Reviewer's report

Title: Lutein-fortified infant formula fed to healthy term infants: evaluation of growth effects and safety in a randomized controlled clinical trial

Version: 1 Date: 24 June 2009

Reviewer: Jatinder Bhatia

Reviewer's report:

- Major Compulsory Revisions

The justification for lutein is given, but no data about lutein and its benefits are provided.

2. Are there epidemiological data demonstrating that lutein deficiency can or has led to visual or other issues?

3. What were the infants fed prior to study entry? Why were no baseline labs obtained to demonstrate the effects of lutein supplementation?

4. Since the data were obtained at an age range, it would be better to depict the data as "Time 1" rather than week one since the enrolment was over a time period of 14 days.

5. The use of z-scores is laudable, but, the weight gain would also be more appropriate to be depicted as g/kg/d since no baseline weight is provided. Were the measurements made in duplicate? were the measurers tested to have "agreement" for the same measurement?

6. The results are well described and probably more than needed. For example, birth order, parity etc are not really needed.

7. Conclusions about safety are fine, but as stated earlier, data about lutein need to be described.

8. Table 1 can be simplified by just at age at entry with a SD and range. The number of infants screened etc, needs to be just put in the text. Same goes for Table 2.

9. Weight at study entry needs to be provided and weight gain expressed as g/kg/d, range

11. Table 4 needs to be redone with data demonstrated as such rather than normal or above normal.

12. Is there a reason why all of the infants are less than P50?

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:

- Have received fees for consultation from Mead Johnson Nutritionals; however, I have no way of knowing whether they would gain or lose. Have you in the past five years received reimbursements, fees, funding, or salary from an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?

  - NO Do you hold any stocks or shares in an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?

  - NO Do you hold or are you currently applying for any patents relating to the content of the manuscript? Have you received reimbursements, fees, funding, or salary from an organisation that holds or has applied for patents relating to the content of the manuscript?

  - NO Do you have any other financial competing interests?

  - NO Do you have any non-financial competing interests in relation to this paper?