



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

SEP 5 2000

NADA 111-104

Michele Bronder
Regulatory Assistant
Farnam Companies, Inc.
301 W. Osborn Road
Phoenix, Arizona 85013

Dear Ms Bronder:

We refer to your Annual Drug Experience Report (DER) dated July 18, 2000 for Furall, furazolidine (NADA 111-104). This product is distributed by Farnam Companies, Inc. and Veterinary Products Industries.

Your company distributed a Furall Sell Sheet, which is misleading in that it does not accurately identify the types of bacterial infections for which the product is approved. This renders your product misbranded under section 502(a) of the Act.

In addition, your distributor, Veterinary Products Industries' promotional piece entitled "Back by popular demand...", makes claims for being a "broad spectrum antibacterial product" and killing "a wide range of infection-causing bacteria". We find this material to be misleading as it tends to insinuate Furazolidine Aerosol Powder has a broader application than indicated in the approved labeling which only provides for *Staphylococcus aureus*, *Streptococcus spp.* and *Proteus spp.* Thusly, the promotional pieces cause your product to be misbranded under 502(a) of the Act.

We request that you discontinue using these promotional items and in the future promote your product only in accord with the approved labeling.

It has been noted that the representations of Furall Aerosol Powder on the sell sheet have the required statement "Caution: Federal law prohibits the use of this product in food producing animals." However, the label submitted for the product does not include the bolded statement as requested by Dr. William Keller, Director, Division of Surveillance, in a letter dated June 14, 1999. We believe this is an inadvertent omission in submitting the label. Please be aware that the most current product labeling is to be submitted with the annual DER.

Please respond within 30 days of the receipt date of this letter. If you have any questions, you may contact us at (301) 827-6642.

Sincerely yours,



M I S

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