



DEC 13 2002

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Mr. Tim Cleland
President
Indiana Botanic Gardens, Inc.
3401 West 37th Avenue
Hobart, Indiana 46342

Dear Mr. Cleland:

This is in response to your letter of November 14, 2002 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Indiana Botanic Gardens, Inc. is making the following claims, among others, for the product **Glucosamine/Chondroitin Capsules**:

“If you suffer from sore, aching joints...joints that seem to freeze up, restricting movement and making life downright miserable...”
“Helps reduce joint tenderness....”

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggest that it is intended to prevent or treat disease because they describe characteristic signs (joint pain, joint mobility impairment) of a disease (i.e., arthritis or other joint disorders). These are disease claims under 21 CFR 101.93(g)(2)(ii). These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

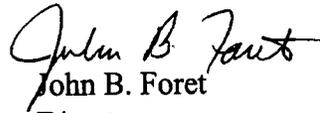
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Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in cursive script that reads "John B. Foret".

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, Detroit District Office, Office of Compliance, HFR-MW240



"Keeping America Healthy Since 1910"



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**NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA
AND 21 CFR § 101.93**

This notification is being filed on behalf of Indiana Botanic Gardens, Inc., which is the distributor of the product which bears the statements in this notification. Its business address is: 3401 West 37th Avenue, Hobart, IN 46342. This notification is being made pursuant to Section 6 of the DSHEA and Rule 21 CFR § 101.93. The dietary supplement product on whose labeling the statements appear is Glucosamine/ Chondroitin Capsules.

The text of each structure-function statement for Glucosamine/ Chondroitin Capsules for which notification is now being given is:

- (statement 1): Our Glucosamine/ Chondroitin Sulfate Formula is the perfect way to help keep joints flexible, mobile, and nourished with the nutrients that the hands of time can steal away. It can actually help protect joint health and let you have greater mobility...studies prove it!
- (statement 2): If you suffer from sore, aching joints... joints that seem to freeze up, restricting movement and making life downright miserable, then you need our Glucosamine/ Chondroitin Sulfate Formula.
- (statement 3): Helps reduce joint tenderness and make joint movement easier because it contains Glucosamine Sulfate.
- (statement 4): Helps protect the joint from pressure and friction because it contains Glucosamine Sulfate.
- (statement 5): Plays a vital role in helping to form healthy cartilage (the natural shock absorber between healthy bones), plus it helps keep joint fluid in balance and at proper levels because it contains Chondroitin Sulfate.

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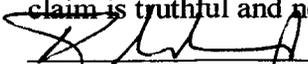
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page 2 (Glucosamine/ Chondroitin Capsules)

The following identifies the brand name of each supplement for which a statement is made:

<u>Statement Number</u>	<u>Brand Name</u>	<u>Label or Labeling?</u>
1	Botanic Choice (Glucosamine/ Chondroitin Capsules)	labeling
2	Botanic Choice (Glucosamine/ Chondroitin Capsules)	labeling
3	Botanic Choice (Glucosamine/ Chondroitin Capsules)	labeling
4	Botanic Choice (Glucosamine/ Chondroitin Capsules)	labeling
5	Botanic Choice (Glucosamine/ Chondroitin Capsules)	labeling

I, Tim Cleland, am authorized to certify this notification on behalf of Indiana Botanic Gardens, Inc. I certify that the information presented and contained in this notification is complete and accurate, and that Indiana Botanic Gardens, Inc., has substantiation that each structure- function claim is truthful and not misleading.



Tim Cleland, President

11-14-02

Date signed

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