Date of Approval : March 23, 2005

# FREEDOM OF INFORMATION SUMMARY

# SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION

# NADA 065-506

# COMBI-PEN-48

**(Penicillin G Benzathine and Penicillin G Procaine Injectable Suspension)**

This supplement provides for a change in the trade name from COMBICILLIN-AG to COMBI-PEN-48 and the addition of the statements "A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal." to the warning section of the product labeling.

**Sponsored by:**

Cross Vetpharm Group Ltd.
Broomhill Rd., Tallaght
Dublin 24, Ireland

## *1. GENERAL INFORMATION:*

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|---|---|---|
| a. | File Number: | NADA 065-506 |
| b. | Sponsor: | Cross Vetpharm Group Ltd.<br>Broomhill Rd., Tallaght<br>Dublin 24, Ireland<br><br>Drug Labeler Code: 061623 |
| c. | Established Name: | Penicillin G Benzathine and Penicillin G Procaine |
| d. | Proprietary Names: | COMBICILLIN-AG (OTC label) trade name change to COMBI-PEN-48;<br><br>(COMBICILLIN (Rx label) trade name is not being changed; this product is not currently being marketed.) |
| e. | Dosage Form: | Injectable sterile aqueous suspension |
| f. | How Supplied: | 100, 250, and 500 mL, multi-dose vials |
| g. | How Dispensed: | OTC |
| h. | Amount of Active Ingredients: | 150,000 units per mL of penicillin G benzathine and 150,000 units per mL of penicillin G procaine |
| i. | Route of Administration: | Subcutaneous (SC) |
| j. | Species/Class: | Beef cattle |
| k. | Recommended Dosage: | 2 mL per 150 lb body weight given subcutaneously only (2000 units penicillin G procaine and 2000 units penicillin G benzathine per lb of body weight). Treatment should be repeated in 48 hours. |
| l. | Pharmacological Category: | Antimicrobial |
| m. | Indications: | The product is indicated for the treatment of the following bacterial infections in beef cattle due to penicillin-susceptible microorganisms that are susceptible to the serum levels common to this particular dosage form, such as:<br><br>1. Bacterial pneumonia (shipping fever complex) (*Streptococcus* spp., *Corynebacterium pyogenes*, and *Staphylococcus aureus*)<br><br>2. Upper respiratory infections such as rhinitis or |

pharyngitis (*Corynebacterium pyogenes*)

3. Blackleg (*Clostridium chauvoei*)

n. Effect of Supplement: This supplement provides for a change in the proprietary name on the OTC label product from COMBICILLIN-AG to COMBI-PEN-48 and the addition of the statements "A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal." to the warning section of the product labeling.

## *2. DRUG EFFECTIVENESS:*

No new effectiveness data were required for the approval of this supplement. The product's effectiveness was established in the original Freedom of Information (FOI) Summary dated November 8, 1993 (Folder B).

## *3. TARGET ANIMAL SAFETY:*

No new target animal safety data were required for the approval of this supplement. The product's target animal safety was established in the original FOI Summary dated November 8, 1993 (Folder B).

## *4. HUMAN FOOD SAFETY:*

No further human safety data were required from the original approval as discussed in the parent NADA 65-506 FOI Summary dated November 8, 1993. There is a 30-day withdrawal period for slaughter and a withdrawal period has not been established for pre-ruminating calves.

## *5. AGENCY CONCLUSIONS:*

The information submitted in support of this supplemental NADA satisfies the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act and 21 CFR Part 514 of the implementing regulations and provides for a change in the proprietary name for the OTC label product.

The following has been added to the residue information section of the labeling: "A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal".

The Agency has concluded that this product may retain over-the-counter marketing status because adequate directions for use have been written for the layperson and the conditions of use prescribed on the label are likely to be followed in practice.

In accordance with 21 CFR 514.106(b)(2)(ix), this is a Category II change. The approval of this change is not expected to have any adverse effect on the safety or effectiveness of

this new animal drug. Accordingly, this approval did not require a reevaluation of the safety and effectiveness data in the parent application.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act, this approval for food-producing animals does not qualify for marketing exclusivity because the application does not contain substantial evidence of the effectiveness of the drugs involved, any studies of animal safety, or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for the approval of the application and conducted or sponsored by the applicant.

No patents were submitted with this application.

## *6. ATTACHMENTS:*

Facsimile Labeling is attached as indicated below:

Penicillin G Benzathine and Penicillin G Procaine Injectable Suspension product insert
COMBI-PEN-48 100 mL bottle label
COMBI-PEN-48 250 mL bottle label
COMBI-PEN-48 500 mL bottle label