



FILE COPY

October 31, 2002

Robert D. Gunderson
Phoenix Scientific, Inc.
3915 S. 48th St. Terrace
St. Joseph, MO 64503

Dear Mr. Gunderson:

Your petition requesting the Food and Drug Administration to file an ANADA consisting of a different concentration of the active drug substance in a drug product than Denagard (tiamulin) soluble antibiotic (NADA 134-644) contains 45% tiamulin hydrogen fumarate, was received by this office on 10/31/02. It was assigned docket number 02P-0474/CP 1 and it was filed on 10/31/02. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Helen K. Harris
Dockets Management Branch

02P-0474

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