

NOTE TO FILE

Confidential - Communication with FDA

Product NDA 28705, Zyprexa (olanzapine)
Identifiers
NDA 28,705
Zyprexa
Subject of Communication October 17, 2002 FDA meeting and Briefing Document

Author Name: Melanie A. Bruno Title: USRA
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Participants

Name	Title, including Functional Area	Affiliation (e.g. FDA including div.)
Alan Breier	Vice President, Zyprexa Team Leader	Lilly
Gregory Brophy	Director, US Regulatory Affairs	Lilly
Melanie Bruno	Senior Regulatory Research Scientist	Lilly
Patrizia Cavazzoni	Medical Director, Safety Subteam	Lilly
Russell Katz	Director, Neuropharm Division	FDA
Steve Hardeman	Project Manager	FDA

Location	Date: October 15, 2002	Time: 11:00
	Place: Brougher Building	
Type of Communication	<input checked="" type="checkbox"/> Completed Telephone Call	<input type="checkbox"/> Video-conference Call
	<input type="checkbox"/> Message Left on Lilly Voice Mail	<input checked="" type="checkbox"/> Meeting Minutes
	<input type="checkbox"/> Message Left on Regulator's Voice Mail	<input type="checkbox"/> Other

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Discussion Details

This phone call was based on a request from Dr. Katz to speak to us after the Division held their premeeting in preparation for the October 17, 2002 FDA meeting to discuss glucose dysregulation.

Dr. Katz began the meeting by noting that the Division was not at a point in their work to be able to provide Lilly with complete answers to our questions in the October 17, 2002 Briefing Document. When asked whether they agreed generally with the conclusions in the Briefing Document, Dr. Katz responded that they didn't necessarily agree with all the conclusions. In terms of the TED data, Dr. Katz stated that they had a concern regarding the methodology of including the clozapine information, as they believe that clozapine is an "outlier." Dr. Cavazzoni was able to provide clarification that the clozapine data were not used in the calculation of the hazard ratios, thereby alleviating the concern of bias in the data results. Dr. Katz acknowledged that there are some intrinsic methodological problems with some of the studies (such as cohort). In addition, Dr. Katz noted that the mechanistic clamp studies (HGIM and SO13) would need to be consulted out to the Endocrine Division at FDA, as this would be Endocrine's area of expertise. The Division's first evaluation of the clamp studies included potential criticisms such as the short-term nature of the trial, the lack of a positive control and the generalizability of the healthy study population data to the psychiatric patient population.

Dr. Katz noted that the Division was not in a position at this time to draw conclusions regarding glucose dysregulation. He stated that they expected to have results from the "VA" study "fairly soon" (they have a query into the VA about timing) and that they had actually expected the results in the summer. Dr. Katz told us that Dr. Judy Racoosin was leading this effort and the Division could get back to us on the methodology of the VA study and the expected timing of the data being sent to the Division from the VA.

Dr. Katz told us that the Division would not be asking Lilly to perform any additional studies. In addition, Dr. Katz stated that the Division was "not planning on doing anything precipitous" and was "not going to take any action" immediately because they "don't have all the data they need yet." He further stated that the Division feels that the VA information will go a long way in addressing potential metabolic issues.

It was pointed out to Dr. Katz that many of the people in the VA study might have been exposed to Agent Orange. While Dr. Katz said he could not comment on the relevance of Agent Orange, they are aware that the VA database may not be a true reflection of the population at large.

When asked if Lilly could obtain the VA dataset, Dr. Katz responded that this would be unlikely. However, he stated that the Division would "make all the relevant Sponsors" aware of the data. In addition, Dr. Katz stated that the Division was "not going to make a decision until all relevant Sponsors weighed in" on the VA data.

When asked if the Division would share the VA data at a group meeting with Sponsors, Dr. Katz noted that would be unlikely and that rather Sponsors would be addressed individually.