

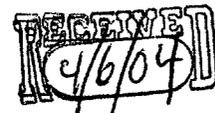
LEE B. DEXTER & ASSOC.
TECHNOLOGY CONSULTANTS

21-4 TEL. RM 21 21:56

15704 WEBBERVILLE ROAD
AUSTIN, TEXAS 78724 USA

TELEPHONE (512) 276-7408
FAX (512) 276-7489

July 20, 2002



Dr. Christine Lewis
Office of Nutritional Products,
Labeling and Dietary Supplements (HFS-810),
Center for Food Safety and Applied Nutrition,
Food and Drug Administration,
5100 Paint Branch Pkwy.
College Park, MD 20740

Dear Dr. Lewis:

In accordance with 21 CFR 101.93 this letter and its accompanying documents, will serve as notification that Garden of Life, Inc., West Palm Beach, Florida, 33407, the manufacturer, and its distributors are marketing Primal Defense™, a dietary supplement comprising whole plant foods and minerals fermented with a probiotic blend of microorganisms. The complete address of the manufacturer is as follows:

Garden of Life, Inc.
1449 Jupiter Park Drive, Suite 16
Jupiter, FL 33458

The marketing divisions of Garden of Life, Inc. and its distributors will utilize the following statements in their product literature covering the dietary supplement, Primal Defense™:

These Statements Include:

Homeostatic Soil Organisms (HSOs) are available in a product called Primal Defense™.

HSOs bring about restoration of the gut lining.

HSOs crowd out harmful bacteria and fungi.

The establishment of HSOs in the colon brings about gut regeneration and homeostasis.

HSOs balance colonic pH and set the stage for restoring all the body's systems.

Regular consumption of HSOs promotes optimum health.

HSOs supply the nutrients that ordinarily would be consumed with food grown on nutrient dense soil.

975 0162 LET 13958 88003

Dr. Christine Lewis, 2

HSOs help maintain a state of homeostasis in the human GI tract.

HSOs increase intestinal absorption.

HSOs keep harmful microorganisms from attaching to the gut wall.

HSOs in the diet replenish colonic microflora.

Primal Defense™ improves overall health and well being.

Primal Defense™ enhances gut metabolism.

HSOs help overcome bloating and gas.

Primal Defense™ improves gastro-intestinal health.

Primal Defense™ normalizes bowel function.

Primal Defense™ supplies all of the living nutrients present in pristine, healthy soil.

Primal Defense™ supplies Phyto-Sterols and Sterolins, which aid the immune system to function at peak levels.

Primal Defense™ strengthens the immune system.

Daily ingestion of HSOs promotes regular, comfortable bowel movements.

HSOs eliminate parasites and enhance the cleansing function of the gut

HSOs are a source of probiotics for children.

These functional claims are supported by published peer reviewed scientific literature. Papers describing the safety and efficacy of the components contained in Primal Defense™ have been published on several continents. Each constituent of the product has been extensively characterized by qualified scientists, and a safe history of use has been established.

Substantiation for the claims listed above is contained in the document which accompanies this letter. We are providing the agency with three copies of the document, as stipulated in 21 CFR 101.93. The manufacturer requests that this information be entered into an FDA master file for reference. The master file number can be sent to my attention at the address listed above.

In conclusion I certify that the information contained in this notice is complete and accurate, and that the notifying firm has substantiation that the statements to be made in the labeling Primal Defense™ are truthful and not misleading.

Dr. Christine Lewis. 3

Thank you very much for your consideration.

Sincerely,

Lee B. Dexter

Lee B. Dexter
Technical Consultant

C: Dr. Jordan Rubin, Garden of Life, Inc.