



Suitability Petition

October 24, 2002

Dockets Management Branch
HFA-305, Room 123
Food and Drug Administration
Park Building
12420 Parklawn Dr.
Rockville, MD 20857

Dear Sir or Madam:

Enclosed is a Suitability Petition submitted in accord with FFDC A Section 512 (n) (3) on behalf of Phoenix Scientific, Inc., St. Joseph, MO 64503.

The Petition concerns a change in the concentration of the active drug substance in a generic Tiamulin Water Soluble Powder from the approved product, DENAGARD™ (tiamulin) Soluble Antibiotic for oral use in swine, approved under NADA 134-644, for Boehringer Ingelheim. The requested change is from 45% tiamulin hydrogen fumarate for the pioneer to 45% tiamulin as tiamulin hydrogen fumarate for the generic.

If there are any questions concerning this petition, or when you have completed your review, please call me at (816) 364-3777.

Sincerely:

Phoenix Scientific, Inc.

A handwritten signature in black ink, appearing to read "Robert D. Gunderson", is written over the printed name.

Robert D. Gunderson

Vice President, Regulatory Affairs

02P-0474

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SUITABILITY PETITION

Identification of Petitioner:

This Suitability Petition is submitted on behalf of Phoenix Scientific, Inc., (PSI) 3915 South 48th Street Terrace, St. Joseph, MO 64503 under Section 512 (n) (3) of the Federal Food, Drug, and Cosmetic Act.

Action Requested:

PSI requests permission from the Commissioner to file an Abbreviated New Animal Drug Application (ANADA) consisting of a different concentration of the active drug substance in a drug product than the approved product. The approved product, DENAGARD™ (tiamulin) Soluble Antibiotic (NADA 134-644) contains 45% tiamulin hydrogen fumarate. The proposed generic product will contain 45% tiamulin as tiamulin hydrogen fumarate. The amount of active ingredients administered in the water to the swine will be the same for both products.

The indications for the use of the generic product will be the same as for the approved product. The label for the increased concentration product will be revised to adjust the amount of finished product added to the drinking water. A copy of the approved product labeling is enclosed.

Statement of Grounds:

The proposed product contains the same active ingredient and has the same indications, cautions, and warnings as the approved product. Both products are for oral use in swine. The products will differ only in the concentration of the active drug substance contained in the product. The label copy will vary only as it relates to the different amount of drug product required to provide the dose.



Environmental Impact:

The action of submitting and reviewing of this Suitability Petition will not normally be expected to have an environmental impact. Therefore, under 21 CFR 25.30(h), we request a categorical exclusion from the requirement to prepare an environmental assessment (EA), since, to the best of our knowledge, no extraordinary circumstances exist.

Economic Impact:

An "Economic Impact" analysis of this action will be provided upon request by the Commissioner.

Certification:

Attached is a statement that Phoenix Scientific, Inc. has included all information known to us, which is unfavorable to this Suitability Petition.

Approval to file an ANADA for this Tiamulin Soluble Powder based upon this Suitability Petition is requested.

Sincerely:

Phoenix Scientific, Inc.

Robert D. Gunderson

Vice President, Regulatory Affairs



Certificate of Inclusion of Unfavorable Information

As the Chief Executive Officer for Phoenix Scientific, Inc., I certify that no unfavorable information related to this Suitability Petition has been withheld from the attached Suitability Petition.

October 24, 2002

Kevin M. Schinze
President and CEO
Phoenix Scientific, Inc.
St. Joseph, MO 64503