

HOGAN & HARTSON
L.L.P.

MARTIN J. HAHN
PARTNER
(202) 637-5926
MJHAHN@HHHLAW.COM

September 10, 2004

COLUMBIA SQUARE
555 THIRTEENTH STREET, NW
WASHINGTON, DC 20004-1109
TEL (202) 637-5600
FAX (202) 637-5910

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

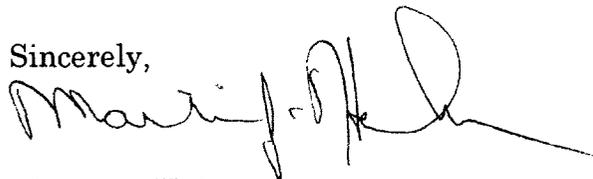
Re: Health Claim Petition: Dietary supplementation of Crystalline
Glucosamine Sulfate (Glucosamine Sulfate Sodium Chloride-USP/NF
2003) reduces the risk of osteoarthritis joint deterioration and related
joint pain and limitation of function.

Dear Ms. Ellwood:

We are writing this letter on behalf of our client, Rotta
Pharmaceuticals Inc. (Rotta). In our letter of September 9, we agreed to extend the
agency review period for the above-referenced health claim until October 1, 2004.
In this letter, we agree to extend the review period until October 7, 2004.

If you have any questions, please contact us.

Sincerely,



Martin J. Hahn

cc: Louisa T. Nickerson, Esq.
Gloria J. Overholser, Esq.

2004R 0060

LET 10