



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

~ June 1, 99

ANADA 200-181

Mr. Robert D. Gunderson
Vice President Regulatory Affairs
Phoenix Scientific, Inc.
3915 South 48th Street
St. Joseph, MO 64503

Dear Mr. Gunderson:

We refer to your drug experience report (DER) dated May 7, 1999, covering the period from March 1998-March 1999, for Amikacin Sulfate Solution, ANADA 200-181. The Division of Epidemiology and Surveillance has reviewed three promotional pieces submitted in this DER.¹

We note a one page promotional piece for VETTEK™'s Amikacin Sulfate Solution/Injection, which provides information on "Indications," "Benefits," "Dosage and Administration," and "Packaging." Similarly, we note that Phoenix Pharmaceutical's promotional piece for Amikacin E Solution, as well as other veterinary prescription drugs, only provides information on "Indications." We consider these pieces to be labeling as stipulated under 21 Code of Federal Regulations §202.1(l)(2). The promotional pieces fail to include full product disclosure information, i.e., adequate directions for use as required under 21 Code of Federal Regulations §201.105(d)(1). This requirement could be met by including a reproduction of the approved package insert (s).

Also, it should be noted that all promotional labeling and advertising materials used in promotion must be submitted to FDA according to the post-marketing reporting requirements for labeling and advertising, 21 Code of Federal Regulations §510.300(b)(3). Phoenix Pharmaceutical, Inc. has failed to do so.

As a sponsor, it is your responsibility to see that all of your products are promoted in conformance with the Code of Federal Regulations. Therefore, we request that you and your distributor immediately discontinue distribution of the promotional pieces in question and make sure all such future promotional material is in compliance with the Code of Federal Regulations.

1. Amifuse E (Burns Veterinary Supply, Inc.), Amikacin E Solution (Phoenix Pharmaceutical, Inc.), and Amikacin Sulfate Solution/Injection (VETTEK™).

Please inform us of your action as soon as possible or in any event within 30 days of receipt of this letter. If you have any additional questions, you may contact us at 301.827.6642.

Sincerely yours,



Vitolis Vengris, D.V.M, Ph.D. /
Scientific and Regulatory Reviewer Team
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and Surveillance
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