

**Michele Sharp**  
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To: Robert W Baker/AM/LLY@Lilly, Charles M Beasley Jr/AM/LLY@Lilly,  
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cc: H John Roth/AM/LLY@Lilly, Michele Sharp/AM/LLY@Lilly  
Subject: Proposed Zyprexa USPI revision---hyperglycemia

Following a meeting on Friday, March 24 with Charles, Barry, Bruce and Paula, a new proposal for the Zyprexa USPI change with regards to hyperglycemia was developed. These words are in alignment with the Core Data Sheet wording.

Attached is the Adverse Reactions section of the label with the new words in large font (under the Laboratory Changes subsection). Please review the words that I crafted based on the conversation from Friday and send me any suggestions for improvement **by Thursday, March 30**. Also note that I included "diabetic coma" under the Post-Introduction Reports subsection. We had previously proposed the inclusion of this COSTART term based on spontaneous reports, but we did NOT discuss this on Friday. *I am assuming that we will be including this term in the label.*



4.0 PV3331 Adv Reactions hyperglycemia

Following your review, I am planning to send the proposed text to our marketing colleagues in preparation for next Tuesday's (April 4) meeting (Weight Gain and Hyperglycemia--Advisory Group). Please let me know if you will NOT be attending the April 4th meeting.

Thanks,  
Michele  
7-8382

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