



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington DC 20204

6380 '04 FEB 13 P1 50

Martin J. Hahn
Hogan & Hartson, L.L.P.
555 13th Street NW
Washington, DC 20015

FEB 13 2004

Re: Health claim petition that glucosamine sulfate reduces the risk of osteoarthritis joint deterioration and related joint pain and limitation of function

Dear Mr. Hahn:

This letter is in reference to the subject health claim petition that you submitted on behalf of Rotta Pharmaceuticals, Inc. We received this petition on September 23, 2003. We informed you on October 8, 2003, that the date by which FDA would either file or deny your petition is January 1, 2004. We mutually agreed to extend that date first to February 2, 2004, and then to February 20, 2004. As stated in your February 12, 2004 letter to Kathleen Ellwood, you agreed to amend the claim language to "Glucosamine sulfate reduces the risk of osteoarthritis."

We have completed our initial review of this petition. Based on your agreement to amend the claim language as stated above, we are filing your petition as specified in section 403(r)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(r)(4)). The filing date of your petition is February 13, 2004. FDA will either publish a Federal Register notice of a proposed regulation in response to the petition or deny the petition within 90 days of the filing date.

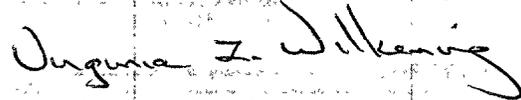
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Please feel free to contact Dr. Julie Schimpf at 301-436-1450 if you have questions concerning this petition.

Sincerely yours,



for Laura Tarantino, Ph.D.
Acting Director
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition