



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

M30241

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

Via Federal Express

Our Reference: 29-54420

October 7, 1999

Johnny R. Williams  
32175 Pleasant Oaks Drive  
Springville, California 93265

**WARNING LETTER**

Dear Mr. Williams:

An investigation of your veterinary drug distribution practices on April 6 and 8, 1999, by Food and Drug Administration (FDA) Investigators Robert J. Anderson and Thomas W. Gordon has revealed the sale and distribution of a human prescription drug for veterinary purposes. This sale and distribution was made without a written order of a licensed veterinarian based on a valid veterinarian/client/patient relationship. This is a serious violation and causes the drug to be adulterated under Section 501(a)(5) in that it is unsafe within the meaning of Section 512(a)(5)(A) of the Federal Food, Drug, and Cosmetic Act (the Act).

On February 1, 1999, you obtained approximately [REDACTED] vials of the human drug SoloPak brand of cefazolin sodium, U.S.P., from [REDACTED] a calf raising operation. You then sold the cefazolin sodium to [REDACTED] a calf raising operation. The act of dispensing a human prescription drug intended for veterinary use causes the drug to be misbranded within the meaning of Section 503(f)(1)(C). The cefazolin sodium you sold and distributed is misbranded within the meaning of Section 502(f)(1) in that the labeling indicates this drug is for human use and the drug fails to bear adequate directions for veterinary use. The drug is not exempt from such requirements since it is a human drug used for veterinary purposes, which, because of toxicity or other potential harmful effects, or the method of its use, is not safe for use except under the supervision of a licensed veterinarian. The drug fails to qualify for exemption based on the conditions described in Title 21 Code of Federal Regulations 201.105, in that the drug is not safe for animal use except under the professional supervision of a licensed veterinarian. Causing the adulteration and misbranding of drugs after receipt in interstate commerce is a violation of Section 301(k) of the Act.

Williams. Johnny R.  
Springville, California

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The above is not intended to be an all-inclusive list of violations. 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.

We request that you take prompt action to correct these violations and to establish procedures to prevent their recurrence. 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, California 93721.

Sincerely yours,



Patricia C. Ziobro  
Director  
San Francisco District

cc:

