



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration  
555 Winderley Place, Suite 200  
Maitland, Florida 32751

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**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

**WARNING LETTER**

FLA-99-13

November 20, 1998

Leonard Edelman, President  
Spectramin, Incorporated  
5401 NW 102nd Avenue, #119  
Sunrise, Florida 33351

Dear Mr. Edelman:

This letter is in reference to your firm's marketing, labeling (including promotional materials), and distribution of a number of products that make disease claims. These products and examples of disease claims include:

- "Ultra Prost-Aide 2000": "offers hope for men who struggle with the unpleasant and often disabling effects of prostate disorders".

The Final Rule, dated February 27, 1990, and the Non-Traditional Drug Bulletin #20, dated March 18, 1997, addressed Benign Prostatic Hypertrophy (BPH) Drug Products for Over-the-Counter (OTC) Human Use. It was determined that any drug product offered for OTC human use for BPH is not generally recognized as safe and effective and is, therefore, misbranded. The name of the product also implies intended use as a drug.

- "Stop Smoking Formula," which contains lobelia extract, cayenne pepper, vitamin A, vitamin C, ginger root, ephedra extract, and scull cap herbs, bears claims on the label that it is ". . . DESIGNED TO HELP REDUCE THE DESIRE TO SMOKE AND THE CRAVING FOR NICOTINE. Additionally, the Spectramin Health Catalog bears claims that the "Stop Smoking Formula" will help ". . . you *kick the habit*. It reduces the yen to smoke and addictive nicotine cravings. Lobelia extract acts as a substitute for nicotine so you can quit without withdrawal symptoms."

The product is subject to a final rule (Title 21 Code of Federal Regulations part 310.544) covering OTC drug product offered as smoking deterrents. Under that rule, any OTC drug product that is labeled, represented, or promoted as a smoking deterrent is considered a "new drug" (section 201(p) of the Act) which may not be legally marketed unless the product has an approved New Drug Application (NDA).

- "Form-U-Life": "cancers, heart disease, bacterias, arthritis, high blood pressure, mood swings, ... ulcers";
- "Melatonin": "helps control the sleep/wake cycle";

Melatonin is not generally recognized as safe and effective under the final rules concerning OTC sleep-aid drug products (21 CFR 338).

- "Echinacea & Goldenseal Formula": "fight viral, bacterial and fungal infections"; and
- "Miracle Heart": "total nutrition against ... heart disease and protection for the entire cardiovascular system"

Based on the claims noted above, these products are drugs [section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act)] and also "new drugs" [section 201(p) of the Act]. Therefore, they may not be marketed in the United States without approved new drug applications [section 505(a) of the Act].

These drugs are also misbranded [section 502(f)(1) of the Act] because the labeling fails to bear adequate directions for use. 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].

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 also object to the claims made for the following products because these claims cause them to appear to be new drugs. We strongly recommend that you address these apparent violations at this time. Examples of the products and their disease claims include:

- "DHEA": "anti-obesity, anti-cancer";
- "Glucosamine": "effective in relieving pain and inflammation of arthritis";
- "Chondroitin Sulfate": "deterioration of cartilage and collagen damages the connective tissues. This leads to autoimmune disorders including arthritis; lupus; scleroderma";
- "Diabetic Support Complex": "helps normalize and balance glucose uptake ... help diabetics protect against illness and long-term complications ... helps control and stabilize blood sugar. It works hand-in-glove with insulin in the body";
- "Super Vitamin E": "menstrual pain, blood clots ... epicondylitis arthritis ... has therapeutic effect on diseases affecting vital organs including heart, lungs, and liver";
- "Beta Carotene": "linked to the prevention of heart disease, irregular heart beats, strokes and cancers. ... helps offset ... cataract formation";
- "Vitamin B-12": "integral in treating pernicious anemia and low red cell count; multiple sclerosis; alcohol-related diseases; diabetes mellitus; osteoarthritis; osteoporosis";
- "Shark Cartilage": "breakthrough for possible prevention of serious illness ... are resistant to all diseases including cancer";
- "Grape Seed Extract": "if you have a disease which makes you prone to free radicals, grape seed extract could help. Grape seed extract greatly helps joint stiffness, injury, inflammation";
- "Garlic 500mg" claims include "clot-dissolving; lowering blood pressure ... flushing plaque; ... asthmatic tendencies"; and
- L-Lysine": "helps prevent and heal herpes ... fights off cold sores, fever blisters, and side effects of viral infections, postviral neuralgia".

We request that you take prompt action to correct these violations. Failure to promptly correct 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. You should also include 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 Jimmy E. Walthall, Compliance Officer, U.S. Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, telephone (407) 475-4731.

Sincerely,

A handwritten signature in black ink that reads "Douglas D. Tolen". The signature is written in a cursive style with a large, stylized initial "D".

Douglas D. Tolen  
Director, Florida District