



DEC - 1 1997 1 4 9 3 '98 FEB 18 A8 :02

Ms. Caroline Yeh
President
Green Life USA, Inc.
709 Brea Canyon Road
Suite 8
Walnut, California 91789

Dear Ms. Yeh:

This is in response to your letter of October 31, 1997 to the Food and Drug Administration (FDA) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act). Your submission states that Green Life USA, Inc. is making the following statement for the product TriACT AntiToxin Formula: "Nutritional and Herbal formula that contains immune enhancing anti-oxidants and anti-mutagenic nutrients."

Section 403(r)(6) of the act 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 suggests that it is intended to prevent disease in that it is intended to prevent mutagenesis. Mutagenesis is the term for the process of producing genetic alterations and is generally understood to mean the process that results in the development of tumors and other cancers. This claim does not meet the requirements of section 403(r)(6) of the act. This claim suggests that this product is intended for use as a drug within the meaning of section 201 (g)(1)(B) of the act, and that it is subject to regulation under the drug provisions of the act. If you intend to make a claim of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-3 10,7520 Standish Place, Rockville, Maryland 20855.

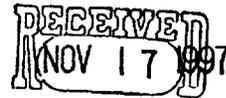
Please contact us if we may be of further assistance.

Sincerely yours,

James T. Tanner, Ph.D.
Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritional
Center for Food Safety
and Applied Nutrition

975-0163

LET 98



October 31, 1997

Office of Special Nutritional (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 "C" Street S. W.
Washington, D.C. 20204

Section 403(r)(6) Notification

Dear Sir or Madam:

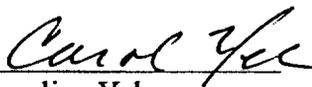
In accordance with the requirement of section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, **Green Life USA Inc.** notifies the FDA that it has begun using the following **phrase** and statement:

**Nutritional and Herbal formula that contains immune enhancing
anti-oxidants and anti-mutagenic nutrients.**

on the following product(s):

TriACT® AntiToxin Formula

Very truly yours,



Caroline Yeh
President

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