Reviewer's report

Title: Bone Mineral Density (BMD) Changes in a Bone Health Plan Using Two Versions of a Bone Health Supplement: A Comparative Effectiveness Research (CER) Study

Version: 3 Date: 10 September 2010

Reviewer: Jeannette Beasley

Reviewer's report:

1. The authors acknowledge that comparing actual to expected change in BMD are based on assumptions, and elaborate that the expected change will always be negative. This assures that the supplement will look more favorable than the appropriate comparison, which is change from baseline. If the authors consider this information a valuable addition to the manuscript, it should be limited to the discussion rather than the results (much less the primary finding discussed in the abstract).

2. The rationale provided in the methods for choosing not to conduct a randomized, controlled trial is problematic. The desire to evaluate the plan under real world conditions is listed as the reason for not conducting a placebo-controlled trial, however participants were paid incentives for providing daily reports of side effects and supplement usage (p8). This would not happen under natural conditions

3. Though presenting results as annualized change with only six months of data does not affect the statistical significance of the finding, it does multiply the effect size by two. The authors state the purpose of using annualized change is to allow for comparisons with other studies; however, the manuscript provides no such comparisons with other studies. The results section should present the actual observed changes over six months, and if the authors wish to compare annualized changes to other studies, this could be added to the discussion.

4. The authors state that the information regarding the site of BMD measurement (femoral neck, proximal femur, lumbar spine) was added to the paper – page 9 has a deleted sentence indicating it was “total body”. As typically reported in the literature, this information should be clearly stated in the tables and figures.

5. Recommend removing the listing of Blood Chemistries and changes (if not, correct P value for calcium ) and QOL measures from the manuscript. This information could be summarized in the text.

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.