Vétoquinol

4646 '01 MAR 21 A10:38

March 1, 2001

Dr. Lonnie Luther
Quality Assurance Support Team (HFV-102) Room 387
FDA Center for Veterinary Medicine
7500 Standish Place
Rockville, MD 20855

Dear Dr. Luther,

Please find enclosed a suitability petition submitted on behalf of Vetoquinol, N.-A. Inc. of Canada. Vétoquinol requests consideration of this suitability petition to file an ANADA for Amoxicillin Oral Paste.

Please call if you have questions.

Sincerely,

RECEIVED
MAR 15 2001
BY:

Pierre Gadbois d.m.v.
Manager, Regulatory Affairs – Vétoquinol N.-A. Inc.

01P-0141

CP1

Vétoquinol N.-A. Inc. - 2000, chemin Georges, Lavaltrie (Quebec) Canada J0K 1H0
Tel.: (450) 586-2252 - Fax: (450) 586-4649 - www.vetoquinol.ca

SUITABILITY PETITION

IDENTIFICATION OF PETITIONER:

This Suitability Petition is submitted on behalf of Vétoquinol N.-A., Inc. of Canada under Section 512 (n)(3) of the Federal Food, Drug, and Cosmetic Act.

ACTION REQUESTED:

The petitioner requests permission from the Commissioner to file an Abbreviated New Animal Drug Application (ANADA) for a different dosage form of an approved pioneer product. The pioneer product is Pfizer Animal Health's AMOXI-DROP® (amoxicillin trihydrate) Veterinary Oral Suspension, approved by the Food and Drug Administration under NADA 055-085. Amoxicillin is a semi-synthetic antibiotic with a broad spectrum of activity approved for use in dogs and cats. A copy of the pioneer product labeling (package insert) is included (Attachment 1).

The ANADA will provide for the use of an oral paste dosage form for administration to dogs and cats rather than the oral suspension form of the pioneer product. The product will be formulated to contain 20 or 100 mg amoxicillin [as the trihydrate] per mL of palatable paste in an oil base. The pioneer product is formulated to contain 50 mg of amoxicillin [as the trihydrate] per mL when reconstituted according to label directions. Both the proposed and pioneer products are administered to affected animals at the rate of 5 mg/lb of body weight twice daily for 5-7 days (dogs) and 50 mg (5-10 mg/lb) administered once daily for 5-7 days.

The product labeling will provide for indications, recommended dosages, contraindications, precautions and warnings identical to the pioneer product. Draft labeling for the proposed product is provided (Attachment II).

The proposed product label will differ from the pioneer product specifically as follows:

1. Labeled as "Oral Paste" rather than "Oral Suspension".
2. Contents are labeled as amoxicillin per 20 or 100 mg per mL of paste rather than amount per container.
3. The Administration instructions will be revised to describe delivery of the paste drug product using an HDPE syringe with an adjustable ring to deliver the desired dose.
4. It is anticipated that stability studies will support storage of the generic product at room temperature conditions.
5. The net contents of the containers are yet to be determined.

STATEMENT OF GROUNDS:

The proposed product contains the same active ingredient and will be labeled with the same indications, recommended dose rates, contraindications, precautions and warnings as the approved pioneer product. Because of oral administration and absorption after the amoxicillin is dissolved in the stomach, the clinical effect for both drugs is expected to be similar. The sponsor intends to provide results of blood level bioequivalency testing to demonstrate efficacy and safety of the product as well as palatability information for the product.

ENVIRONMENTAL IMPACT:

The action of submitting this Suitability Petition and its review by the FDA - Center for Veterinary Medicine is not expected to have an environmental impact. The action requested qualifies for categorical exclusion under 21 CFR Part 25.30(h) from the requirement for an environmental assessment and, to the best of the sponsor's knowledge, no extraordinary circumstances exist.

ECONOMIC IMPACT:

An "Economic Impact" analysis of this action will be provided if requested by the Commissioner.

CERTIFICATION:

Vetoquinol certifies that this suitability petition contains all information known to them which is unfavorable to the petition.

03/01/2002

Pierre Gadbois d.m.v.
Manager, Regulatory Affairs

Vétoquinol N.-A. Inc.
2000 chemin Georges
Lavaltrie, Qc, Canada
J0K 1H0

Attachments

1. Pioneer Product Label
2. Proposed Product Label

ATTACHMENT I

Pfizer's Amoxi-Drop® Labeling

Enlarged 105%

A99
9405932

amoxi◆drop®

(amoxicillin)

For veterinary oral suspension

For use in dogs and cats

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

DESCRIPTION: Amoxi-Drop (amoxicillin) is a semisynthetic antibiotic with a broad spectrum of activity. It provides bactericidal activity against a wide range of common gram-positive and gram-negative pathogens. Chemically, it is D(-)-α-amino-p-hydroxybenzyl penicillin trihydrate.

ACTION: Amoxi-Drop is stable in the presence of gastric acid and may be given without regard to meals. It is rapidly absorbed after oral administration. It diffuses readily into most body tissues and fluids with the exception of brain and spinal fluid, except when meninges are inflamed. Most of the amoxicillin is excreted unchanged in the urine.

Amoxicillin is similar to ampicillin in its bactericidal action against susceptible organisms. It acts through the inhibition of biosynthesis of cell wall mucopeptide. *In vitro* and/or *in vivo* studies have demonstrated the susceptibility of most strains of the following gram-positive and gram-negative bacteria: α- and β-haemolytic streptococci, nonpenicillinase-producing staphylococci, *Streptococcus faecalis, Escherichia coli,* and *Proteus mirabilis.* Because it does not resist destruction by penicillinase, it is not effective against penicillinase-producing bacteria, particularly resistant staphylococci. All strains of Pseudomonas and most strains of Klebsiella and Enterobacter are resistant.

INDICATIONS:

Dogs: Amoxi-Drop is indicated in the treatment of susceptible strains of the organisms causing the following infections:

Respiratory tract infections (tonsillitis, tracheobronchitis) due to *Staphylococcus aureus, Streptococcus* spp., *E. coli,* and *Proteus mirabilis.*

Genitourinary tract infections (cystitis) due to *Staphylococcus aureus, Streptococcus* spp., *E. coli,* and *Proteus mirabilis.*

Gastrointestinal tract infections (bacterial gastroenteritis) due to *Staphylococcus aureus, Streptococcus* spp., *E. coli,* and *Proteus mirabilis.*

Bacterial dermatitis due to *Staphylococcus aureus, Streptococcus* spp., and *Proteus mirabilis.*

Soft tissue infections (abscesses, lacerations, and wounds) due to *Staphylococcus aureus, Streptococcus* spp., *E. coli,* and *Proteus mirabilis.*

Cats: Amoxi-Drop is indicated in the treatment of susceptible strains of the organisms causing the following infections:

Upper respiratory tract infections due to *Staphylococcus aureus, Staphylococcus* spp., *Streptococcus* spp., *Haemophilus* spp., *E. coli, Pasteurella* spp., and *Proteus mirabilis.*

Genitourinary tract infections (cystitis) due to *Staphylococcus aureus, Streptococcus* spp., *E. coli, Proteus mirabilis,* and *Corynebacterium* spp.

Gastrointestinal tract infections due to *E. coli, Proteus* spp., *Staphylococcus* spp., and *Streptococcus* spp.

Skin and soft tissue infections (abscesses, lacerations, and wounds) due to *Staphylococcus aureus, Staphylococcus* spp., *Streptococcus* spp., *E. coli,* and *Pasteurella multocida.*

CONTRAINDICATIONS: The use of this drug is contraindicated in animals with a history of an allergic reaction to penicillin.

ADVERSE REACTIONS: Amoxicillin is a semisynthetic penicillin and has the potential for producing allergic reactions. If an allergic reaction occurs, administer epinephrine and/or steroids.

WARNINGS: For use in dogs and cats only. Not for use in animals which are raised for food production.

DOSAGE AND ADMINISTRATION:

Dogs: The recommended dosage is 5 mg/lb of body weight. Administer twice daily for 5–7 days. Continue for 48 hours after all symptoms have subsided.

Cats: The recommended dosage is 50 mg (5–10 mg/lb). Administer once daily for 5–7 days. Continue for 48 hours after all symptoms have subsided.

DIRECTIONS FOR MIXING ORAL SUSPENSION: Add required amount of water (see table below) to the bottle and shake vigorously. Each mL of suspension will contain 50 mg of amoxicillin as the trihydrate.

Enlarged 105%

Bottle Size	Amount of Water Required for Reconstitution
15 mL	12 mL
30 mL	23 mL

Note: Any unused portion of the reconstituted suspension must be discarded after 14 days. After mixing, refrigeration preferable, but not required.

Do Not Store Dry Powder at Temperatures Above 25°C (77°F)

HOW SUPPLIED: Amoxi-Drop is supplied in 15-mL bottles containing 0.75 g and 30-mL bottles containing 1.5 g of amoxicillin activity. When reconstituted with required amount of water, each mL contains 50 mg of amoxicillin as the trihydrate.

NADA #55-085, Approved by FDA

Manufactured by:
SmithKline Beecham Pharmaceuticals
Philadelphia, PA 19101

Distributed by:
Pfizer
Animal Health
Exton, PA 19341, USA
Div. of Pfizer Inc
NY, NY 10017

9405932
A99

75-8000-04
January 1999
Printed in USA

ATTACHMENT II

Vetoquinol Amoxicillin Paste Labeling

ANADA XXX-XXX, Approved by FDA

Edition Date: March 1, 2001

VETOQUINOL AMOXICILLIN PASTE

DRAFT LABELING

(amoxicillin)
Veterinary oral paste
For use in dogs and cats

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

DESCRIPTION: Amoxicillin is a semisynthetic antibiotic with a broad spectrum of activity. It provides bactericidal activity against a wide range of common gram-positive and gram-negative pathogens. Chemically, it is D(-)-α-amino-p-hydroxybenzyl penicillin trihydrate.

ACTION: Amoxicillin is stable in the presence of gastric acid and may be given without regard to meals. It is rapidly absorbed after oral administration. It diffuses readily into most body tissues and fluids with the exception of brain and spinal fluid, except when meninges are inflamed. Most of the amoxicillin is excreted unchanged in the urine.

Amoxicillin is similar to ampicillin in its bactericidal action against susceptible organisms. It acts through the inhibition of biosynthesis of cell wall mucopeptide. *In vitro* and/or *in vivo* studies have demonstrated the susceptibility of most strains of the following gram-positive and gram-negative bacteria: α- and ,β-haemolytic streptococci, nonpenicillinase-producing staphylococci, *Streptococcus faecalis, Escherichia coli,* and *Proteus mirabilis.* Because it does not resist destruction by penicillinase, it is not effective against penicillinase-producing bacteria, particularly resistant staphylococci. All strains of Pseudomonas and most strains of Klebsiella and Enterobacter are resistant.

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- Genitourinary tract infections (cystitis) due to *Staphylococcus aureus, Streptococcus* spp., *E. coli,* and *Proteus mirabilis.*
- Gastrointestinal tract infections (bacterial gastroenteritis) due to *Staphylococcus aureus, Streptococcus* spp., *E. coli,* and *Proteus mirabilis.*
- Bacterial dermatitis due to *Staphylococcus aureus, Streptococcus* spp., and *Proteus mirabilis.*
- Soft tissue infections (abscesses, lacerations, and wounds) due to *Staphylococcus aureus, Streptococcus* spp., *E. coli,* and *Proteus mirabilis.*

Cats: Amoxicillin is indicated in the treatment of susceptible strains of the organisms causing the following infections:

- Upper respiratory tract infections due to *Staphylococcus aureus, Staphylococcus* spp., *Streptococcus* spp., *Haemophilus* spp., *E. coli, Pasteurella* spp., and *Proteus mirabilis.*
- Genitourinary tract infections (cystitis) due to *Staphylococcus aureus, Streptococcus* spp., *E coli, Proteus mirabilis,* and *Corynebacterium* spp.
- Gastrointestinal tract infections due to *E. coli, Proteus* spp., *Staphylococcus* spp., and *Streptococcus* spp.
- Skin and soft tissue infections (abscesses, lacerations, and wounds) due to *Staphylococcus aureus, Staphylococcus spp., Streptococcus* spp., *E. coli,* and *Pasteurella multocida.*

CONTRAINDICATIONS: The use of this drug is contraindicated in animals with a history of an allergic reaction to penicillin.

ADVERSE REACTIONS: Amoxicillin is a semisynthetic penicillin and has the potential for producing allergic reactions. If an allergic reaction occurs, administer epinephrine and/or steroids.

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DOSAGE AND ADMINISTRATION:

*Dogs:*The recommended dosage is 5 mg/lb of body weight. Administer twice daily for 5-7 days. Continue for 48 hours after all symptoms have subsided.

Cats:The recommended dosage is 50 mg (5-10 mg/lb). Administer once daily for 5-7 days. Continue for 48 hours after all symptoms have subsided.

DIRECTIONS FOR USE: Each mL of paste will contain either 20 or 100 mg of amoxicillin as the trihydrate. Adjust the ring on the syringe to the desired dose and deliver the product orally.

STORAGE CONDITIONS WILL BE DETERMINED.

HOW SUPPLIED: Amoxillin Paste is supplied in ready to use syringes with an adjustable ring that may be set to deliver the desired dose. The product is available in concentrations of 20 or 100 mg/mL of palatable paste.

Manufactured by:
Vetoquinol
[ADDRESS TO BE INCLUDED]