



██████████ Veterinary Pharmacy
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To Whom It May Concern:

This letter is in regard to the compounding and sale of phenylbutazone powder products. The U.S. Food and Drug Administration (FDA) has received information that your firm may currently be marketing a compounded phenylbutazone product. The FDA's concern is that firms are compounding drugs for use when an approved drug, in an available dosage form and concentration, would appropriately treat the animal. These compounded products of the same concentration, slightly different concentration, or similar type dosage forms are therefore unapproved versions of an approved animal drug.

An abbreviated new animal drug application (ANADA #200-333), filed by Superior Equine Pharmaceutical, Inc., was approved for the use of a sweetened and apple flavored phenylbutazone powder in horse feed for the relief of inflammatory conditions associated with the musculoskeletal system. The notification of this approval was published in the May 18, 2007, *Federal Register*, and a copy of that notice is attached.

In the event that your firm is engaged in the compounding of these products, this practice is a violation of the Federal Food, Drug, and Cosmetic Act. If your firm has not already done so, your firm should immediately cease the compounding and sales of these illegal phenylbutazone products.

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Any questions regarding this letter may be forwarded to my attention at:

Food and Drug Administration
Center for Veterinary Medicine
Division of Compliance
7519 Standish Place (HFV-232)
Rockville, Maryland 20855

Sincerely,



Lydia I. Rosas-Marty
Consumer Safety Officer
Division of Compliance (HFV-232)
Center for Veterinary Medicine

cc: [REDACTED] Executive Director
[REDACTED] Board of Pharmacy
[REDACTED]
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