

Vétoquinol

May 12, 2003

Dr Lonnie W. Luther, Chief
Generic Animal Drug Team
FDA CVM (HFV-104) Room 106
7519 Standish Place
Rockville, Maryland 20855
U.S.A.

SUBJECT : SUITABILITY PETITION – Amoxicillin Oral Paste

Dear Dr. Luther:

Please find enclosed a suitability petition submitted on behalf of VÉTOQUINOL N.-A. INC. of Canada.

VÉTOQUINOL N.-A. INC. Requests consideration of this suitability petition to file an ANADA for Amoxicillin Oral Paste.

Hoping that everything will be to your satisfaction, but feel free to contact the undersigned for any questions or comments. We remain,

Sincerely yours,



Pierre Gadbois, d.m.v.
Director, Scientific Affairs

/cm
Encl.

2003P-0219

CP1

PRODUITS VÉTÉRINAIRES - VETERINARY PRODUCTS

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 Fort Dodge Animal Health's Robamox[®]-V (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. A copy of the pioneer product labelling (package insert) is included (Attachment 1).

The ANADA will provide for the use of an oral paste dosage form for administration to dogs 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 to 7 days.

The product labelling 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 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 labelled 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

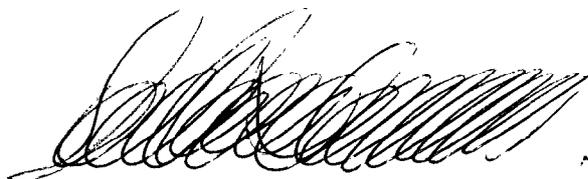
The action of submitting this Suitability Petition and its review by the FDA – Center for Veterinary Medicine is not expected to have an environmental impact. The action requested qualifies for categorical exclusion under 21 CFR Part 25.30(h) from the requirement for an environmental assessment and, 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

VÉTOQUINOL N.-A. INC.. certifies that this Suitability Petition contains all information known to them which is unfavorable to the petition.



Pierre Gadbois, d.m.v.
Director, Scientific Affairs

/cm

Enclosures : Attachment 1 – Pioneer Product Label
Attachment 2 – Proposed Product Label

ATTACHMENT I

Fort Dodge's Robamox[®]-V

NADA# 65-495, Approved by FDA



Robamox[®]-V brand of amoxicillin

Veterinary For Oral Suspension For use in DOGS only.

I52463
Rev. A 2/99

DESCRIPTION: Robamox[®]V (amoxicillin) is a broad spectrum, semisynthetic antibiotic which provides bactericidal activity against a wide range of common gram-positive and gram-negative pathogens. Amoxicillin chemically is D-(-)-α-amino-p-hydroxybenzyl penicillin trihydrate.

Inactive Ingredients: Cherry Flavor, Colloidal Silicon Dioxide, FD&C Red #40, Polyoxyethylene-Polyoxypropylene Glycol, Sodium Benzoate, Sodium Citrate, Sodium Saccharin, and Sucrose.

ACTION: Amoxicillin has bactericidal activity against susceptible organisms similar to that of ampicillin. It acts by inhibiting the biosynthesis of bacterial cell wall mucopeptide. Most strains of the following gram-positive and gram-negative bacteria have demonstrated susceptibility to amoxicillin, both *in vitro* and *in vivo*: non-penicillinase-producing staphylococci, alpha- and beta-hemolytic streptococci, *Streptococcus faecalis*, *Escherichia coli*, and *Proteus mirabilis*. Amoxicillin does not resist destruction by penicillinase; therefore, it is not effective against penicillinase-producing bacteria, particularly resistant staphylococci. Most strains of *Enterobacter* and *Klebsiella* and all strains of *Pseudomonas* are resistant.

Amoxicillin may be given without regard to meals because it is stable in gastric acid. It is rapidly absorbed following oral administration and diffuses readily into most body fluids and tissues. It diffuses poorly into the brain and spinal fluid except when the meninges are inflamed. Most of amoxicillin is excreted in the urine unchanged.

INDICATIONS: Robamox[®]V (amoxicillin) for oral suspension is indicated in the treatment of the following infections in dogs when caused by susceptible strains of organisms:

BACTERIAL DERMATITIS due to *Staphylococcus aureus*, *Streptococcus spp.*, *Staphylococcus spp.*, and *E. coli*.

SOFT TISSUE INFECTIONS (abscesses, wounds, lacerations) due to *Staphylococcus aureus*, *Streptococcus spp.*, *E. coli*, *Proteus mirabilis*, and *Staphylococcus spp.*

As is true with all antibiotic therapy, appropriate *in vitro* cultures and sensitivities should be conducted prior to treatment.

CONTRAINDICATIONS: Use of amoxicillin is contraindicated in animals with a history of an allergic reaction to penicillin.

ADVERSE REACTIONS: Amoxicillin is a semisynthetic penicillin and, therefore, has the potential for producing allergic reactions. Epinephrine and/or steroids should be administered if an allergic reaction occurs.

WARNINGS: For use in dogs only.

PRECAUTIONS: Until adequate reproductive studies are accomplished, Robamox[®]V (amoxicillin) for oral suspension should not be used in pregnant or breeding animals.

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

DOSAGE AND ADMINISTRATION: The recommended dosage is 5 mg per pound of body weight administered twice daily for 5 to 7 days. Continue for 48 hours after all symptoms have subsided. If no improvement is noted in 5 days, the diagnosis should be reconsidered and therapy changed.

DIRECTIONS FOR MIXING ORAL SUSPENSION: Add sufficient water to the bottle as indicated in the table below and shake vigorously. Each mL of suspension will contain 50 mg of amoxicillin as the trihydrate.

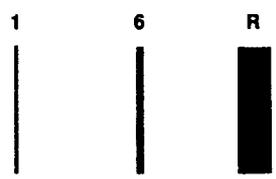
Bottle Size	Amount of Water to Add for Reconstitution
15 mL	11 mL

Note: When stored at room temperature or in refrigerator, discard unused portion of reconstituted suspension after 14 days.

SUPPLY: Robamox[®]V (amoxicillin) for oral suspension is supplied in bottles containing 0.75 g of amoxicillin activity in bottles of 15 mL. After reconstitution with the required amount of water, each mL will contain 50 mg of amoxicillin as the trihydrate.

Manufactured For:
FORT DODGE ANIMAL HEALTH
Fort Dodge, Iowa 50501 USA
by
TEVA PHARMACEUTICALS USA
Sellersville, PA 18960

I52463
Rev. A 2/99
92658
5120C



ATTACHMENT II

Vétoquinol Amoxicillin Paste Labeling

ANADA XXX-XXX, Approved by FDA

VÉTOQUINOL AMOXICILLIN PASTE

(Amoxicillin)

VETERINARY ORAL PASTE FOR USE IN DOGS

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

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

ACTION: Amoxicillin has bactericidal activity against susceptible organisms similar to that of ampicillin. It acts by inhibiting the biosynthesis of bacterial cell wall mucopeptide. Most strains of the following gram-positive and gram-negative bacteria have demonstrated susceptibility to amoxicillin, both *in vitro* and *in vivo*: non-penicillinase-producing staphylococci, alpha- and beta-hemolytic streptococci, *Streptococcus faecalis*, *Escherichia coli*, and *Proteus mirabilis*. Amoxicillin does not resist destruction by penicillinase; therefore, it is not effective against penicillinase-producing bacteria, particularly resistant staphylococci. Most strains of *Enterobacter* and *Klebsiella* and all strains of *Pseudomonas* are resistant.

Amoxicillin may be given without regard to meals because it is stable in gastric acid. It is rapidly absorbed following oral administration and diffuses readily into most body fluids and tissues. It diffuses poorly into the brain and spinal fluid except when the meninges are inflamed. Most of amoxicillin is excreted in the urine unchanged.

INDICATIONS: AMOXICILLIN Oral Paste is indicated in the treatment of the following infections in dogs when caused by susceptible strains of organisms:

BACTERIAL DERMATITIS due to *Staphylococcus aureus*, *Streptococcus spp.*, *Staphylococcus ssp.*, and *E. coli*.

SOFT TISSUE INFECTIONS (abscesses, wounds, lacerations) due to *Staphylococcus aureus*, *Streptococcus spp.*, *E. coli*, *Proteus mirabilis*, and *Staphylococcus spp.*

As is true with all antibiotic therapy, appropriate *in vitro* cultures and sensitivities should be conducted prior to treatment.

Contraindications: Use of amoxicillin is contraindicated in animals with a history of an allergic reaction to penicillin.

Adverse reactions: Amoxicillin is a semisynthetic penicillin and, therefore, has the potential for producing allergic reactions. Epinephrine and/or steroids should be administered if an allergic reaction occurs.

Warnings: For use in dogs only.

Precautions: Until adequate reproductive studies are accomplished, AMOXICILLIN Oral Paste should not be used in pregnant or breeding animals.

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

Dosage and administration:

The recommended dosage is 5 mg per pound of body weight administered twice daily for 5 to 7 days. Continue for 48 hours after all symptoms have subsided. If no improvement is noted in 5 days, the diagnosis should be reconsidered and therapy changed.

Direction 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.

Supply: AMOXICILLIN Oral 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:
VÉTOQUINOL N.-A. INC.
2000 chemin Georges
Lavaltrie (Québec) J0K 1H0
Canada