



Food and Drug Administration  
Denver District Office  
Building 20 - Denver Federal Center  
P. O. Box 25087  
Denver, Colorado 80225  
TELEPHONE: 303-236-3000

October 19, 1998

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

**WARNING LETTER**

Ms. Judy Hennessy  
Wind River Herbs  
150 East Hansen  
Jackson, Wyoming 83001

Dear Ms. Hennessy,

This letter is in reference to your firm's marketing and distribution of Lomatium Root, Valerian Root, and St. Johns Wort. Your product catalog titled, "**THE TRADITIONAL USE OF HERBS**," makes therapeutic claims which cause the products to be drugs as defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act).

Examples of these claims include the following:

- LOMATIUM ROOT:** "This anti-viral herb is used in Epstein Bar virus, Herpes Simplex I and II, Candida Albicans and AIDS. Used for colds, flu and respiratory infections." "HIV"
- VALERIAN ROOT:** "... It may be used safely to reduce tension, anxiety and hysteria. Used for insomnia ... Its anti-spasmodic action makes it helpful in relieving menstrual cramps, intestinal colic and pain associated with tension. Can help in migraines and rheumatic pain." "Neuralgia: Internal" "Ovarian Pain" "Headache: ... Tension" "Cramps: Intestinal - Anti-spasmodic"
- ST. JOHN'S WORT:** "... Most helpful in its use for neuralgia, anxiety and tension due to its sedative and pain-reducing effects. ... Helpful with long-term use in depression. Currently being used and monitored for treatment of HIV, AIDS." "Nerve Pain" "Carpel Tunnel: Internal"

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These products are "new drugs" because there is no evidence that they are generally recognized as safe and effective for their intended uses [section 201(p) of the Act]. Therefore, they may not be legally marketed in this country without approved New Drug Applications [section 505(a) of the Act].

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

These drugs are labeled to contain 50 - 60% USP grain alcohol. Over the counter drugs for ingestion which are labeled for adult use may not contain more than 10% alcohol [Title 21 Code of Federal Regulations (CFR), section 328.10].

Further, your product catalog includes disease claims for the majority of its listed products and these claims may cause additional products to be new drugs and misbranded drugs. The association of treatment claims with an ingredient, rather than a specific product, may represent a disease claim for any of the products which contain that ingredient.

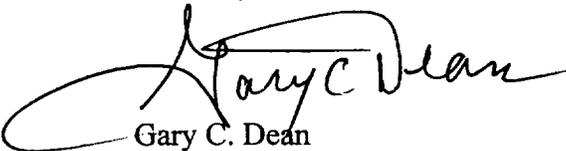
This letter is not intended to be an all inclusive review of all labeling and products your firm markets. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

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.

Your reply should be directed to Russell W. Gripp, Compliance Officer, at the above address.

Sincerely,



Gary C. Dean  
District Director

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