

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

NADA 132-337

B. Sponsor

Miles, Inc.
Agriculture Division Animal Health Products
P. O. Box 390
Shawnee Mission, Kansas 66201

C. Proprietary Name

Proban® 90 mg tablets

D. Established Name

cythioate

E. Dosage Form

90 mg tablet

F. Dispensing Status

Rx

G. Dosage Regimen

30 mg cythioate per 20 pounds of body weight every third day or twice a week

H. Route of Administration

Oral

I. Indication

The indications for use remain the same as currently approved. Proban® tablets are indicated for the control of fleas on infested dogs.

J. Effect of Supplement

This supplement amends the NADA to provide for a 90 mg tablet and minor labeling changes. The currently approved tablet is 30 mg.

II. TARGET ANIMAL SAFETY AND EFFECTIVENESS

The approval of the 90 mg tablet did not require safety and effectiveness data, as the dosage remains the same.

The supplement provides for minor revisions to the labeling for the product, as follows:

1. The veterinary prescription legend has been moved from the back panel to the front panel of the package insert.
2. The "Indications" section has been revised to read, as follows:

"INDICATIONS: PROBAN (cythioate) is indicated for the control of fleas on infested dogs. It may be used to treat dogs of all ages (see contraindications)."
3. The replacement of the "Duration of Treatment" section with an "Efficacy" section to read, as follows:

EFFICACY: Well controlled laboratory tests have demonstrated the effectiveness of PROBAN in killing fleas on the dog, when administered according to the recommended treatment schedule for one week. When used on a regular basis, PROBAN also kills fleas that infest the dog between treatments. Clinical field trials confirmed these results.

Note: As with all flea control products for dogs, treatment with Proban ® must be used with a control program aimed at reducing flea populations and flea breeding areas in the dog's environment (bedding, carpets, yard, etc. - see Precautions)."
4. An addition to the "Precautions" section relating to a controlled safety study where no adverse reactions were observed in dogs which received three times the labeled dosage for a one year duration.
5. The addition of the FDA approval statement

III. HUMAN FOOD SAFETY

A. Human Food Safety

Data on human safety, pertaining to consumption of drug residues in food, were not required for approval of this NADA. The formulation is labeled for use in dogs only.

B. Human Safety Relative to Possession, Handling and Administration

The labeling contains adequate directions for use and thus poses no human safety hazard. The labeling contains adequate "WARNING" and "CAUTION" statements.

IV. AGENCY CONCLUSIONS

Under the Center's supplemental approval policy 21 CFR 514.106 (b)(2), this is a Category II change because it provides for a new tablet size. The approval of this supplemental new animal drug application had no adverse effect on the safety and effectiveness of this new animal drug. Accordingly, this approval did not require a re-evaluation of the safety and effectiveness data in the parent application.

Under Section 512 (c)(2)(F)(iii) of the Generic Animal Drug and Patent Term Restoration Act of 1988, this supplemental new animal drug application does not qualify for marketing exclusivity. The additional studies submitted with the supplement were conducted as requested by FDA to correct deficiencies in the original data supporting

safety and efficacy of the 1968 approval, and were not essential to the approval of this supplement.

The agency has determined under 21 CFR 25.24(d)(1)(iii) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

The expertise of a trained professional is required for a definitive diagnosis, to monitor the results of treatment, and determine the occurrence of adverse effects; therefore, the drug is a prescription product.

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.