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816 364-3777 • Fax 816 364-3778

Suitability Petition

January 27, 2000

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 FDCA Section 512 (n) (3) on behalf of Phoenix Scientific, Inc., St. Joseph, MO 64503.

The Petition concerns a change in the salt form of the active drug substance in a generic Spectinomycin Sterile Solution from the approved product, Adspec™ Sterile Solution for subcutaneous injection in cattle, approved under NADA 141-077, for Pharmacia & Upjohn. The requested change is from active drug substance Spectinomycin sulfate tetrahydrate for the approved to Spectinomycin dihydrochloride pentahydrate 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.

Robert D. Gunderson
Vice President, Regulatory Affairs

00P-0444

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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) containing a different form of the active drug substance than the approved product. The approved product, AdspecTM Sterile Solution (NADA 141-077) contains Spectinomycin sulfate tetrahydrate equivalent to 100 mg/mL spectinomycin. The proposed generic will contain Spectinomycin dihydrochloride pentahydrate equivalent to 100 mg/mL spectinomycin. The amount of active ingredients administered per dose to the animal 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. 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 subcutaneous injections in cattle. The products will differ only in the salt form of the active drug substance used, Spectinomycin dihydrochloride pentahydrate for the generic rather than Spectinomycin sulfate tetrahydrate for the approved product. The label copy will vary only as it relates to the different active drug substance.



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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 Spectinomycin Sterile Solution based upon this Suitability Petition is requested.

Sincerely:

Phoenix Scientific, Inc.

Robert D. Gunderson

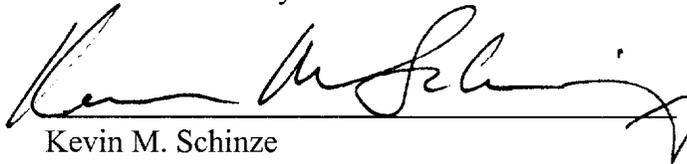
Vice President, Regulatory Affairs



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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.

 January 27, 2000

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

NDC 0009-7383-05

Adspec™

Sterile Solution

spectinomycin sulfate
sterile solution

Equivalent to

100 mg per mL spectinomycin

For subcutaneous injection in cattle.

Caution: Federal (USA) law restricts this drug to use
by or on the order of a licensed veterinarian.

Restricted Drug—Use Only As Directed (California)
For Use in Animals Only

NADA #141-077, Approved by FDA

See package insert for complete product information.

Warning: Not for human use. Keep out of reach of children.

RESIDUE WARNINGS

Treated animals must not be slaughtered for 11 days
following last treatment.

A withdrawal period has not been established for
this product in pre-ruminating calves. Do not use in
calves to be processed for veal.

Do not use in female dairy cattle 20 months of age
or older. Use of spectinomycin in this class of cattle
may cause drug residues in milk.

Store at controlled room temperature 20° to 25° C
(68° to 77° F) [for additional information see USP].

Protect from freezing.

Each mL contains spectinomycin
sulfate (sterile) equivalent
to 100 mg spectinomycin
also 9.45 mg benzalkonium
added as preservative.
pH was adjusted with
hydrochloric acid or
sodium hydroxide.



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Pharmacia
& Upjohn

Pharmacia & Upjohn, S.A. de C.V.
Carretera de Jalpan # 2962
0470 Mexico, D.F., Mexico

MM1018

09/2000

Lot:

Exp:

Adspec™ Sterile Solution
brand of spectinomycin sulfate sterile solution

Pharmacia
& Upjohn

For subcutaneous injection in cattle.

CAUTION: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

DESCRIPTION

ADSPEC Sterile Solution contains the sulfate salt of spectinomycin, an aminocyclitol antibiotic produced by *Streptomyces spectabilis*.

Each mL of ADSPEC Sterile Solution contains spectinomycin sulfate tetrahydrate equivalent to 100 mg spectinomycin; and 9.45 mg benzyl alcohol, added as preservative. The pH was adjusted with hydrochloric acid or sodium hydroxide.

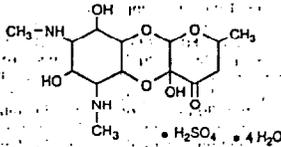


Figure 1. Chemical structure of spectinomycin sulfate tetrahydrate

The chemical name of spectinomycin sulfate tetrahydrate is: Decahydro-4a,7,8-trihydroxy-2-methyl-6,8-bis(methylamino)-4H-pyrimido[2,3-b][1,4]benzodioxin-4-ylsulfate tetrahydrate.

MICROBIOLOGY

Spectinomycin is bacteriostatic and exerts its antibacterial effect by binding to the 30S ribosome and inhibiting bacterial protein synthesis. Spectinomycin has activity against a variety of gram-negative bacteria, some mycoplasma, and a limited number of gram-positive bacteria. Generally, it is not active against anaerobic bacteria.

Spectinomycin has demonstrated *in vitro* and *in vivo* activity against the three major pathogenic bacteria (*Pasteurella haemolytica*, *Pasteurella multocida*, and *Haemophilus somnus*) associated with bovine respiratory disease (pneumonia).

Spectinomycin has also demonstrated *in vitro* activity against *Actinomyces pyogenes*, *Mycoplasma bovis*, and *Mycoplasma dispar*. The clinical significance of this *in vitro* activity in cattle has not been demonstrated.

INDICATIONS

ADSPEC Sterile Solution is indicated for the treatment of bovine respiratory disease (pneumonia) associated with *Pasteurella haemolytica*, *Pasteurella multocida*, and *Haemophilus somnus*.

CONTRAINDICATIONS

As with all drugs, the use of ADSPEC Sterile Solution is contraindicated in animals previously found to be hypersensitive to the drug.

RESIDUE WARNINGS

Treated cattle must not be slaughtered for 11 days following last treatment. Dosages administered either in excess of the approved maximum dose or by unapproved routes may result in illegal residues in edible tissues.

A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

A milk discard period has not been established for this product in lactating dairy cattle. Do not use in female dairy cattle 20 months of age or older. Use of spectinomycin in this class of cattle may cause drug residues in milk.

HUMAN WARNINGS

NOT FOR HUMAN USE. KEEP OUT OF REACH OF CHILDREN.

As with other antibiotics, allergic reactions may occur in previously sensitized individuals. Repeated or prolonged exposure may lead to sensitization. Avoid direct contact with skin, eyes, mouth, and clothing. Persons with a known hypersensitivity to spectinomycin should avoid exposure to this product.

In case of accidental eye exposure, flush with water for 15 minutes. In case of accidental skin exposure, wash with soap and water. Seek medical attention if allergic reactions occur.

The material safety data sheet contains more detailed occupational safety information. To report adverse effects in users, to obtain more information or obtain a material safety data sheet, call 1-800-253-8600.

PRECAUTIONS

The safety of ADSPEC Sterile Solution has not been determined for cattle intended for breeding.

Adspec Sterile Solution
brand of spectinomycin sulfate sterile solution

Discoloration at the injection site may persist beyond 11 days after injection. This may necessitate trimming of the injection site and surrounding tissues at slaughter.

ADVERSE REACTIONS

The use of ADSPEC Sterile Solution may result in mild swelling at the injection site.

Anaphylactic reactions may occur in animals previously sensitized.

ANIMAL SAFETY

Cattle: When spectinomycin sulfate sterile solution was administered at 10 times (150 mg/kg/day) the maximum daily recommended therapeutic dose for 5 days, treatment-related effects included increased relative kidney weights in heifers and steers, squamous and transitional epithelial cells in the urine of steers, and decreased urinary pH in steers. Urinalysis was not performed on the heifers in this study. Minimal injection site reactions were also present at 1 day and 4 days post injection.

When spectinomycin sulfate sterile solution was administered at doses of 15, 45, or 75 mg/kg/day (1X, 3X, or 5X the maximum daily recommended therapeutic dose) for 15 days, treatment-related effects included decreased urinary pH and mild swelling at injection sites. At necropsy, labeled injection sites examined at 1 day and 8 days after injection of 30 mL of spectinomycin sulfate sterile solution had dark red, tan, brown, and/or dark brown areas, often with some expansion (thickening) of the subcutis. Only mild discoloration was observed on gross examination of injection sites at 15 days after injection.

When spectinomycin sulfate sterile solution was administered subcutaneously at a dose of 15 mg/kg/day to 152 crossbred beef calves with naturally occurring BVD in clinical field trials, one calf died following the second daily injection. The cause of death following a gross necropsy was reported as an anaphylactic reaction.

DOSAGE AND ADMINISTRATION

ADSPEC Sterile Solution is to be administered to cattle at a daily dose of 10 to 15 mg spectinomycin per kg of body weight (4.5 to 6.8 mL per 100 lb body weight). Treatment should be administered at 24-hour intervals for 3 to 5 consecutive days. Selection of dose (10 to 15 mg/kg/day) and duration of treatment (3 to 5 days) should be based on an assessment of the severity of disease, pathogen susceptibility, and clinical response. Do not inject more than 50 mL per site.

ADSPEC Sterile Solution is to be administered to cattle by subcutaneous injection in the neck.

STORAGE CONDITIONS

Store at controlled room temperature 20° to 25° C (68° to 77° F) [for additional information see USP]. Protect from freezing.

HOW SUPPLIED

ADSPEC Sterile Solution is available in the following package size:

500 mL vial

NDC 0009-7383-05

NADA #141-077, Approved by FDA

Made in Mexico for
Pharmacia & Upjohn Company
Kalamazoo, MI 49001, USA
by
Pharmacia & Upjohn, S.A. de C.V.
Calzada de Tlalpan #2962
04870 Mexico, D.F.

May 1998

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CERTIFIED

Z 462 357 019

MAIL



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