

To: CN=Patrizia Cavazzoni/OU=AM/O=LLY@Lilly; CN=Gregory A Kust/OU=AM/O=LLY@Lilly
CC: CN=Melanie A Bruno/OU=AM/O=LLY@Lilly; CN=Christopher Carlson/OU=AM/O=LLY@Lilly;
CN=Jared G Kerr/OU=AM/O=LLY@Lilly; CN=H John Roth/OU=AM/O=LLY@Lilly
Date: 02/24/2003 02:30:22 PM
From: CN=Jared G Kerr/OU=AM/O=LLY
Subject: Re: FDA request for info re: TED data - URGENT

Greg:

Please review and provide Nitai with necessary information as suggested by Patrizia.

Thanks.

Sincerely,

Jared Kerr
Critical Issues-Customer Response Team
Zyprexa Product Team

O: (317)-433-7216
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jkerr@lilly.com

Patrizia Cavazzoni

02/24/2003 01:46 PM

To: H John Roth/AM/LLY@Lilly
cc: Melanie A Bruno/AM/LLY@Lilly, Christopher Carlson/AM/LLY@Lilly, Jared G Kerr/AM/LLY@Lilly
Subject: Re: FDA request for info re: TED data - URGENT

I am forwarding this to Nitai. See my comments IN RED

Jared

Nitai needs 1) copy of BD as originally submitted to FDA 2) most recent copy of manuscript (pls liaise with Chris)

Page: 1 of 4

Nitai

I have answered question 1), **pls let me know if this is not correct.**

We need you for Question 2)

This is HIGH PRIORITY

Thank you

Patrizia

H John Roth

02/24/2003 10:13 AM To: Melanie A Bruno/AM/LLY@Lilly, Jared G Kerr/AM/LLY@Lilly
cc: Patrizia Cavazzoni/AM/LLY@Lilly
Subject: FDA request for info re: TED data

Melanie, Jared:

As per my voice mail to Melanie and my discussion with Jared, here's the e-mail request from Steve Hardeman.

Melanie:

I'll get back back to Steve to tell him you're the appropriate contact person on this...

John

----- Forwarded by H John Roth/AM/LLY on 02/24/2003 10:07 AM -----

**"Hardeman, Steven
D"**

<HARDEMANS@cder
.fda.gov> To: "John H. Roth Ph. D. (E-mail)" <roth_h_john@lilly.com>
cc:
Subject: Request for info
02/24/2003 09:58 AM

Page: 2 of 4

John,

Dr. Boehm has the following requests for information (if you aren't working on this, let me know):

The division has been reviewing the analysis of treatment emergent diabetes (TED) with olanzapine (submitted 10/2/02) and we have the following questions/requests:

1. Your proportional hazards analysis relied on comparison of risk with olanzapine to the pooled risk with other antipsychotics. Table 3.5 (p.31) suggests that clozapine may be different, that is, it appears to have a higher risk for glucose elevations, when compared to the rest of the non-olanzapine antipsychotics. We are interested in viewing the results of an analysis that compares olanzapine to non-olanzapine antipsychotics excluding the clozapine data.

This is the same question Russel Katz asked during our tc in October, and I had clarified it for him verbally. To my understanding, the HR of olz vs other antipsychotics EXCLUDED clozapine from the " non-olanzapine antipsychotics"

Nitai, am I correct?

2. You provided the hazard ratio and p value for the unadjusted model, but when you provided the results for the final model, you provided only the p value. Please provide the HR for the final model.

Nitai, could you pls take a look at Briefing Document and provide the required information? It may be contained in the manuscript.

Thanks,
Steve

CAPT Steven D. Hardeman, R.Ph.
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Page: 4 of 4