Reviewer’s report

Title: Safety of phosphatidylserine containing omega-3 fatty acids in non-demented elderly: a double-blind placebo-controlled Trial followed by an open-label extension

Version: 1 Date: 26 February 2011

Reviewer: Jeffrey Lewis

Reviewer’s report:

The authors are reporting data on the safety and tolerability of a novel form of phosphatidylserine (PS) with omega-3 long chain polyunsaturated fatty acid attached to its backbone. A single site, double blinded, randomized placebo-controlled trial with this compound has been completed by the study authors with efficacy results already published. The purpose of this manuscript is to report on the safety of this formulation. The study design was clearly described, and the fact this was in industry-supported study was made clear. Overall, the manuscript was well-written and the claims were supported.

Major Compulsory Revisions: None

Minor Essential Revisions

1. It is important to know how many in each study group were diagnosed with hypertension, diabetes and hyperlipidemia and taking medications for these conditions since this may affect the physiologic response to the PS formulation.

2. While reading the background, I became confused about whether the formulation tested is soy derived or from a different source. Soy derived PS was mentioned first, then safe-sourced PS was mentioned next. Safe-sourced is not defined in the manuscript. Consistent use of soy-derived (if that is the correct source) and avoiding the term safe-sourced is preferred.

3. In the hematological parameters, basophils were also significantly different in females before correction for multiple comparisons but this is not mentioned in the manuscript text.

4. In the statistical analysis section, Bonferroni correction for multiple comparisons was listed, but later in the manuscript Bonferroni_Holm (I believe this is misspelled Bonferroni-Holme) was listed. If Bonferroni-Holm correction was used, this should be stated in the statistical analysis section.

Discretionary Revisions: None

Level of interest: An article whose findings are important to those with closely related research interests
**Quality of written English:** Needs some language corrections before being published

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

**Declaration of competing interests:**

I declare that I have no competing interests