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

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Reviewer: Edward Huey

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This article gives the tolerability and safety results of an open-label trial of a new formulation of phosphatidylserine-DHA (PS-DHA) for the treatment of memory complaints in elderly patients with memory complaints. They conclude that the PS-DHA is well-tolerated and administration was not associated with changes in most biochemical and clinical safety parameters. Efficacy data is presented in a separate publication.

My main criticism of this paper is that I believe that it does not warrant a separate publication from the publication on efficacy. Rather the data from this paper should have been summarized in the paper on efficacy. Given that they conclude that there were not significant changes in biochemical and clinical parameters, it does not seem worth publishing 9 pages of tables of negative results of every laboratory study they performed in the study. This information could either have been summarized in the text, or made accessible to readers as supplemental on-line information associated with the efficacy study.

There are other aspects of this study that suggest that it should have been included as part of the efficacy study. The subjects are not characterized, only described as “non-demented with memory complaints” and the reader is referred to the efficacy paper. Much of the Discussion is devoted to discussing the parameters that differed significantly on t-tests between the groups. But then the authors conclude that these differences are not actually significant when corrected for multiple comparisons.