



DEPARTMENT OF HEALTH & HUMAN SERVICES

9200A
New York District

Food & Drug Administration
300 Pearl Street, Suite 100
Buffalo, NY 14202

November 28, 2001

WARNING LETTER NYK 2002-16

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

Jean Argus, Owner
Jean's Greens
119 Sulphur Springs Road
Norway, New York 13416

Dear Ms. Argus:

An inspection of your facility at Norway, New York, was conducted by Food and Drug Administration (FDA) Investigator Denise L. Terzian March 29, 2001. This letter is written in reference to Forticel products which are manufactured and/or distributed by your firm.

The inspection, and a product sample obtained subsequent to the inspection, revealed the Forticel products are "new drugs" within the meaning of Section 201(p) of the Federal Food, Drug and Cosmetic Act (the Act), and are in violation of provisions of the Act.

Product labeling, and specifically your firm's "Fall 2000 – Fall 2001" catalog," and the pamphlet "The Forticel Story," suggest the products are useful for treating various disease conditions, as discussed below. The claims made for these products cause them to be drugs as described in Section 201(g) of the Act.

- **Forticel (pre-brewed tea) and Forticel Mix:** "...cure ...cancers and tumors," "...treat ulcer and kidney disorders," "...treat digestive and intestinal problems," "headache reliever," "...contain antibiotic, antimicrobial, and antitumor properties," and "...chronic and degenerative conditions."

We are not aware of any evidence to show the previously mentioned drug products are generally recognized as safe and effective for their intended uses. Therefore, these drugs are "new drugs" [Section 201(p)] which may not be legally marketed in this country without approved New Drug Applications [Section 505].

These drugs are also misbranded because their labeling is false and misleading because it suggests they are safe and effective for their intended uses when this is not the case [Section 502(a)]. The drugs are further misbranded because their labeling fails to bear adequate directions for use for the purposes for which they are intended [Section 502(f)(1)].

This letter neither represents a comprehensive review of all products distributed by your firm, nor a complete review of all product related literature or labeling including immediate container labels, brochures, pamphlets, catalogs, articles or newsletters. As the owner of your company, it is your responsibility to assure all products distributed are in compliance with the requirements of the Act and applicable regulations.

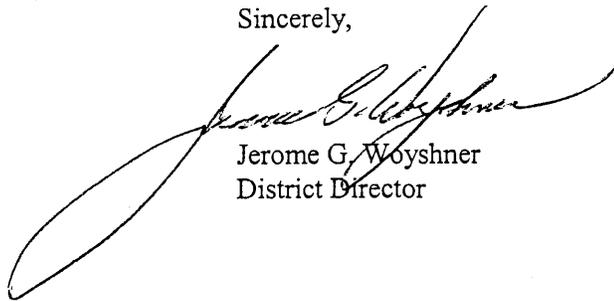
Under the Act, as amended by the Dietary Supplement Health and Education Act (DSHEA), dietary supplements may be legally marketed with claims that they are intended to affect the structure or function of the body (structure/function claims) if certain conditions are met. Claims that dietary supplements are intended to prevent, diagnose, mitigate, treat, or cure disease (disease claims) may not be made because they cause the products to be drugs.

The intended use for a product may be established through product labels and labeling, catalogs, brochures, audio and videotapes, Internet sites, or other circumstances surrounding the distribution of the product. FDA has published a Final Rule intended to clarify the distinction between statements allowed as structure/function claims and those that represent disease claims. This document is available on the Internet at <http://vm.cfsan.fda.gov/~lrd/fr000106.html>.

You should take prompt action to correct these violations, and all other violations existing at your firm. Failure to achieve prompt correction may result in regulatory action - without further notice. This action may include, but is not limited to, seizure of illegal products [Section 303] and injunction of the manufacturer and/or distributor of illegal products [Section 302].

Please notify this office in writing, within 15 days, of the specific steps you have taken, or intend to take, to correct these violations and to assure all products marketed by your company are distributed in accordance with the Act. Your response may be directed to James M. Kewley, Compliance Officer/Team Leader, at the above address.

Sincerely,

A handwritten signature in black ink, appearing to read "Jerome G. Woyshner", written over a large, stylized loop.

Jerome G. Woyshner
District Director