

## FREEDOM OF INFORMATION SUMMARY

### I. GENERAL INFORMATION

#### A. File Number

NADA 055-101

#### B. Sponsor

Pfizer Inc.  
235 East 42nd Street  
New York, New York 10017

#### C. Proprietary Name

Clavamox<sup>®</sup> Drops

#### D. Established Name

amoxicillin trihydrate/clavulanate potassium

#### E. Dosage Form

Suspension

#### F. Dispensing Status

Rx

#### G. Dosage Regimen

##### Dogs:

The recommended dosage is 6.25 mg (5.0 mg amoxicillin trihydrate/1.25 mg clavulanate potassium)/lb (1 mL/10 lb) of body weight twice a day. Skin and soft tissue infections such as abscesses, cellulitis, wounds, and superficial/juvenile pyoderma and periodontal infections should be treated for 5-7 days or for 48 hours after all symptoms have subsided. If no response is seen after 5 days of treatment, therapy should be discontinued and the case reevaluated. Deep pyoderma may require treatment for 21 days; the maximum duration of treatment should not exceed 30 days.

##### Cats:

The recommended dosage is 62.5 mg (50.0 mg amoxicillin trihydrate/12.5 mg clavulanate potassium) (1 mL) twice a day. The duration of treatment should be 48 hours after all symptoms have subsided, not to exceed 30 days. If no response is seen after 3 days of treatment, therapy should be discontinued and the case reevaluated.

#### H. Route of Administration

Oral

## I. Indication

Clavamox Drops are indicated in the treatment of:

### **Dogs:**

Skin and soft tissue infections such as wounds, abscesses, cellulitis, superficial/juvenile and deep pyoderma due to susceptible strains of the following organisms:  $\beta$ -lactamase-producing *Staphylococcus aureus*, non- $\beta$ -lactamase-producing *Staphylococcus aureus*, *Staphylococcus* spp., *Streptococcus* spp., and *E. coli*.

Periodontal infections due to susceptible strains of aerobic and anaerobic bacteria. Clavamox® has been shown to be clinically effective for treating cases of canine periodontal disease.

### **Cats:**

Skin and soft tissue infections such as wounds, abscesses, and cellulitis/dermatitis due to susceptible strains of the following organisms:  $\beta$ -lactamase-producing *Staphylococcus aureus*, non- $\beta$ -lactamase-producing *Staphylococcus aureus*, *Staphylococcus* spp., *Streptococcus* spp., *E. coli*, and *Pasteurella* spp.

Urinary tract infections (cystitis) due to susceptible strains of *E. coli*.

Therapy may be initiated with Clavamox® prior to obtaining results from bacteriological and susceptibility studies. A culture should be obtained prior to treatment to determine susceptibility of the organisms to Clavamox®. Following determination of susceptibility results and clinical response to medication, therapy may be reevaluated.

## J. Effect of Supplement

Adds claims for periodontal infections in dogs.

## II. EFFECTIVENESS

The clinical efficacy and safety of Clavamox Tabs in dogs for the treatment of periodontal infections due to susceptible strains of aerobic and anaerobic bacteria are evaluated in the FOI Summary for NADA 55-099 for Clavamox® Tabs. Two studies were undertaken to provide these data. The first study utilized 36 dogs with early signs of gingivitis and periodontal disease, half of which were treated with Clavamox® Tabs and the other half with a placebo. No adverse effects were noted in any of the animals, and the overall sum of the periodontal pocket depths was decreased from those treated with placebo, showing an improvement in the overall periodontal health of the oral cavity. The second study utilized 42 dogs treated with Clavamox® Tabs compared to 50 dogs treated with Antirobe® capsules to treat clinical signs associated with periodontal disease. Both treatments improved the overall periodontal health of the oral cavity by decreasing the periodontal pocket depths of the teeth which were measured, and no adverse reactions were noted.

Since data demonstrating the bioequivalence of Clavamox® Drops to Clavamox® Tabs are discussed in the parent NADA 55-101 FOI Summary (approval date February 5, 1986), the studies summarized above are used in support of the efficacy and safety for this new claim for Clavamox® Drops.

### III. TARGET ANIMAL SAFETY

Studies demonstrating the safety of Clavamox® for use in canines is contained in the FOI Summary for the original approval for Clavamox® Tabs under NADA 55-099. No further studies were conducted with Clavamox® Drops.

### IV. HUMAN FOOD SAFETY

#### Human Safety Relative to Food Consumption:

Data on human food safety, pertaining to consumption of drug residues in food, were not required for approval of this supplemental NADA. Clavamox® is approved for use in dogs and cats only.

#### Human Safety Relative to Possession, Handling and Administration:

Labeling contains adequate caution/warning statements.

### V. AGENCY CONCLUSIONS

The data in support of this NADA comply with the requirements of Section 512 of the Act and Part 514 of the implementing regulations. The data demonstrate that Clavamox® Drops (Amoxicillin trihydrate / clavulanate potassium), when used under labeled conditions of use are safe and effective.

The drug is restricted to use by or on the order of a licensed veterinarian because professional expertise is judged to be critical for the periodontal infections and for the safe use of the product.

Under section 512(c)(2)(F)(iii) of the Federal Food Drug and Cosmetic Act, this approval for non food producing animals qualifies for THREE years of marketing exclusivity beginning on the date of approval because the supplemental application contains substantial evidence of the effectiveness of the drug involved, or any studies of animal safety, required for the approval of the application and conducted or sponsored by the applicant. The three years of marketing exclusivity applies only to the treatment of periodontal infections caused by susceptible strains of aerobic and anaerobic bacteria for which the application was approved.

The following patent numbers apply to NADA #55-101 for Clavamox® Drops:

Patent #	Expiration date
4367175	01/04/2000
4525352	06/25/2002
4529720	07/16/2002
4560552	12/24/2002

## VI. ATTACHMENTS

1. Revised package insert
2. Revised carton label

Copies of applicable labels may be obtained by writing to the:

Food and Drug Administration  
Freedom of Information Staff (HFI-35)  
5600 Fishers Lane  
Rockville, MD 20857

Or requests may be sent via fax to: (301) 443-1726. If there are problems sending a fax, call (301) 443-2414.

The format of this FOI Summary document has been modified from its original form to conform with Section 508 of the Rehabilitation Act (29 U.S.C. 794d). The content of this document has not changed.