



DEPARTMENT OF HEALTH & HUMAN SERVICES

Via Federal Express

Our Reference: 29-54417

October 7, 1999

Edward T. Henry, D.V.M.  
Dairy Veterinary Services  
1299 Fairview Avenue  
Tulare, California 93274

**WARNING LETTER**

Dear Dr. Henry:

An investigation of your veterinary medical practice on March 29, 1999, at Tulare, California, and at one of your clients, [REDACTED], by Food and Drug Administration (FDA) Investigator Robert J. Anderson have revealed serious deviations of Extralabel Drug Use In Animals (Title 21, Code of Federal Regulations, Part 530). Such deviations cause veterinary drugs prescribed by you to be misbranded within the meaning of Section 502(f)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) in that they do not display a proper veterinarian's label bearing adequate directions for use.

Our investigation found that you prescribed gentamicin sulfate, not approved for use in cattle, for use by [REDACTED] your client, in its calf raising operation. Also, you prescribed sulfamethoxazole and trimethoprim (SMZ) tablets, U.S.P., a human drug, for use by the same calf operation. You authorized veterinary drug distributors to sell and deliver the gentamicin sulfate and SMZ tablets but did not authorize them to place your full disclosure veterinary label bearing adequate directions for use including withdrawal times on the drugs, nor did you place the labels on the drugs yourself. The gentamicin and SMZ tablets are adulterated under Section 501(a)(5) in that they are unsafe within the meaning of Section 512(a)(1)(A) of the Act because they are not approved for use in cattle.

The following conditions must be met for an extralabel use in food-producing animals of approved new animal and human drugs:

1. There is no approved new animal drug that is labeled for such use and that contains the same active ingredient which is in the required dosage form and concentration, except where a veterinarian finds, within the context of a valid veterinarian-client-patient relationship, that the approved new animal drug is clinically ineffective for its intended use.
2. Prior to prescribing or dispensing an approved new animal or human drug for an extralabel use in food animals, the veterinarian must:

Make a careful diagnosis and evaluation of the conditions for which the drug is to be used.

Establish a substantially extended withdrawal period prior to marketing of milk, meat, eggs, or other edible products supported by appropriate scientific information.

Institute procedures to assure that the identity of the treated animal or animals is carefully maintained.

Take appropriate measures to assure that assigned timeframes for withdrawal are met and no illegal drug residues occur in any food-producing animal subjected to extralabel treatment.

The prescribed or dispensed extra-label drug bears labeling information which is adequate to assure the safe and proper use of the product. At a minimum, the following label information is recommended:

The name and address of the veterinary practitioner.

The established name of the drug (active ingredient), or if formulated from more than one ingredient, the established name of each ingredient.

Any directions for use specified by the practitioner (including the class/species or identification of the animals; and the dosage, frequency, route of administration, and duration of therapy).

Any caution statements specified by the veterinarian.

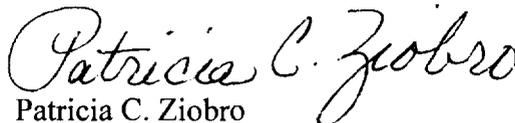
The veterinarian's specified withdrawal/discard time(s) for meat, milk, eggs, or any food which might be derived from the treated animal(s).

We request that you take prompt action to ensure that veterinary drugs you prescribe are properly labeled. Causing the adulteration and misbranding of drugs after receipt in interstate commerce is a violation of Section 301(k) of the Act.

The above is not intended to be an all-inclusive list of violations. As a licensed veterinarian, you are responsible for assuring that all drugs you prescribe bear the proper veterinarian's label. It is your responsibility to ensure that all requirements of the Act are being met. Failure to achieve prompt corrections may result in enforcement action without further notice, including seizure and/or injunction.

Within fifteen (15) days of the receipt of this letter, please notify our Fresno office in writing of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed. Your response should address each discrepancy brought to your attention during the inspection and in this letter, and should include copies of any documentation demonstrating that corrections have been made. Please direct your reply to United States Food and Drug Administration, Robert J. Anderson, Investigator, 2202 Monterey Street, Suite 104E, Fresno, CA 93721.

Sincerely yours,



Patricia C. Ziobro

Director

San Francisco District