



Atlanta District Office  
60 Eighth Street, NE  
Atlanta, GA 30309

November 6, 2003

**VIA FEDERAL EXPRESS**

Bjarte Rene'  
Owner/President  
American Nutraceuticals Company  
3340 Peachtree Rd., Suite 1110  
Atlanta, GA 30326

**Warning Letter**  
(04-ATL-01)

Dear Mr. Rene':

On July 1, 2003, FDA investigators Leah M. Andrews and Jacqueline D. Mitchell inspected your firm's facility. During the investigation, our investigators collected a list of products distributed by your firm and samples of all available labels and promotional materials for products marketed and distributed by your firm. As a result of our investigation and review of these labels and promotional materials, we have determined that a number of your products fail to comply with provisions of the Federal Food, Drug and Cosmetic Act (the Act).

Under Section 201(g)(1)(B) of the Act (21 U.S.C. § 321(g)(1)(B)), articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease are drugs. The following claims on your products' labels and promotional materials indicate that these products are intended to be used as drugs:

- Cholester LOW 2™ - product literature claims:
  - "Clinically proven to reduce cholesterol levels."
  - "Act to lower cholesterol levels by blocking the formation of cholesterol in the liver."
  - "One of the best known answers for fighting cholesterol levels and actively lowering them safely and effectively ...."
  - "Of primary concern is the risk of a buildup in the arteries of fatty deposits composed of cholesterol and calcium. Left untreated, this condition may lead to arteriosclerosis and its more advanced form, atherosclerosis, causing the walls of the arteries to thicken and harden.... This may greatly increase the risk of stroke, coronary heart disease and heart attacks."
- Coral Calcium – product literature claims:
  - "People have ... taken Coral Calcium to treat symptoms of heart disease, arthritis, cancer, diabetes, ... Alzheimer's disease, chronic fatigue,... high blood pressure, and high cholesterol."
- Apple Cider Vinegar – product literature claims:
  - "A naturally occurring antibiotic and antiseptic that fights germs and bacteria ...."

- “A number of outstanding authorities have proven the therapeutic advantages of using cider vinegar for numerous complaints ranging from obesity ... to arthritis.”
- Staying Power Rx – product literature claims:
  - “Helpful in treating impotence – regardless of the cause ....”
  - “Has been used successfully to treat erectile dysfunction ....”
- Horny Goat Weed – product literature claims:
  - “Has been used successfully to treat erectile dysfunction ....”
  - “It is used ... to treat men with erectile dysfunction ...”
  - “Helpful in treating impotence – regardless of cause ....”
  - “Fights impotence, ... inflammation of the bladder ....”
- epa-sol™ High Concentrate Omega-3 – product literature claims:
  - “These omega-3 fatty acids ... keep blood triglycerides in check (high triglycerides are generally linked with increase [sic] of heart disease) and may inhibit the progression of atherosclerosis.”
  - “Used to help people with various inflammatory conditions such as Crohn’s disease and rheumatoid arthritis.”
  - “Helps some people with kidney diseases and may help protect against chronic obstructive pulmonary disease.”
  - “Uses include: Heart Disease, Arthritis, Diabetes, ... High Blood Pressure, Alzheimer’s, Cancer, Asthma, Crohn’s Disease, ADD/ADHD, ... Depression ....”
- ProstaMAX-1265 –
  - Product label claims:
    - “Specifically formulated to help with disorders of the prostate.”
  - Product literature claims. The following claims in the product literature for ProstaMAX-1265, taken together, are evidence that this product is intended to treat a disease, namely benign prostate hypertrophy (BPH):
    - “BPH (benign prostatic hypertrophy or enlarged prostate)”
    - “Specifically formulated to help with problems of the prostate.”
    - “Inhibits DHT production and stimulates urine flow ....”
    - “Stimulates urine flow and is also said to have some anti-inflammatory properties”

These claims cause the products to be drugs as defined in Section 201(g)(1)(B) of the Act (21 U.S.C. § 321(g)(1)(B)). Because the products are not generally recognized as safe and effective when used as labeled, they are also new drugs as defined in Section 201(p) of the Act (21 U.S.C. § 321(p)). New drugs may not be legally marketed in the United States without prior approval from FDA as described in Section 505(a) of the Act (21 U.S.C. § 355(a)). Furthermore, the products are also misbranded under Section 502(f)(1) of the Act (21 U.S.C. § 352(f)(1)) because their labeling fails to bear adequate directions for use for the conditions for which they are offered.

Under the Act, labeling for a dietary supplement may include claims that, among others, describe the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, or characterize the documented mechanism by which a dietary ingredient acts to maintain such

structure or function (see 21 U.S.C. § 343(r)(6)(A)). However, these “structure/function” claims must be truthful and not misleading (see 21 U.S.C. §§ 343(a)(1), 343(r)(6)(B)). Upon review of the labeling, including promotional materials, for some of your products, we have determined that they include the following structure/function claims:

- Snooze & Lose™
  - Product label claims:
    - “Night Time Weight Loss Formula”
  - Product literature claims:
    - “Lose weight while you sleep”
    - “Lose inches”
    - “The amino acids in Snooze & Lose™ are utilized by the body to rebuild muscle tissue while you sleep.”
    - “It is not unusual for Snooze and Lose™ users to report a reshaping of their body, losing inches even before they notice losing pounds.”
- DownSize™ – product literature claims:
  - “Lose Weight While You Sleep”
  - “Lose Inches”
  - “The amino acids in DownSize™ are utilized by the body to rebuild muscle tissue while you sleep.”
  - “It is not unusual for DownSize™ users to report a reshaping of their body, losing inches even before they notice losing pounds.”

We have reviewed these claims and have concluded that they are not supported by reliable scientific evidence. Because these claims lack substantiation, they cause your products to be misbranded within the meaning of Sections 403(a)(1) and 403(r)(6) of the Act (21 U.S.C. §§ 343(a)(1) and 343(r)(6)).

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 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.

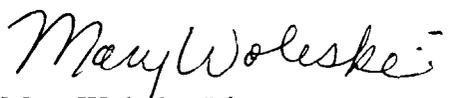
In addition, during the inspection, the investigators noted that you also distribute topical cream products, some of which may be subject to OTC drug monographs. You should review your products to ensure that they meet all applicable regulatory requirements, including the requirements of any applicable monographs.

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 ensure 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 directed to the attention of Serene N. Ackall, Compliance Officer, at the address noted in the letterhead. Ms. Ackall can be reached at 404-253-1296 to discuss the content of this letter or any questions you have about the promotion of your other products.

Sincerely,

A handwritten signature in cursive script that reads "Mary Woleske".

Mary Woleske, Director  
Atlanta District