

**U.S. Sales Organization Backgrounder and Verbatim**  
**FDA Notification of Class Labeling for Atypical Antipsychotics**  
**Regarding Hyperglycemia and Diabetes**

**Introduction:**

What an exciting time to be selling Zyprexa at Eli Lilly and Company! As we are all too aware, over the past couple of years the competition has really hammered Zyprexa on the issue of diabetes. After having reviewed diabetes data from all of the manufacturers, as well as the recent Cunningham VA data, the U.S. FDA has weighed in on this subject. The FDA has provided detail that we believe will truly help physicians and patients understand this issue better and get on with the business of choosing medication based on the individual needs of the patient. Read on for the details!

**Background:**

Eli Lilly and Company has been notified by the U.S. Food and Drug Administration (FDA) that the agency has asked for updated product labeling for all atypical antipsychotics to include a warning about additional information on hyperglycemia and diabetes. This applies to Geodon® (ziprasidone), Abilify® (aripiprazole), Seroquel® (quetiapine), Risperdal® (risperidone), and Clozaril® (clozapine).

The requested labeling echoes what Lilly has said for several years: that there is an increased risk of diabetes mellitus in patients with schizophrenia, along with an ever-increasing incidence of diabetes in the general population.

The requested class label states that patients with diabetes who begin taking **atypical antipsychotics (not just Zyprexa)** should be monitored for a worsening of glucose control, and those with risk factors for diabetes (e.g., obesity, family history of diabetes) should undergo fasting glucose testing at baseline, and periodically throughout treatment. In addition to Zyprexa, the atypical antipsychotic class includes Clozaril® (clozapine, Novartis), Risperdal® (risperidone, Janssen), Seroquel® (quetiapine, AstraZeneca), Geodon® (ziprasidone, Pfizer), and Abilify® (aripiprazole, Bristol Myers Squibb).

Lilly is committed to continuing to provide resources for complete wellness for patients. This is a great time to be part of the Neuroscience division. What an opportunity to build trust and credibility! By educating on this topic, we have the ability to re-focus physicians on doing what's right for patients...choosing the medication that is best based on the overall efficacy and safety of the product. It's up to us! We will stay competitive in the market place, as always, continuing to comply with GPP guidelines. Let's take advantage of this opportunity to improve patient lives! Keep in mind that the drug labels, including that of Zyprexa®, have not actually been changed yet.

**Verbatim to be used in response to unsolicited questions:**

Doctor, I would like to share some very important NEW information with you today regarding the topic of atypical antipsychotics and diabetes. The FDA has spoken on this issue: ALL atypical antipsychotic makers have been asked to update their product labeling to include a warning about hyperglycemia and diabetes.

The FDA requested that the updated labeling state that patients with diabetes who begin taking ANY atypical antipsychotic should be monitored for a worsening of glucose control, and those with risk factors for diabetes (e.g., obesity, family history of diabetes) should undergo fasting glucose testing at baseline, and periodically throughout treatment. No one medication was singled out among atypical antipsychotics.

We appreciate the FDA's acknowledgement that changing the labeling for the entire class of atypical antipsychotics can only lead to improved overall healthcare for patients with severe mental illness and will allow clinicians to focus on choosing the most effective treatment for a patient's psychiatric illness first and foremost.

**Should a physician request further information, request a medical letter or refer the HCP to 1-800-Lilly-Rx pursuant to Lilly guidelines.**

**Questions and Answers regarding the FDA label change:**

Q Can I have a copy of the updated label/package insert for Zyprexa?

A Doctor, this information is so new that we do not have updated package inserts printed at this time. I will be happy to request a copy of the label change be sent to you directly from our medical department.

Q Why haven't I heard this information from other antipsychotic manufacturer sales representatives yet?

A That's a good question, but I don't know the answer. I would encourage you to discuss this issue with your other atypical antipsychotic sales representatives to gain further clarification.

Q Are Abilify®, Geodon®, and Seroquel ®, Clozaril®, and Risperdal® included in this labeling change?

A Yes. Abilify®, Geodon®, and Seroquel ®, Clozaril®, and Risperdal® are included in this labeling change and the FDA has requested that the same label wording be applied to these products. For more details, ask your Bristol Myers-Squibb, Pfizer, Astra Zeneca, Jantzen and Novartist representatives.