



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

OCT 8 2003

Food and Drug Administration  
College Park, MD 20740

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

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:

The Food and Drug Administration (FDA) has received the health claim petition, dated September 17, 2003, that you submitted on behalf of Rotta Pharmaceuticals, Inc. (the petitioner) pursuant to sections 403(r)(4) and 403(r)(5)(D) of the Federal Food, Drug, and Cosmetic Act (FFDCA; 21 U.S.C. § 343(r)(4) and 21 U.S.C. § 343(r)(5)(D)) and in accordance with the agency's guidance, "Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements" (the interim procedures guidance). FDA received this petition on September 23, 2003.

The subject of the petition is the relationship between glucosamine sulfate and osteoarthritis for human dietary supplements. The petition proposes the model health claim that daily dietary supplementation with glucosamine sulfate reduces the risk of osteoarthritis joint structure deterioration and related joint pain and limitation of function.

FDA is conducting its initial review of the petition. In accordance with section 403(r)(4)(A)(i) of the FFDCA and 21 CFR 101.70(j)(2), FDA will notify you of the agency's decision either to file the petition for comprehensive review or to deny the petition within 100 days of receipt of the petition. A denial may be either FDA action within the initial 100-day period, which ends on January 1, 2004, or lack of FDA action within this initial 100-day period in which case the petition shall be deemed to be denied unless an extension is mutually agreed upon by FDA and the petitioner. If, during its initial review, the agency concludes that the proposed claim does not meet the significant scientific agreement standard, FDA will contact you about its interim procedures for having the petition reviewed as a qualified health claim.

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If you have any questions about the petition, contact me at 301-436-1743.

Sincerely yours,

*Paulette M. Gaynor*

**Paulette M. Gaynor, Ph.D.  
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and, Dietary Supplements  
Center for Food Safety  
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