

HOGAN & HARTSON
L.L.P.

August 11, 2003

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VIA ELECTRONIC AND FIRST CLASS MAIL

Christine L. Taylor, Ph.D.
Director, Office of Nutritional Products,
Labeling and Dietary Supplement
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
Harvey W. Wiley Building
5100 Paint Branch Parkway
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College Park, Maryland 20740

Re: Intent to File a Health Claim Petition for Glucosamine Sulfate

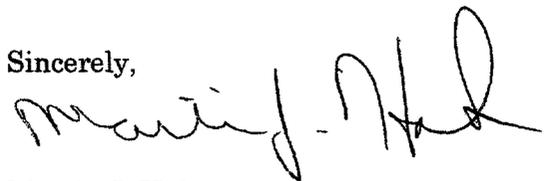
Dear Dr. Taylor:

We are writing to notify your office that our client, Rotta Pharmaceuticals, Inc. (Rotta), intends to file a health claim petition regarding the relationship between glucosamine sulfate consumption and a reduced risk of osteoarthritis and other conditions associated with joint pain. On May 29, 2003, the agency received a similar health claim petition filed by Emord & Associates on behalf of their client Weider Nutrition International.

Rotta manufacturers glucosamine sulfate, which is the form of glucosamine that has been studied in over 90 percent of the published clinical studies on glucosamine and joint pain. Rotta has reviewed the health claim petition filed by Emord & Associates and has identified several issues with that petition that it intends to bring to the agency's attention. Rotta has concluded that it would be most effective to bring these issues to the agency's attention by filing its own health claim petition for glucosamine sulfate.

We intend to file this health claim petition in the next several weeks. We are writing this letter merely as a courtesy to bring this issue to the agency's attention. If you have any questions on this or other matters, please contact us.

Sincerely,



Martin J. Hahn

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