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BY ELECTRONIC AND REGULAR MAIL

Ms. Kathleen Ellwood
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Office of Nutritional Products, Labeling and
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CFSAN, U.S. Food and Drug Administration
Room 4A026, HFS-830
5100 Paint Branch Parkway
College Park, MD 20740

**Re: Health Claim Petition: Dietary supplementation of
Crystalline Glucosamine Sulfate (Glucosamine Sulfate Sodium
Chloride-USP/NF 2003) reduces the risk of osteoarthritis joint
structure deterioration and related joint pain and limitation of
function.**

Dear Ms. Ellwood:

We are writing this letter to confirm our earlier e-mail correspondence in which our client, Rotta Pharmaceuticals Inc. (Rotta), agreed to truncate the model health claim found in the above-referenced petition. It is our understanding that the agency review of this petition has been delayed, in part, because the Food and Drug Administration (FDA) is evaluating whether it is appropriate to include as part of a health claim, information regarding the relationship between crystalline glucosamine sulfate and "joint structure deterioration and related joint pain and limitation of function."

The original petition contains a model claim that we believe accurately characterizes the science for which there is significant scientific agreement (SSA). Unlike other diseases, the etiology for osteoarthritis is less defined and we considered it important to characterize the manner in which crystalline glucosamine sulfate has been shown to prevent osteoarthritis. We believe there is SSA supporting the ability of crystalline glucosamine sulfate to reduce the risk of osteoarthritis joint structure deterioration and related joint pain and limitation of function. While we also believe there is SSA supporting the ability of crystalline glucosamine sulfate to reduce the risk of osteoarthritis, the studies have primarily

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focused on the effect of glucosamine sulfate on joint structure, joint pain and limitation of function, as prescribed by current scientific recommendations. We, therefore, proposed to include in the model health claim these effects of crystalline glucosamine sulfate.

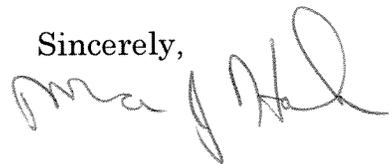
It is our understanding that for purposes of its SSA review, the agency will focus exclusively on whether crystalline glucosamine sulfate has been shown to reduce the risk of osteoarthritis. Because we have been advised that the agency's SSA review will focus on the ability of crystalline glucosamine sulfate to reduce the risk of developing osteoarthritis and will not include an assessment of the more specific claim found in the original petition (*i.e.*, reduce the risk of osteoarthritis joint structure deterioration and related joint pain and limitation of function), we are amending the language recommended for the model health claim, as set forth below.

Dietary supplementation of Crystalline Glucosamine Sulfate
(Glucosamine Sulfate Sodium Chloride-USP/NF 2003) reduces
the risk of osteoarthritis.

It is our further understanding that under the circumstances, FDA will not treat this letter as a substantive amendment that would restart the agency's clock for purposes of completing its review of the health claim petition. Consistent with our letter of January 30, 2004 in which we agreed to extend by an additional three weeks the agency's review of the petition, we are looking forward to receiving by February 22, 2004, the agency's decision on the petition.

If you have any questions, please contact us.

Sincerely,



Martin J. Hahn