

Reviewer's report

Title: Phellodendron and Citrus extracts benefit joint health in osteoarthritis patients: a pilot, double-blind, placebo-controlled study

Version: 1 **Date:** 11 June 2009

Reviewer: Kevin Ruff

Reviewer's report:

Major Compulsory Revisions

1) Clinical results are generally presented as mean treatment effect, absolute treatment effect, etc. followed by statistical significance [i.e. the rate of response of XXXXX treatment was 25% higher than placebo ($P < 0.05$) at 4 weeks or the absolute treatment effect for XXXXX versus placebo was 25% ($P < 0.05$)] at 4 weeks. At a minimum, the raw results should be presented [i.e. the LAI score at 8 weeks was significantly improved at $6.3 \pm XX$ ($P < 0.05$)]. This type of reporting is absent from both the abstract and the results section of the manuscript. This information (for LAI) is only reported in Table 3.

2) Considerable attention needs to be devoted to the very high drop out rate (44% overall and as high as 55% in the normal weight treatment arm). Specifically, how was the patient data handled with respect to withdrawals. That is, was the last observation carried forward (LOCF) approach used to minimize treatment bias? If only those people that are having positive effects remain in the trial then the results become biased to the extent of the positive effect. If the data presented are a completer analysis ONLY, then this should be stated clearly. If this is the case, this calls into question the validity of the treatment effects seen in the trial.

Minor Essential Revisions

1) Was patient compliance monitored at least at study visits? A statement detailing monitoring method and patient compliance should be added.

2) There appear to be a number of discrepancies between the raw data and the %changes reported in Tables 3 & 5. For example (Table 3) NP baseline 11.7, 4 weeks -1.4, %change is reported as 0.09. 1.4 is 14.5% lower than 11.7, not 9%. Also the way the %change data is presented in Table 3 (i.e. NP 0.09) could be misinterpreted as 0.09% instead of 9%. They are more correctly presented in Table 5. There are also typographical errors in the data (i.e. Table 5, NT CRP 8 weeks is reported as -5.0 – appears that it should be -0.5).

3) Typically, limitations of the clinical trial are delineated clearly in a grouping, often including modifications for follow-up trials. This should be done as this trial clearly had some limitations.

Discretionary Revisions

1) How was the trial size determined? Was a statistical power analysis performed based upon expected treatment responses and expected drop out rate? Greater detail with regard to this would be helpful.

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

Quality of written English: Acceptable

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

Declaration of competing interests:

I am currently employed in the dietary supplement industry and my company produces a joint health ingredient.