Author’s response to reviews

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

Authors:

Julius Oben PhD (juliusoben@hotmail.com)
Ebangha Enonchong MSc (juliusoben@hotmail.com)
Shil Kothari MS (shilkothari@hotmail.com)
Walter Chambliss PhD (chamblissw@aol.com)
Robert Garrison RPh (ddolnick@nextpharmaceuticals.com)
Deanne Dolnick MS (ddolnick@nextpharmaceuticals.com)

Version: 2 Date: 1 April 2008

Author’s response to reviews: see over
April 1, 2008

Re: 5501858541627122 “Effects of a preparation of Phellodendron and Citrus extracts on the joint and cardiovascular health of osteoarthritis patients: a pilot, double-blind, placebo-controlled study”.

Nutrition Journal

Thank you for reviewing our manuscript (5501858541627122) titled “Effects of a preparation of Phellodendron and Citrus extracts on the joint and cardiovascular health of osteoarthritis patients: a pilot, double-blind, placebo-controlled study”. We thank the reviewers for their comments. We have responded to them in this letter and have made changes to the manuscript. We hope that these revisions have improved the manuscript; making it acceptable for publication.

We have revised the publication to focus on the effects of NP06-1 on cardiovascular risk factors. Accordingly we have changed the title of the manuscript to: Phellodendron and Citrus extracts benefit cardiovascular health in osteoarthritis patients: a double-blind, placebo-controlled pilot study.

We have eliminated the data on osteoarthritis and inflammation that was previously in this manuscript. We plan to publish this data elsewhere in a more complete form as requested by one of the reviewers.

We understand your questions regarding the significance of the number of dropouts. We contracted a biostatistician, Ginny Gildengorin, PhD, to look over the manuscript along with the raw data report and to give us her opinion. We include a letter from her along with her CV. She found that there was no clear evidence of bias due to the dropouts. She also stated that we had insufficient information regarding the dropouts to run a comparative analysis of their demographics versus the demographics of those who stayed in the study.

Thanks you for your inquiry regarding berberine and PMFs as chemical markers for NP06-1. They were chosen as constituent markers for the extracts because they have each demonstrated biological activity. Information regarding the eulipidemic effects of berberine and PMFs has been added to the discussion section. There is no important ratio between berberine and PMFs. Each one is the chemical marker representing its perspective extract. The amount of each extract in the blend is proprietary information.

Methods for measuring body weight and height have been added. Information regarding the instrument used to measure blood pressure is not available. The participants were instructed regarding the dosage protocol. Those who did not drop out were assumed to be compliant. Participants were told to maintain their normal exercise and diet regiments. We have no indication that increased activity levels might have caused the weight loss.
There is no trial registration number. This study was conducted before such a requirement became common.

The safety investigation comprised of collecting information regarding adverse events and the manuscript has been revised to reflect this.