



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

Public Health Service

01915b

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

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

**WARNING LETTER**

FLA-98-54

June 24, 1998

Evidio Sanchez, President  
Nutrigen Vitamins and Supplements  
1762 Coral Way  
Miami, Florida 33145

Dear Mr. Sanchez:

This letter is in written reference to your firm's marketing, labeling (including promotional materials), for distribution of your products and the disease claims made for those products:

- "Neurogen": "speeds the healing of ulcers ... helps control alcoholism, schizophrenia..."; and
- "Reumagen" (aka "Reumakil"): "arthritis" and "... ingredients which each in its own right have proven themselves in the fight against osteoarthritis"; and
- "Complex M": claims include "sexual dysfunction" and the product lists "raw prostate concentrate" and "raw orchic concentrate" among its ingredients.

We regard your promotional brochures as labeling, as they make therapeutic claims and, therefore, these products are drugs [section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act)]. These products are also "new drugs" [section 201(p) of the Act] and, 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 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].

Mr. Evidio Sanchez

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Additionally, "Progel" is a product for topical application which contains lidocaine HCl and is labeled to prolong sexual pleasure for men. Based on its formulation and labeling, this product is subject to the final rule for male genital desensitizers found in Title 21, Code of Federal Regulations (21 CFR), Part 348. Lidocaine is an acceptable active ingredient in a metered spray with approximately 10 mg per spray, but it is not acceptable in any OTC male desensitizer product that is not in a metered spray. Because of this, "Progel" fails to conform to 21 CFR Part 348, and is a new drug. The labeling for "Progel" also fails to bear the warning statements required by 21 CFR 330.1(g) for topical OTC drugs, the statement of identity required by 21 CFR 348.50(a)(1), the warnings required by 21 CFR 348.50(c), and the directions for use required by 21 CFR 348.50(d)(1)(ii). Therefore, "Progel" is misbranded.

We also note the following products with disease claims:

- "Shark cartilage": claims to be an "eliminator of cancer and tumors" and
- "Melatonin": claims include "eases insomnia".

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 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.

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Your reply should be sent to Martin E. Katz, Compliance Officer, Florida District, Food and Drug Administration, 555 Winderley Place, Ste. 200, Maitland, Florida 32751, telephone no. (407) 475-4729.

Sincerely,

A handwritten signature in black ink that reads "Douglas D. Tolen". The signature is written in a cursive style with a large, prominent "D" at the beginning.

Douglas D. Tolen  
Director, Florida District