



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

OCT 26 1999

• **NADA 91-818**

Robert D. Gunderson
Vice President, Regulatory Affairs
Phoenix Scientific, Inc.
3915 South 48th Street Terrace
P.O. Box 6457
St. Joseph, MO 64506-0457

Dear Mr. Gunderson:

This is in reference to your approved New Animal Drug Application (NADA 91-818) concerning Phenylbutazone Tablets, USP.

We noted a discrepancy in your product's package insert. The "References" section lists reference # 15 [Gabriel, KL., Martin JE: J. Am. Vet. Med. A. 140;334-41(Feb. 1962)], but there was no text provided in the "BACKGROUND PHARMACOLOGY" section. This may be an inadvertent omission. Nevertheless, we request that you revise your labeling either by including the text of the reference in the "Background Pharmacology" section or by deleting the bibliographic reference # 15 from the "References" section. This may be accomplished within six months of the receipt of this letter or at the next printing, whichever occurs first.

Please inform us of your intentions as soon as possible. If you have any questions, you may contact us at (301) 827-6642.

Sincerely yours,

Mohammad I. Sharar, DVM., M.Sc.
Team Leader, Marketed Product Scientific
And Regulatory Review Team II, HFV-216
Division of Surveillance
Center for Veterinary Medicine