

Alan Breier  
02/24/2000 09:51 AM

To: \_ZYPREXA  
cc: Alan Breier/AM/LLY@Lilly  
Subject: Overview of Bipolar Labeling Meeting

I am very pleased to inform you that we have successfully completed our negotiations with the FDA for our bipolar mania label. We anticipate final signoff of the label within one week. We have achieved a very strong label. We were successful in obtaining essentially all we asked for regarding safety in demented patients. There are no new safety issues related to dementia in the Warnings section of the label. In addition, we were successful in retaining our initial broad claim for psychosis, as opposed to the narrower claim of schizophrenia. The agency has accepted our proposal to deal with this as a class-labeling issue and will be sending a class labeling-letter to all relevant sponsors including Eli Lilly. Thus, conformity to this issue will occur over some time and not put us at a competitive disadvantage. In addition, we were successful in favorably modifying the wording of one negative trial in the label.

I want to commend the efforts of the entire Zyprexa Product Team, particularly members of the bipolar subteam and key individuals in the U.S. Affiliate, Regulatory Sciences, and other affiliate/functional areas who labored long and hard to make the Zyprexa bipolar mania indication a reality. We look forward to partnering with our sales and marketing colleagues to fully maximize the success of commercialization of Zyprexa in bipolar illness. This is a historic moment in the field. As you know this will be the first drug of this class approved for bipolar illness, and therefore allows patients with this devastating disorder to have a novel, state-of-the-art and first class treatment. Thank you very much!

Alan

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