



AUG 9 2004

1758 104 AUG 10 12 58

Jonathan W. Emord, Esq.
Emord and Associates P.C.
5282 Lyngate Court
Burke, Virginia 22015

Dear Mr. Emord:

This letter responds to a portion of the July 1, 2004 letter you sent to Michael M. Landa and Louisa T. Nickerson at the Food and Drug Administration (FDA) on behalf of your client, Weider Nutrition (Weider). In that letter, you asked FDA to consider revised versions of claims regarding reduced risk of osteoarthritis-related joint pain, tenderness, and swelling that FDA rejected in its October 3, 2003, and February 13, 2004 letters to you because they refer to disease treatment. You asserted that the evidence of pain reduction in the record is substantial and follows logically from evidence demonstrating construction of cartilage matrix. You further stated that Weider will supply the FDA with a supplemental scientific evaluation for these three claims, which are:

- Glucosamine may reduce the risk of joint-related pain
- Chondroitin sulfate may reduce the risk of joint-related pain
- Glucosamine and chondroitin sulfate may reduce the risk of joint-related pain

FDA's consideration of your original proposed claims about reduced risk of osteoarthritis-related joint pain, tenderness, and swelling terminated when the agency denied those claims. Moreover, the new claims in your July 1 letter are broader in scope than those that FDA previously reviewed in that they cover any type of joint-related pain, not merely joint pain related to osteoarthritis. Under FDA's health claim regulations, to obtain agency review of these new claims, you must submit a new health claim petition (rather than a supplemental scientific evaluation) requesting that the agency authorize a health claim characterizing the relationship between the consumption of glucosamine and/or chondroitin sulfate and a reduced risk of joint-related pain (See 21 CFR 101.70).

2004P-0059

ANS 2

Page 2 - Jonathan W. Emord, Esq.

Based on statements in your July 1 letter, we understand that the new petition will rely at least in part on scientific studies and other information submitted with your May 29, 2003 glucosamine and chondroitin sulfate petition. You need not resubmit information previously submitted to us if you cross-reference to it in the new petition. As provided in 21 CFR 101.70(b), references to previously submitted material must be specific so that we can identify and retrieve the pertinent information.

Sincerely,

A handwritten signature in black ink that reads "Barbara O. Schneeman". The signature is written in a cursive style with a large initial 'B'.

Barbara O. Schneeman, PhD
Director
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition