



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration  
Detroit District Office  
Central Region  
1660 East Jefferson Avenue  
Detroit, MI 48207-3179  
Telephone: (313) 226-6260  
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CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

WARNING LETTER  
2000-DT-15

March 21, 2000

Carl K. Barniak, President  
Nutrisoy International, Inc.  
424 South Kentucky Avenue  
Evansville, Indiana 47714

Dear Mr. Barniak:

This letter is in reference to your firm's marketing and distribution of **Essential Pro Plus**, **Essential Pro tein**, and **California Joe Drink**. Labeling for these products contains therapeutic claims which cause the products to be drugs [section 201 (g) of the Federal Food Drug, and Cosmetic Act (the Act)]. Labeling includes the immediate product containers, all promotional literature which you distribute in connection with your products, and your Internet web site. In addition, therapeutic claims for soy protein that are not product specific can apply to all of your products that contain soy protein.

Objectionable claims include the following:

- Essential Pro Plus:** significantly lower serum cholesterol, cancer, osteoporosis, diabetes, breast cancer, colon cancer, hip fractures, kidney disease, slow down or prevent kidney damage in people with impaired kidney function, lung cancer, prostate cancer, heart disease, prevent cancer, help the liver recover from the damage of alcohol, ... viruses, and other toxic agents, nephrotic syndrome, kidney stones, diabetes, stroke, bronchitis, nasal congestion, stomach ulcers, [reducing] morbidity and mortality after surgery, atherosclerosis, end stage renal disease, wound healing, dialysis, surgical wounds, diarrhea, lowers cholesterol, helping the body fight disease
- Essential Pro tein:** help the liver recover from the damage of alcohol, viruses, and other toxic agents, nephrotic syndrome, kidney stones, diabetes, stroke, osteoporosis, prevent cancer, bronchitis and nasal congestion, stomach ulcers, [reducing] morbidity

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and mortality after surgery, atherosclerosis, end-stage renal disease, wound healing, high blood pressure, decreased urine flow, urinary tract infections, arthritic decay

**California Joe Drink:** combat wasting disease, heart disease, osteoporosis, breast cancer

**Essential Pro Plus, Essential Pro tein, and California Joe Drink** are "new drugs" [section 201 (p) of the Act]. Therefore, they may not be legally marketed in this country without approved New Drug Applications [section 505(a) of the Act].

These drugs are also misbranded because their labeling fails to bear adequate directions for the conditions for which they are offered [section 502(f)(1) of the Act] and their labeling is false and misleading because it suggests that these products are safe and effective for their intended uses, when in fact, this has not been established [section 502(a) of the Act].

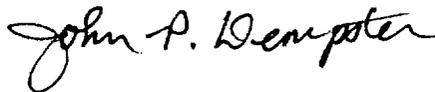
This letter is not intended to be an all inclusive review of all labeling and products your firm may market. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

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.

Your reply should be sent to the attention of Compliance Officer, Sandra Williams, at the letterhead address.

Sincerely,



for Raymond V. Mlecko  
District Director  
Detroit District