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JUL 22 2002

Mr. Tim Cleland  
President  
Indiana Botanical Gardens, Inc.  
3401 West 37\* Avenue  
Hobart, Indiana 46342

Dear **Mr.** Cleland:

This is in response to your letters of June 20, 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)). In your letter, you notified us about a claim you intend to use for your dietary supplements Ginkgo Biloba **30 mg Extract** and **60 mg Extract Capsules**.

The products Ginkgo Biloba **30 mg Extract** and **60 mg Extract Capsules** use the claim "inhibits the clumping of blood platelets." This claim is a disease claim under 21 CFR 101.93(g)(2)(ii). In the preamble to the January 6, 2000 final rule, we stated that although platelet aggregation (i.e., platelet "clumping") is a normal function needed to maintain homeostasis, inhibiting or decreasing platelet aggregation is a well-recognized therapy for the prevention of stroke and recurrent heart attack (65 FR 1000 at 1016). External intervention to affect platelet aggregation is not necessary except in conditions where an underlying disease calls for intervention. In fact, absent a need to alter platelet aggregation, intervention to increase or decrease it may result in untoward effects, such as increased clotting or bleeding. Consequently, any claim that a product affects platelet aggregation would appear to implicitly represent the product as being necessary to correct some deviation in platelet function from the normal. Therefore, the claim "inhibits the clumping of blood platelets" is a disease claim.

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 statement that you are making for these products suggests that they are intended to treat, prevent, or mitigate diseases. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you intend to make

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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.

Please contact us if you require further assistance.

Sincerely,

  
----- J. 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 Compliance, HFR-MW240



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

JUL 03 2002

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 Ginkgo Biloba 30 mg Extract and 60 mg Extract Capsules.

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

(statement 1): Research and clinical studies demonstrate that Ginkgo Biloba:

- dilates the blood vessels, allowing improved circulation.
- supports and improves mental clarity in people of **all** ages.
- is an effective antioxidant that **inhibits free** radicals.
- increases the oxygen content of the blood.
- increases circulation to the retina.
- increases oxygen and blood flow to the brain and extremities.
- supplies nutritional support to entire body.
- inhibits the clumping of blood platelets.
- helps the **body** adapt to stress.

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 (ginkgo Biloba extract)	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, Presided

6-20-02  
Date signed

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