

**NOTE TO FILE**

**Confidential - Communication with FDA**

**Product** Olanzapine (Zyprexa)  
**Identifiers**  
 (IND 28,705)  
**Subject of Communication** Communication regarding labeling change in Japan

**Author** Name: Michele Sharp Title: USRA  
 Issued: April 19, 2002 Dept: MC675  
 Archive File Date:

**Participants**

Name	Title, including Functional Area	Affiliation
Greg Brophy	Director, US Regulatory Affairs	Lilly
Alan Breier	Product Team Leader, Zyprexa Product Team	Lilly
Charles Beasley	Medical Advisor	Lilly
Jim Kotsanos	Director, Pharmacovigilance	Lilly
Michele Sharp	Regulatory Scientist, US Regulatory Affairs	Lilly
Tom Laughren	Psychiatric Team Leader, Division of Neuropharmacological Products	FDA
Paul Seligman	Office of Drug Safety	FDA
Steve Hardeman	Project Manager, Division of Neuropharmacological Products	FDA

<b>Location</b>	Date: April 12, 2002 – April 16, 2002	Time:
	Place:	
<b>Type of Communication</b>	<input checked="" type="checkbox"/> Completed Telephone Call <input type="checkbox"/> Message Left on Lilly Voice Mail <input checked="" type="checkbox"/> Message Left on Regulator's Voice Mail	<input type="checkbox"/> Video-conference Call <input type="checkbox"/> Meeting Minutes <input checked="" type="checkbox"/> Other—e-mail communication
<b>Discussion Details</b>	<p>On Friday, April 12, 2002, Drs. Breier and Brophy contacted Dr. Laughren to inform the Division of Neuropharmacological Drug Products that the olanzapine label in Japan was being revised to include information regarding hyperglycemia and diabetes in the Warnings and Contraindications sections. It was agreed that a data package would be sent to Dr. Laughren before the end of the working day on Friday, April 12. On Friday afternoon, a follow-up call was made by Drs. Beasley and Brophy to Dr. Laughren indicating that the data package was not ready but would be sent to him by e-mail before the end of the day on Friday (see attached e-mail message). On Friday afternoon, Drs. Beasley and Kotsanos contacted Dr. Seligman to inform the Office of Drug Safety of this labeling change and to provide the same data package that was sent to the Division of Neuropharm (see attached e-mail message). On Monday, April 15, 2002, Dr. Kotsanos followed-up with Dr. Seligman who stated that he received the materials and that no additional action was required. Dr. Sharp left Steve Hardeman a voice mail on April 15, 2002 in follow-up to the materials sent on Friday. As no response was received, Dr. Sharp contacted Steve Hardeman on Tuesday, April 16, 2002. Mr. Hardeman indicated that he had not received any follow-up questions from Dr. Laughren. Mr. Hardeman indicated that if Dr. Laughren would need additional information Mr. Hardeman would contact Dr. Sharp promptly.</p>	

ZY 3043 2362

**NOTE TO FILE**

**Action Items**

<b>Action</b>	<b>Responsible Person</b>	<b>Deadlines</b>
Data package to Division of Neuropharm and Office of Drug Safety	Michele Sharp and Jim Kotsanos	Friday, April 12

ZY 3043 2363

Please return to Michele Sharp



**James G Kotsanos**  
04/13/2002 10:09 AM

To: seligmanp@cder.fda.gov  
cc: Charles M Beasley Jr/AM/LLY@Lilly, Gregory T Brophy/AM/LLY@Lilly,  
Patrizia Cavazzoni/AM/LLY@Lilly, James G Kotsanos/AM/LLY@Lilly,  
Michele Sharp/AM/LLY@Lilly  
Subject: follow-up to Friday's phone message

Dr. Paul Seligman  
Director, Office of Pharmacoepidemiology and Statistical Sciences  
CDER, FDA

Dear Paul,

Per the voice mail message that Charles Beasley and I left for you yesterday afternoon, we are sending the documents describing the Zyprexa labeling change in Japan with copies of the MedWatch reports that were the basis of the labeling change. These materials were also sent in a separate e-mail note to Dr. Tom Laughren in the reviewing division.



FINAL Report to FDA-Japan Cases 12 April 2002 Appendix A- Medwatch Reports.z

Following your review of these materials, we would be happy to discuss this information in more detail with you on Monday.

Jim

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James G. Kotsanos, M.D., M.S.  
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Global Regulatory Affairs  
Lilly Corporate Center  
Indianapolis, IN 46285  
317-276-1087 (phone)  
317-276-6445 (fax)

ZY 3043 2364

Please return to Michele Sharp



**Michele Sharp**

04/12/2002 09:15 PM

To: Laughren@cder.fda.gov

cc: Charles M Beasley Jr/AM/LLY@Lilly, Alan Breier/AM/LLY@Lilly,  
Gregory T Brophy/AM/LLY@Lilly, hardemans@cder.fda.gov, Michele  
Sharp/AM/LLY@Lilly

Subject: Olanzapine Labeling Change in Japan

Dr. Laughren,

Thank you for your attention today regarding the olanzapine labeling change in Japan. As you discussed with Drs. Brophy, Breier and Beasley, attached is the document describing this labeling change with copies of the MedWatch reports that were the basis of the labeling change.



FINAL Report to FDA-Japan Cases 12 April 2002 Appendix A- Medwatch Reports.z

Following your review of these materials, we would be happy to discuss this information in more detail with you on Monday.

Michele Sharp  
Regulatory Affairs  
Eli Lilly and Company

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