



AUG 25 2000 2 8 00 PM -5 P3 69

Mr. Steven P. Kornblatt
President
Mariposa Botanicals
151 West 30th Street
Suite 601
New York, New York 10001
Intelligent Nutrients

Dear Mr. Kornblatt

This is in response to your letter of August 14, 2000 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 Mariposa Botanicals is making the following claim for the product **Allergy Support Formula**:

“Provides nutritional support for people with allergies.”

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 this product, as well as the use of the word “allergy” in the name of the product, suggests that it is intended to treat, prevent, cure, or mitigate disease, namely, allergies. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests 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.

Please contact us if we may be of further assistance.

Sincerely,

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

975-0163

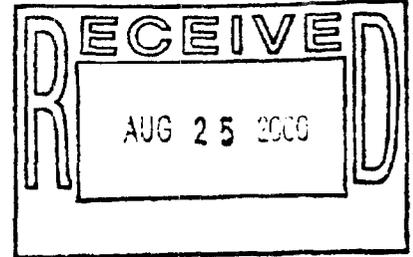
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**MARIPOSA
BOTANICALS™**

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August 14, 2000

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

Gentlemen:

The following statements are being included on the labeling of products marketed by:

Mariposa Botanicals Ltd.
151 West 30th Street Suite 601
New York, NY 10001

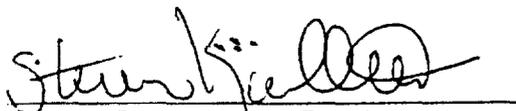
All of the named Dietary Supplements are marketed under the Mariposa brand name.

- 1) Dietary Supplement – Probiotic Digestive Aid
Statement: Supports healthy digestion.
- 2) Dietary Supplement – Glucosamine Sulfate
Statement: Provides nutritional support for healthy connective tissue and Joint function.
- 3) Dietary Supplement – Mental Alertness Formula
Statement: Supports healthy mental function.
- 4) Dietary Supplement – Allergy Support Formula
Statement: Provides nutritional support for people with allergies.

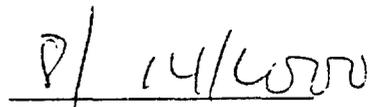
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Very truly yours,

Steven P. Kornblatt
President



Steven P. Kornblatt, President



Date