EXHIBIT 7

From: McKenna, Kevin
Sent: Thursday, November 06, 2003 1:55 PM
To: Limp, Gerald L; Melville, Margaret G; Manning, Julia W; Davies, Laura J
Subject: Privileged and Confidential - Attorney/Client Communication

Importance: High

Attachments: RE: diabetes labeling in Risperdal Consta approval

All,

Attached please find a draft e-message to Steve Hardeman explaining the annotation and requesting a telephone conversation with Dr. Katz. Please feel free to edit away as I am not married to the language.

Thanks,

Kevin

To: Hardeman, Steven D
Subject: RE: diabetes labeling in Risperdal Consta approval
Steve,

I have conveyed the essence of our discussions relating to the diabetes and hyperglycemia warning language as well as forwarding the subject language from the approved risperidine labeling to the SEROQUEL bipolar mania sNDA team. The team proposal is to submit the label with suggested edits to the bipolar mania language and to include the diabetes/hyperglycemia language verbatim from the CONSTA (risperidone) label. The primary reason for including it is to demonstrate that AstraZeneca agrees to include the class warning in the SEROQUEL label with the aim of keeping the review and approval of the sNDAs on track. In our submission, we include an annotation for the diabetes/hyperglycemia language that reads "The sponsor understands that the agency already has agreed to these changes to its proposed class warning in connection with its approval of the risperidone label. The sponsor also is involved in continuing discussions with the Division of Neuropharmacological Drug Products concerning the class warning." The last sentence is in reference to the scheduled December 5, 2003 meeting with the Division.

Please note that it is the team's intention to update Dr. Doris Bates, Senior Regulatory Project Manager for the SEROQUEL bipolar mania sNDAs, on the status of my conversations with you. The reason for apprising Dr. Bates of the status of the class warning language negotiations is make the SEROQUEL bipolar mania Division Review Team is aware that AstraZeneca is working with the Division on their request to update the Warning Section of the SEROQUEL label.

With respect to the December 5th meeting, the SEROQUEL Team would like to know how receptive Dr. Katz would be to having a brief telephone conversation, anticipated to take 30 minutes or less, to discuss the class warning language. There would be 3-4 AstraZeneca participants. The majority of which would be from Regulatory Affairs. Please note that this conversation would be in lieu of the December 5th meeting. The aim of the conversation would be to explore how open the Division is to further edits to the warning language that would make it more accurate with respect to the clinical experience with SEROQUEL and what information AstraZeneca would need to submit to support the additional edits. If we were to have this telephone conversation, it is our belief that a satisfactory resolution to this important public safety issue will be reached in an expedited manner.

If Dr. Katz is agreeable to the proposed conversation, AstraZeneca respectfully requests that it occur before December 5th.

If you require any clarification or further information, please do not hesitate to contact me.

Kevin McKenna, Ph.D.
Executive Director, Regulatory Affairs
(302) 886-2742

-----Original Message-----
From: Hardeman, Steven D [mailto:HARDEMANS@cder.fda.gov]
Sent: Tuesday, November 04, 2003 7:50 AM
To: McKenna, Kevin
Subject: diabetes labeling in Risperdal Consta approval

Hyperglycemia and Diabetes Mellitus
Hyperglycemia, in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics including Risperdal. Assessment of the relationship between atypical antipsychotic use and glucose abnormalities is complicated by the possibility of an increased background risk of diabetes mellitus in patients with schizophrenia and the increasing incidence of diabetes mellitus in the general population. Given these confounders, the relationship between atypical antipsychotic use and hyperglycemia- related adverse events is not completely understood. However, epidemiological studies suggest an increased risk of treatment- emergent

hyperglycemia- related adverse events in patients treated with the atypical antipsychotics. Precise risk estimates for hyperglycemia- related adverse events in patients treated with atypical antipsychotics are not available.

Patients with an established diagnosis of diabetes mellitus who are started on atypical antipsychotics should be monitored regularly for worsening of glucose control. Patients with risk factors for diabetes mellitus (e. g., obesity, family history of diabetes) who are starting treatment with atypical antipsychotics should undergo fasting blood glucose testing at the beginning of treatment and periodically during treatment. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia during treatment with atypical antipsychotics should undergo fasting blood glucose testing. In some cases, hyperglycemia has resolved when the atypical antipsychotic was discontinued; however, some patients required continuation of anti- diabetic treatment despite discontinuation of the suspect drug.

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