regards.

Cover letter

Briefing Document

Appendices

Draft US Package Insert proposed changes highlighted

Draft Dear Healthcare Professional Letter

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EXHIBIT
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Plaintiff Exhibit
PX-008