DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

JUN 29 2001 01 AUG -8 P2:21

Martin G. Crosby, R.Ph.
IDist Laboratories, LLC
9 East Loockerman Street
Suite 205
Dover, Delaware 19901

Dear Mr. Crosby:

This is in response to your submission to the Food and Drug Administration (FDA), dated June 15, 2001. Your submission is intended to be the notification required by 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)) and 21 CFR 101.93(a).

21 CFR 101.93(a) requires that no later than 30 days after the first marketing of a dietary supplement that bears one of the statements listed in 21 U.S.C. 343(r)(6), the responsible manufacturer, packer, or distributor notify FDA that it has included such a statement on the label or in the labeling of its product. Among other things, the notification must include the text of the statement that is being made pursuant to 21 U.S.C. 343(r)(6) (see 21 CFR 101.93(a)(2)(ii). Your notification does not identify the relevant claim; instead, the notice appears only to indicate that the product labeling bears the disclaimer required by 21 U.S.C. 343(r)(6) when a claim defined by that section is made in labeling. If your product labeling bears a claim pursuant to 21 U.S.C. 343(r)(6), your submission does not fulfill the notification requirement in 21 U.S.C. 343(r)(6) and you must submit a notification in accordance with the requirements in 21 CFR 101.93(a) in order to claim from 21 U.S.C. 321(g)(1)(C) that is provided for in 21 U.S.C. 343(r)(6).

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Please contact us if we may be of further assistance.

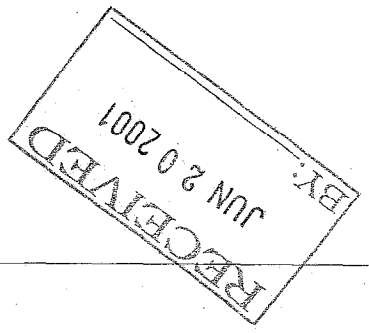
Sincerely,

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, Philadelphia District Office, Compliance Branch, HFR-MA140

76470



June 15, 2001

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St. SW.
Washington, DC 20204

Dear Office of Special Nutritionals (HFS-450),

According to 21CFR101.93(a)(1), we are required to notify you that we are distributing a dietary supplement that bears the statement: "*This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent any disease.*"

The dietary ingredients are: **Passiflora coerulea leaf extract (chrysin), Griffonia seed extract (L-5 hydroxytrptophan), pyridoxal 5-phosphate, pyridoxine HCl, and folic acid**. The brand name of the dietary supplement that is the subject of the statement is: **Deferol™** . The name and address of the distributor of the dietary supplement that bears the statement is:

IDist Laboratories, LLC
9 East Loockerman St.
Suite 205
Dover, DE 19901

I attest that I am a responsible individual who can certify the accuracy of the information presented and contained in this notice. I hereby certify that the information contained in this notice is complete and accurate, and I have substantiation that our statement is truthful and not misleading. We wish to take advantage of the exemption to section 201(g)(1)(C) of the act that is provided by our compliance with section 403(r)(6) of the act.

Sincerely,

Martin G. Crosby

Martin G. Crosby, R.Ph.
IDist Laboratories, LLC
9 East Loockerman St.
Suite 205
Dover, DE 19901

/enclosures: two copies of this original.