



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

HFI-35
MOYAN
Food and Drug Administration
Florida District
555 Winderley Place
Suite 200
Maitland, Florida 32751

Telephone: 407-475-4700
FAX: 407-475-4769

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-99-76

July 7, 1999

Dr. Marc A. Puleo
President, Petmed Express
3350 N.W. 53rd Street, #103
Fort Lauderdale, Florida 33309

Dear Dr. Puleo:

An investigation by the Food and Drug Administration into the operations of your firm, PetMed Express, has determined that prescription veterinary drugs have been dispensed without obtaining a lawful written or oral order from a licensed veterinarian within the course of the veterinarian's professional practice.

The Food, Drug, and Cosmetic Act (the Act) requires that veterinary prescription drugs be approved by the Food and Drug Administration and comply with the conditions prescribed by 21 U.S.C. 353(f)(1)(A) and 21 CFR 201.105 for the lawful dispensing of prescription drugs. Among the conditions for lawful dispensing are: refills must have been authorized in the original order; there must be a valid veterinarian-client-patient relationship; the drug must be in the possession of a person regularly and lawfully engaged in drug distribution and authorized to distribute under state law; and, the drug must bear the prescription legend: "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian". Failure to comply with these conditions would result in the drug being adulterated and/or misbranded.

Veterinary drugs that are dispensed without obtaining proper authorization are misbranded while held for sale after shipment in interstate commerce within the meaning of Section 502(f)(1) in that the labeling fails to bear adequate directions for use, and they are not exempt from such requirements since they are veterinary drugs which, because of toxicity or other potentiality for harmful effect, or the method of their use, are not safe for use except under the supervision of a licensed veterinarian. Prescription drugs which are not in compliance with all the conditions of 21 U.S.C. 353(f)(1)(A) and 21 CFR 201.105 are not exempt under 21 U.S.C. 353(f)(2)(A) from Section 502(f)(1) of the Act.

This letter is not intended to be an all inclusive review of all products your firm distributes. It is your responsibility to ensure that all products dispensed by your firm are in compliance with all requirements of the Act and its implementing regulations. We want to emphasize that under federal regulations, 21 CFR 201.105(a), you must be in compliance with all applicable state laws for dispensing prescription drugs.

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 a 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 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,



Douglas D. Tolen
Director, Florida District