



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Certified/Return Receipt Requested

m3631n
Food and Drug Administration
Kansas City District
Southwest Region
P.O. Box 18905
Lenexa, Kansas 66285-8905

Telephone: (913) 762-2100

April 6, 2000

WARNING LETTER

Mr. Kevin M. Schinze, President
Phoenix Scientific, Inc.
3915 S. 48th Street Terrace
St. Joseph, MO 64506-0457

Ref# KAN 2000-011

Dear Mr. Schinze:

During an inspection of your veterinary drug manufacturing facility located at St. Joseph, Missouri conducted on February 15 - March 7, 2000 our Investigators found significant deviations from the Good Manufacturing Practice for Finished Pharmaceuticals, Title 21, Code of Federal Regulations, Part 211 [21 CFR 211]. These deviations cause your drug product(s) to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act).

Significant deviations documented by our Investigators include, but are not limited to the following:

- Failure to properly design, validate and/or implement procedures constructed to control microbiological contamination.
- Failure to adequately perform and document failure investigations. For example the investigation into endotoxin failures of four batches of product found the WFI and most raw materials were not evaluated as to possible contribution to the endotoxin failures.
- Failure to consistently follow and document your laboratory controls.
- Failure to adequately validate all equipment cleaning procedures. For example your procedure does not identify the detergent used or possible detergent residue on cleaned equipment for Sulphadimethoxine Soluble Powder. Per your response detergent is not used in this cleaning operation though the SOPs do not reflect this in a clear manner.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Act and current regulations. We are enclosing a copy of the Form FDA 483 that was issued to John R. Carpenter, Vice President Technical Affairs, at the conclusion of the inspection.

Page 2
Phoenix Scientific, Inc.
Ref # KAN 2000-011
April 6, 2000

Based on these deviations the Kansas City District has recommended to the Center for Veterinary Medicine that the: . until such time the corrections to the violations are verified.

The Food and Drug Administration has reviewed your firm's response dated March 10, 2000 submitted by John R. Carpenter, Vice President, Technical Affairs which is a response to the observations listed on the Form FDA 483. Mr. Carpenter's letter was taken into consideration during the preparation of this letter.

You should know that these serious violations of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizure and/or injunction. Also other Federal agencies are informed about the Warning Letters issued so they may consider this information when awarding government contracts.

Please inform this office, in writing, within fifteen (15) working days of receipt of this letter of the steps you are taking, in addition to those detailed in Mr. Carpenter's letter, you are taking to correct these deviations. If you desire to have Mr. Carpenter's response dated March 10, 2000 stand as your response to this letter please let us know in writing. If the timeframes you stated for the completion of the corrections to the various deficiencies documented please inform us at the time of your response.

You should direct your reply to Ralph J. Gray, Compliance Officer, at the above address.

Sincerely,



Mary H. Woleske
Acting District Director
Kansas City District Office

Enclosure - Form FDA 483

cc: Mr. John R. Carpenter
Vice President Technical Affairs
Phoenix Scientific, Inc.
3915 S. 48th Street Terrace
St. Joseph, MO 64503