

EXHIBIT 3

Law, Heather

From: McKenna, Kevin
Sent: Tuesday, October 28, 2003 4:46 PM
To: Abbott, Brian M; Law, Heather; Minnick, Jim G; Doran, Nigel M; Lloyd (Washington), Lisa M; Duff, David J; Campbell, Denise; Mullen, Jamie A; Brecher, Martin; Leong, Ronald; Manning, Julia W; Beamish, Don G; Schwartz, Jack A; DeFeo, Pat A; Limp, Gerald L; Davies, Laura J
Subject: Privileged and Confidential - Attorney/Client Communication - FDA Contact with Steve Hardeman
Importance: High

All,

Late this morning, Mr. Steve Hardeman, Senior Regulatory Project Manager, Division of Neuropharmacological Drug Products, returned my phone call of last evening. The subject of our conversation was the FDA September 11, 2003 correspondence requesting labeling changes in the Warning Section of the SEROQUEL label relating to diabetes and hyperglycemia.

When asked, Mr. Hardeman stated that all manufacturers of atypicals will incorporate the changes in their respective labels. In fact, he stated that notice of the second manufacturer incorporating the language should appear in the public domain tomorrow (October 29, 2003). Mr. Hardeman alluded to the second manufacturer being Janssen and the product being the intramuscular formulation of risperidone. We discussed the statements that Pfizer has been making in the public press relating to their belief that the class language is not relevant to ziprasidone with the most recent statement being in the October 27, 2003 Pink Sheet. Mr. Hardeman indicated that he was aware of the article, but stated that Pfizer will be changing their label.

I asked if the label language was opened to discussion. Mr. Hardeman stated that major changes would not be entertained because Lilly had accepted the FDA language verbatim. He said that Lilly essentially "hijacked" the situation by accepting the language and "has irritated" the other manufacturers by doing so coupled with their activities in the public arena. However, he did say that the Division agreed to changes with Janssen and they would be reflected in their label. When asked, Mr. Hardeman said that there were 3-4 word changes and that the last sentence of the 1st paragraph was deleted. He did say that it would be acceptable for AstraZeneca to suggest further revisions, but recommended that we review the Janssen label before submitting our proposal.

I asked Mr. Hardeman if the Division has had any discussions on what data would be required to avoid or remove the labeling language. He responded that no manufacturer currently has data that will allow them to justify not incorporating the proposed language. Mr. Hardeman said that Dr. Racoosin, Drug Safety Physician, from the Office of Drug Safety has looked at all the available data on the atypicals. Her findings conclude that no atypical has the data to establish a link to diabetes and hyperglycemia. Her report will not be made public because of proprietary information. With respect to the scope of the data package that would allow the removal of the language, Mr. Hardeman stated that he did not believe the Division had given it much thought. The directive for the label change was driven from Dr. Robert Temple, Director, Office of Drug Evaluation I. He said that Dr. Temple has wanted the label change for years. Mr. Hardeman stated that the timing of the agency's request with respect to the number of manufacturer of atypicals with pending application was not coincidental. He stated that approvals would be contingent upon acceptance of the warning language.

Mr. Hardeman referenced the AstraZeneca correspondence of October 15, 2003 requesting a meeting to discuss the label language. He said that December 5, 2003 at 11:00 am is available. Mr. Hardeman said that other manufacturers have had meetings scheduled but they have been canceled. I asked Mr. Hardeman to keep the meeting as scheduled in the event the team had topics that required further clarification for example what data would be necessary to remove the language. I told Mr. Hardeman that I would try to get back to him before the week is out.

He thanked Mr. Hardeman for his time and attention to this matter. The conversation ended amicably.