Reviewer's report

**Title:** Onset of Efficacy and Tolerability Following the Initiation Dosing of Long-Acting Paliperidone Palmitate: Post-Hoc Analyses of a Randomized, Double-Blind Clinical Trial

**Version:** 2  **Date:** 10 February 2011

**Reviewer:** Nina R. Schooler

**Reviewer's report:**

Major compulsory revisions.

1. This article provides additional information of interest to the article that was published on 2010 in the Journal of Clinical Psychopharmacology. From my perspective, it is important that the new article provide clear additional information and not repeat material that has already been presented in the published literature. Therefore, figures which have already been published should be cited rather than repeated.

2. The authors state that this article will focus on the dose regimen of 234 - initiation dose followed by 156 at day 8. Since the data were drawn from a study that assessed three randomized doses on day 8, this article shold also reflect the full design rather than focusing on what is the labeled recommendation. By doing the latter, the impression is conveyed that the article is meant to support a marketing recommendation rather than provide balanced scientific information. Thus, for example, in Table 2 it is inappropriate to highlight the Day 8 156 column. The conclusion should not focus on this dosing regimen. I would rely on the authors to review the MS to insure that other details of the article that emphaisze the 156 dose are addressed.

3. In keeping with this goal, it is critical that data regarding adverse events be presented separately for the three doses. Thus, Figure 4 presents merged information for all doses compared to placebo. What would be extremely valuable would be to present these data for the 3 day 8 doses.

4. Once data are presented regarding dose and adverse events as well as change in focus from 234 to 156 to a dosage comparison, the discussion will probably require modification as well.

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.
Declaration of competing interests:

Response to item 1 Yes but I do not have records going back five years. The following represents two - three past years.

Grant/research support: Astra Zeneca, Bristol Meyers Squibb, Eli Lilly and Company, HA Lundbeck, OrthoMcNeil Janssen, Pfizer Inc.

Consultant/Advisory Boards: Abbott, Dainippon Sumitomo, Eli Lilly and Company, Hoffman LaRoche, HA Lundbeck, Pfizer, Inc, OrthoMcNeil Janssen, Merck Inc,
Johnson and Johnson.

Response to all other items No