



DEPARTMENT OF HEALTH & HUMAN SERVICES

**Public Health Service
Food and Drug Administration**

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS

Our reference: 2954586

September 29, 2000

Roger J. and Debra L. Peeples
Owners
Health Notification Service
112 Beech Street
Henderson, NV 89105

WARNING LETTER

Dear Mr. and Ms. Peeples:

This letter is written in reference to the marketing of "The Miracle Wild Yam Cream" by your firm. Labeling associated with your product states or suggests that it is useful in treating or preventing osteoporosis, symptoms of menopause, depression, premenstrual syndrome, breast cancer, postpartum depression, ovarian cysts, fibrocystic mastitis, infertility, and other diseases and conditions.

Because this product is intended to be used in the cure, mitigation, treatment or prevention of disease, or because it is intended to affect the structure or any function of the body of man, this product is a "drug" as defined in Section 201(g) of the Federal Food, Drug, and Cosmetic Act (Act). Because of the therapeutic claims found in the literature distributed by your firm, the product meets the definition of "new drug" in Section 201(p) of the Act. A new drug may not be legally marketed in this country without an approved New Drug Application, as required by Section 505 of the Act.

Further, Title 21, Code of Federal Regulations, Part 310.530 (21 CFR 310.530) (copy enclosed) states that over-the-counter topical products containing hormones, including progesterone, are new drugs within the meaning of Section 201(p), and requires that any such drugs have an approved application filed pursuant to Section 505(b) before they can be marketed.

This drug is misbranded within the meaning of Section 502(a) in that its labeling is false and misleading because it represents and suggests that there is substantial scientific

evidence to establish that the drug is safe and effective for its intended uses when in fact, this has not been established.

It is also misbranded within the meaning of Section 502(f)(1) because its labeling fails to bear adequate directions for the uses for which it is being offered.

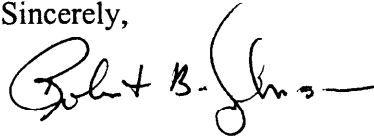
This letter is not intended to be an all inclusive review of all labeling and products your firm may market. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

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 directed to the attention of Suzanne Schenck, Compliance Officer, at the above address.

Sincerely,

A handwritten signature in black ink, appearing to read "Robert B. Johnson", with a horizontal line extending from the end of the signature.

Robert B. Johnson
Acting District Director
San Francisco District

enclosure: 21 CFR 310.530