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January 5, 2004

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BY ELECTRONIC AND REGULAR MAIL

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

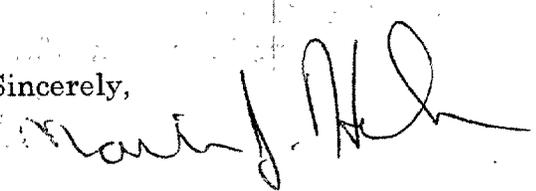
Re: Health Claim Petition: Dietary supplementation of Crystalline
Glucosamine Sulfate (Glucosamine Sulfate Sodium Chloride-USP/NF
2003) reduces the risk of osteoarthritis joint deterioration and related
joint pain and limitation of function.

Dear Ms. Ellwood:

During our telephone conversation in December 2003 you asked whether our client, Rotta Pharmaceuticals Inc., would agree to the agency's request for additional time to complete its review of the health claim petition that we submitted on September 17, 2003. The regulations require the agency to notify health claim petitioners, within 100 days of receipt of health claim petitions, whether the agency will file the petition for comprehensive review or deny the petition. As explained in the agency's October 8, 2003 letter from Paulette M. Gaynor, Ph.D., the 100-day period ended on January 1, 2004.

In this letter we provide written confirmation of our verbal agreement to extend the review period until February 1, 2004. If you have any questions, please contact us.

Sincerely,


Martin J. Hahn

2004P-0060

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