Reviewer's report

Title: Effect of Iron Content on the Tolerability of Prenatal Multivitamins in Pregnancy

Version: 2 Date: 28 January 2008

Reviewer: Leslie W Huson

Reviewer's report:

MAJOR COMPULSORY REVISIONS

92 vs 74 randomized to the two arms - this inequality seems a little unusual in a study being randomized at a single source. The authors should confirm in the MS that this difference was not due to any differential drop-out or refusal to take randomized medication i.e. that this difference is entirely due to different numbers being randomized into the two groups.

Table 1: this table should split all data between the two treatment groups the purpose is surely to try to demonstrate that there are no important differences between the two groups at baseline.

Table 2a/b - the conventional approach to analysis of randomized studies is to report data based on the Intent-to-Treat (ITT) paradigm. This table reports data for Completers only (or Completers with some data) and hence is possibly biased.

This table should as a minimum report for the ITT population, with an assumption that patients who did not complete were not compliant. If the authors also wish to present data for the other groups, they could do so but only after showing the ITT results.

Table 3a/b - the same comment applies - show ITT data as a minimum.

Figures 2 and 3 are badly presented. They show "time-to-event" curves for the same groups of patients, but the labelling style differs between the tables, the color of the plots differs, the unit of time on the x-axis etc.. These two figures should be re-done with more consistency.

Table 4 - it seems likely that this table is biased as a indicator of adverse event rates in relation to iron content, as it presents data only for the patients who complete the study. Completers, almost by definition, probably have a lower probability of experiencing an adverse event. For this reason I think that the authors should omit the statistical significance tests from this table and present the data as descriptive only. They should also present the percentages based on the ITT population as well as the completer population.

What next?: Unable to decide on acceptance or rejection until the authors have
responded to the major compulsory revisions

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

**Quality of written English:** Acceptable

**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**

I declare that I have no competing interests'