

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

NADA 138-657

B. Sponsor

VET LABS Limited, Inc.

C. Established Name

nitrofurazone ointment

D. Dosage Form

Topical ointment containing 0.2% w/w nitrofurazone in a water-soluble base.

E. Dispensing Status

OTC

F. Dosage Regimen

Apply directly on the lesion with a spatula or first place on a piece of gauze. Use of a bandage is optional. The preparation should remain on the lesion for at least 24 hours. The dressing may be changed several times daily or left on the lesion for a longer period.

G. Route of Administration

Topical

H. Indication

For the prevention or treatment of surface bacterial infections of wounds, burns, and cutaneous ulcers of dogs, cats, and horses (not for food use).

II. EFFECTIVENESS AND TARGET ANIMAL SAFETY

Nitrofurazone Ointment (Furacin Dressing Veterinary, NADA 6-475) was the subject of a review by the National Academy of Sciences/National Research Council (NAS/NRC), Drug Efficacy Study Group, the results of which were published in the Federal Register of January 19, 1979 (44 FR 4014). NAS/NRC concluded, and FDA concurred that the product was "effective" for the prevention or treatment of surface bacterial infections of wounds, burns, and cutaneous ulcers. Due to concern for the safety of residues from food-producing animals, FDA concluded that use of this and other NAS/NRC reviewed nitrofurazone topical products must be limited to dogs, cats, and horses (not intended for food use). The Federal Register publication dated January 19, 1979, on Nitrofurazone Topical Preparations for use in non-food animals, states that applications providing for the effective conditions of use identified in that notice need not include data required by 21 CFR 514. 111 to establish the effectiveness of the drug for these uses.

Under Center for Veterinary Medicine policy, the principles of 21 CFR 320.22 providing for a waiver of the requirement for submission of in vivo bioavailability and bioequivalence are applied to NAS/NRC reviewed topicals which have been found to be effective. Therefore, such data were neither required nor submitted.

III. HUMAN FOOD SAFETY

Data on human safety, pertaining to consumption of drug residues in food, were not required for approval of this NADA. The drug is approved for use only on dogs, cats, and horses (not intended for food use) and is labeled: Warning: Do not use on horses intended for food.

IV. AGENCY CONCLUSIONS

The data submitted in support of this NADA comply with the conclusions of NAS/NRC review as concurred in by FDA and with CVM's policy concerning bioequivalence of topical drugs and demonstrate the Nitrofurazone Ointment 0.2%, when used under its approved conditions of use is safe and effective for the prevention or treatment of surface bacterial infections of wounds, burns, and cutaneous ulcers of dogs, cats, and horses (not for food use).

The drug is labeled for over-the-counter (OTC) use for the following reasons.

- a. It is a generic topical antibacterial preparation with a long OTC marketing history of safe and effective use for the above indications.
- b. A diagnosis by a veterinarian is not necessary, as the labeled use conditions are easily recognized by laymen. In view of the above, it is approved for over-the-counter marketing because adequate directions for use by laymen can be written.

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.