
To: Food & Drug Administration – Food Advisory Committee
From: Nutramax Laboratories, Inc. – Edgewood, Maryland
Date: May 28, 2004
Re: Written Comments at Public Meeting – June 7 & 8, 2004
Health Claim Petition: Glucosamine & Chondroitin Sulfate & Osteoarthritis filed by Weider Nutrition International Inc. Docket No. 2004P-0059

We appreciate the opportunity to submit these written comments to the Food & Drug Administration Food Advisory Committee for the above referenced public meeting and health claim petition.

There are four fundamental issues in the Weider petition that should be considered from the scientific perspective:

1. In the process of selecting a material for a multi-center study (Glucosamine/Chondroitin Sulfate Arthritis Intervention Trial¹), the NIH conducted an extensive evaluation of sources of chondroitin sulfate because of the variability in material available in the marketplace. They evaluated material from both the United States and abroad. After careful evaluation of blinded samples analyzed by various laboratories, the NIH selected the 95% minimum purity chondroitin sulfate manufactured by Bioiberica S.A. Currently this NIH multi-center study is ongoing. This specific chondroitin sulfate is not used by the petitioner and to the best of our knowledge no clinical studies have been conducted and published on the petitioner's specific material.
2. The majority of published clinical studies conducted on chondroitin sulfate alone were performed with specific, highly purified 95% minimum material from Bioiberica S.A.²⁻¹⁰ This specific chondroitin sulfate combined with glucosamine hydrochloride has also been used in several additional clinical studies on human subjects¹¹⁻¹⁷, companion animals¹⁸⁻²⁵, research animals²⁶⁻²⁹, as well as basic biochemical³⁰⁻³³ and bioavailability studies³⁴⁻³⁵. No information is provided by petitioner to support the assumption that these same results are obtained with less purified, less characterized forms of chondroitin sulfate. The forms available to the public, differ considerably in source, sulfated disaccharides, molecular weight, and purity, and often fail to meet label claims³⁷. Bioavailability in humans has been shown with the higher purity chondroitin sulfate³⁶ but not on the material used by the petitioner. The presumption of a similar bioavailability and clinical response from the various chondroitin sulfate sources currently available to the public is unjustified.
3. The petitioner, through a letter from its attorney, states that "*the evidence is extremely strong of an actual disease reducing effect: repair and rebuilding of the cartilage matrix.*" There is no claim or direct data in the petition that

substantiates this statement and yet the petitioner gives it considerable weight by virtue of the wording in the last letter from the petitioner to the FDA.

4. The petitioner relies solely on the CPC (cetyl pyridinium chloride) method to assay chondroitin sulfate, with no procedure to prove identity. The CPC method detects **sulfated** glycosaminoglycans, which could be forms other than chondroitin sulfate. While they cite methods that use the CPC to detect sulfated GAGs, they do not address the issue of proof of identity, i.e., that what is being measured is actually chondroitin sulfate. The chondroitin sulfate supplement industry as a whole suffers from a lack of uniformity and full validation of acceptable methods. Until this issue is resolved and consumers can actually rely on labeling and claims of joint support from all manufacturers, it is inappropriate to allow a health claim on a material that in most products lacks careful characterization, especially regarding identity, source and substantiation of bioequivalence and effectiveness.

*For questions, please contact: Kristen E. Blanchard, Vice President, Legal & Government Affairs, Nutramax Laboratories, Inc., 2208 Lakeside Boulevard, Edgewood, Maryland 21040
Phone: 410-776-4000, Fax: 410-776-4053, e-mail: kblanchard@nutramaxlabs.com*

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