



EW
2/5/98

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Food and Drug Administration
7200 Lake Ellenor Drive
Orlando, FL 32809

WARNING LETTER

FLA-98-28

February 5, 1998

Murray J. Cohen, M.D.
President
Metabolic Nutrition, Inc.
2299 N.E. 164th Street
Miami, Florida 33160

Dear Dr. Cohen:

An inspection of your firm in October 1997, found violations of the Federal Food, Drug, and Cosmetic Act (the Act). The promotional material (labeling) associated with your products make therapeutic claims for serious disease conditions. The following products are listed with examples of their labeling claims.

- "opti-Arthrit Rx joint healer" caplets. Inhibiting pain, reducing joint inflammation, supporting ligamentous healing, restore bone growth, reduce morning stiffness and joint swelling, effective in the treatment of arthritis, significant reduction in morning stiffness, pain and disability.
- "opti-Burners" tablets. For hypoglycemics, regulate insulin levels, stabilize blood sugar, lower cholesterol.
- "opti-RECOVERY" shake. For wound healing, resistance to infection. Retards malignant lesions in animal models exposed to carcinogens.

Due to the above claims, these products are drugs [section 201(g) of the Act]. They are also "new drugs" [section 201(p) of the Act] and, therefore, may not be marketed in the United States without an approved new drug application [section 505(a) of the Act].

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

Dr. Murray Cohen
Page 2
February 5, 1998

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 you take prompt action to correct these violations. Failure to promptly correct violations may result in enforcement action being initiated by the FDA without further notice. The 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 (15) working days of receipt of this letter as to the specific steps you have taken to correct these violations. You should also include an explanation of each step being taken to identify and make corrections to assure that similar violations will not occur. 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 Jimmy E. Walthall, Compliance Officer, U. S. Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, telephone no. (407) 475-4700.

Sincerely,


Douglas D. Tolen
Director
Florida District