Approval Date: July 7, 1989

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

NADA 140-851

B. Sponsor

Hess & Clark, Inc.
7th & Orange Sts.
Ashland, OH 44805

C. Proprietary Name

NFZ Wound Dressing

D. Established Name

0.2% nitrofurazone dressing (water soluble) veterinary

E. Dosage Form

Water soluble antibacterial ointment containing 0.2% nitrofurazone

F. Route of Administration

Topical

G. 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 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 evidence 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 for food use) and is labeled: Warning: Do no use on horses intended for food.

Human safety relative to possession, handling and administration:

Labeling contains adequate warning statements. Labeling states:

"HUMAN WARNINGS:

Carcinogenesis: Nitrofurazone has been shown to produce mammary tumors in rats and ovarian tumors in mice.

Some people may be hypersensitive to this product. Either wear gloves when applying, or wash hands afterwards."

In addition, the labeling contains the following statement:

"KEEP OUT OF REACH OF CHILDREN"

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 that NFZ Wound Dressing (0.2% nitrofurazone ointment), when used under its approved conditions of use, is safe and effective for the prevention or treatment of bacterial infections of wounds, burns and cutaneous ulcers on dogs, cats and horses (not for food use).

The drug is labeled for over-the-counter 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 the layman.

In view of the above, it is approved for OTC marketing because adequate directions for use by the layman can be written.

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