

ANADA 200-181

Robert D. Gunderson  
Vice President, Regulatory Affairs  
Phoenix Scientific, Inc.  
3915 S 48th Street Terrace  
St. Joseph, Missouri 64503

MAY 22 1998

Dear Mr. Gunderson:

We refer to your drug experience report dated March 25, 1998, covering the period from September 1997-March 1998, for Amikacin Sulfate Solution, ANADA 200-181.

We note a one page promotional piece included in this submission for Vedco's CaniGlide and EquiGlide provides information on "Indications" and "Dosage and Administration" only. We consider this piece to be a labeling as stipulated under 21 CFR 202.1(i)(2). The promotional piece fails to include full disclosure information, i.e., adequate directions for use as required under 21 CFR 201.105(d)(1). This requirement could be met by including a reproduction of the approved package insert.

As a sponsor of the ANADA, it is your responsibility to see that your distributors promote the product in conformance with the regulations. Therefore, we request that you immediately have your distributor's promotional piece in question discontinued and make sure all such future promotional material is in compliance with the Code of Federal Regulations.

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 questions, you may contact us at (301) 827-6642.

Sincerely yours,



Mohammad I. Sharaf, DVM., M.Sc.  
Team Leader, Marketed Product  
Scientific & regulatory Review, Team II  
Division of Epidemiology & Surveillance  
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