

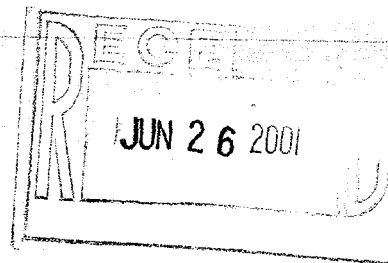


GANEDEN BIOTECH, INCORPORATED

1228 Euclid Avenue, Suite 900
Cleveland, Ohio 44115
216.522.0743 • 216.771.1632 FAX

June 11, 2001

76564



Division of Compliance and Enforcement/ONPLDS
Center for Food Safety and Applied Nutrition
Food and Drug Administration, HFS-810
200 C Street, SW
Washington, DC 20204

Subject: Notification of Structure / Function Claim - Digestive Advantage™

Pursuant to 21 CFR 101.93, Ganeden Biotech Incorporated submits this notification to market a dietary supplement which bears structure/function claims in its labeling. Marketing of the product has been initiated within the past 30 days.

The dietary supplement for which these claims are made is Digestive Advantage™. The ingredients that are the subject of the statements are Lactase Enzyme (3,000 FCC Units) and Lactobacillus Cultures that produce lactase enzyme.

The statements of structure / function claims are:

Product Label

Digestive Advantage™ is the first dietary supplement that utilizes specially isolated lactic acid cultures to help breakdown lactose and the complex sugars found in dairy products and other foods. Digestive Advantage is for you if you experience pain, cramps, bloating or diarrhea related to dairy products*.

*This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent any disease."

Advertising

"A dietary supplement that makes dairy products easier to digest."

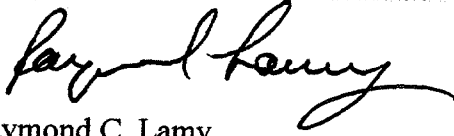
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Please contact me by telephone at (216) 522-0483 or by fax at (216) 771-1632 if you should have any questions regarding this notification.

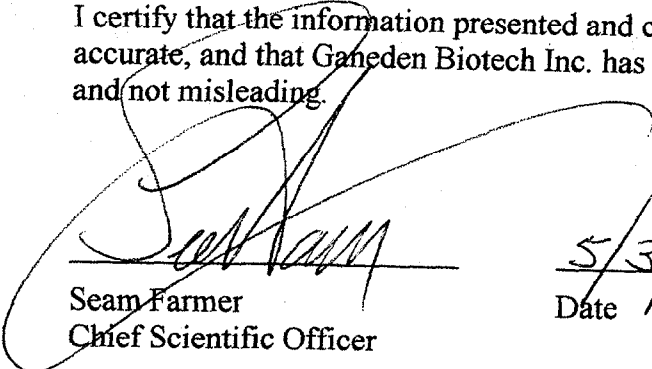
Sincerely,



Raymond C. Lamy
Director - Clinical & Regulatory Affairs

Notification Certification

I certify that the information presented and contained in this notification is complete and accurate, and that Geneden Biotech Inc. has substantiation that the statements are truthful and not misleading.



Seam Farmer
Chief Scientific Officer

5/31/01
Date