



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Mid-Atlantic Region *D1050B*

Telephone (201) 331-2901

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

December 9, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Melchor R. Jayme
President
Consummated Productivity Co.
2013 Strawberry Court
Edison, New Jersey 08817

File No.: 98-NWJ-10

Dear Mr. Jayme:

This letter is written in reference to your firms' marketing and distribution of the product, BIO NORMALIZER. Your brochure (labeling) titled, "Nutritional Approach to Fatal Viral Infections & Advanced Cancer" includes therapeutic claims which cause the product to be a drug (section 201(g) of the Federal Food Drug, and Cosmetic Act (the Act)).

For example, objectionable labeling claims found in the brochure include the following:

- "...Fatal Viral Infection & Advanced Cancer,"
- "...decreases pain and agony of illness..."
- "...prevents spread and metastasis of illness..."
- "Tonsillitis, fever, flu, colds, hypertensive crisis, hypotension, acute asthmatic attack..."
- "Diarrhea and food poisoning," "No hangover or drunkenness," "For other cancer cases, once the course of modalities [chemotherapy/radiotherapy] has been finished, try to administer, BN [BIO NORMALIZER] immediately to repair the affected normal tissue," and "...proven to possess an antigenotoxic property."

RELEASE

REVIEWED BY CEK 1/15/98
DATE

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Since this is a "new drug," (section 201(p) of the Act) it may not be marketed in the U.S. without an approved new drug application (section 505(a) of the Act).

Also, this drug is misbranded (section 502(f)(1) of the Act) because its labeling fails to bear adequate directions for use for the conditions for which it is offered and because its labeling is false and misleading since it suggests that ginseng capsules are safe and effective for their labeled uses, when in fact, this has not been established (section 502(a) of the Act).

For your information, we have also reviewed a testimonial letter and a promotional brochure. The testimonial letter signed by Ms. Maureen Symborski dated August 16, 1997, states that BIO NORMALIZER improved the following symptoms:

"Raynaud's phenomenon is now completely gone,"
"Enlarged lymph glands...returned to normal," "Facial rash improved greatly...," "Joint pains... are 90% improved," and "Chronic sinus infection is no longer present."

The promotional brochure titled, "International Workshop on Nutritional Approach to Aging And Disease" includes the following claims:

"Bio-normalizer Approaches in Management of Patients With Diabetes Mellitus And Hepatitis" "...insulin dependent diabetes (type 1) and in children with chronic virus hepatitis B (HVB) and hepatitis C (HCV),"
"...significant improvement in the clinical conditions of patients with diabetes mellitus. Specific markers of diabetes in the blood and urine decreased simultaneously," "...increasing level of CD14+ monocytes and CD4+/CD8+ lymphocyte ratio," "...BN therapy showed high efficacy in the patients with HCV and HBV that was characterized by decreasing the level of marker liver enzymes (AST and ALT) down to the normal values," "Chronic respiratory failure (CRF) due to

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pulmonary tuberculosis...," "BN might variously ameliorate pulmonary manifestation of CFR patients, especially those with hypoxemia," and "Abstinence-induced Oxidative Stress in Alcoholics Is Improved by Bionormalizer...[BN] is able to fasten the early recovery process, thing of potential clinical application."

If either the letter or the brochure is distributed with the BIO-Normalizer product then they are also considered to be labeling.

This letter is not intended to be an all inclusive review of all labeling and products your firm markets. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to promptly correct these violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug and Cosmetic Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

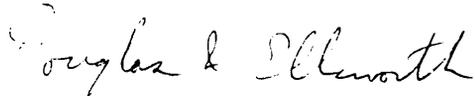
Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations, including an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

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Your reply should be sent to the Food and Drug
Administration, New Jersey District Office, Waterview
Corporate Center, 10 Waterview Boulevard, Parsippany, New Jersey
07054, Attention: Joy R. Kozlowski, Acting Compliance
Officer.

Sincerely,



DOUGLAS I. ELLSWORTH
District Director
New Jersey District