DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

0578 '03 FEB 12 P1:49

JAN 28 2003

David R. Morrison, Esq.
Director, Scientific Affairs
Pharmaton Natural Health Products
Division of Boehringer Ingelheim Pharmaceuticals
900 Ridgebury Road
Ridgefield, Connecticut 06877

Dear Mr. Morrison:

This is in response to your letter (unsigned) of December 17, 2002 to the Food and Drug Administration (FDA) responding to our November 25, 2002 letter concerning claims you intend to use in the labeling of your products **Flexium™ Joint Comfort & Cartilage Renewal** and **Flexium™ Joint Comfort**.

In our November 25, 2002 letter, we stated the claim "...ease the pain from everyday activities" was a disease claim because it suggests that the products are intended to treat, prevent, or mitigate diseases, namely joint disorders such as arthritis. You disagreed with our assertion that this is a disease claim and you cited language in the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1030) that discussed the circumstances under which claims about pain would not imply disease treatment.

We disagree with the conclusion that you draw from that preamble discussion. As we stated then, pain is not a normal state, nor are there "normal pain levels." Consequently, a claim about pain treatment or prevention is ordinarily a disease claim. We stated that pain associated with specific non-disease states, such as muscle pain following exercise, may be appropriate structure/function claims. But, we disagree that "everyday activities" constitutes a qualification that associates your pain claim with pain associated with a non-disease state. In fact, it explicitly is a claim about "normal pain levels" because it associates pain with "everyday activities," that is, those activities associated with simply being alive and functioning. Clearly, everyday activities, such as walking and other non-strenuous physical activity, are not associated with pain unless there is an underlying disease state that causes such activities to induce joint pain. For this reason, we are not persuaded that the position stated in our November 25, 2002 letter is incorrect and we continue to believe that the claim cited in that letter is a disease claim and not a structure or function claim.

975-0163 LET 668

Please contact us if we may be of further assistance.

Sincerely yours,

John B. Foret
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200
FDA, New England District Office, Office of Compliance, HFR-NE240

1/14/03 Cy to Mine

Boehringer Ingelheim

Los to Bob Moore

**Boehringer Ingelheim Pharmaceuticals Inc.**

**Pharmaton Natural Health Products**

Mr. John B. Foret
Director, Division of Compliance and Enforcement
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Food and Drug Administration
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JAN 13 2003

December 17, 2002

**David R. Morrison, Esq.**
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Ridgefield, CT 06877-0368
Telephone (203) 798-9988

Dear Mr. Foret,

This is in response to your letter of November 25, 2002, which refers to the claims made for the Flexium™ products containing glucosamine and/or SAM-e marketed by Pharmaton Natural Health Products. That letter states that our use of the claim " . . ease the pain from everyday activities," is a disease claim because it suggests that the products are intended to treat, prevent, or mitigate diseases, namely joint disorders such as arthritis. We respectfully disagree with this assessment of the claims.

The claims for the Flexium products, which accurately stated are "helps ease pain from everyday activities," were carefully crafted to comply with the final rules on structure/function claims (65 FR 1000). We were careful not to make a claim that the product prevents or treats "joint pain" or "joint disorders." Rather we relied on the FDA statement at 65 FR 1030:

> *FDA agrees that some minor pain relief claims may be appropriate structure/function claims for dietary supplements. A claim that a product is intended to treat minor pain, without reference to any other conditions, symptoms, or parts of the body that would imply disease treatment or prevention, would be an appropriate structure/function claims, because minor pain, by itself, can be caused by a variety of conditions, not all of them disease related.*

83155

cc:
HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO)
HFS-800 (r/f, file)
HFS-810 (file)
HFS-811
HFD-40 (Behrman)
HFD-310
HFD-314
HFS-607
HFV-228 (Benz)
GCF-1 (Nickerson)
f/t:HFS-811:rjm:1/23/03:docname:83155.adv:disc72

1/14/03 Cy to Maine

Boehringer Ingelheim

Los to Bob Moore

**Boehringer Ingelheim Pharmaceuticals Inc.**

**Pharmaton Natural Health Products**

Mr. John B. Foret
Director, Division of Compliance and Enforcement
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Boehringer Ingelheim

We agree that not all pain is the result of a disease condition. The preamble continues to discuss an unqualified "pain" in a product name could imply pain treatment or prevention. In order not to imply generalized pain relief, we qualified the type of pain that will be aided by these products with the nondisease state of "everyday activities." That type of pain would encompass "muscle pain following exercise" as well as pains from overexertion and other nonspecific, nondisease-related pains experienced from everyday activities. The letter states, "everyday activities are not themselves diseases." Furthermore, our claims were specifically made with the required DSHEA disclaimer, thereby evidencing our intent to make a pain claim with a nondisease state. Consequently our qualification of the pain claim with a nondisease state is clearly within the authority of 21 U.S.C. 343 (r)(6).

Sincerely,

David R. Morrison

cc: Ronald J. Spielberger, Esq.
Peter Reichertz, Esq.
Dean DiMaria