ANADA Approval Date: Oct. 22, 1999

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-244

TUCOPRIM® Powder
TUCOPRIM® (sulfadiazine and trimethoprim) is indicated for the control of bacterial infections of horses during treatment of acute strangles, respiratory tract infections, acute urogenital infections, wound infections, and abscesses.

Sponsored by:

Pharmacia & Upjohn Co.
7000 Portage Road
Kalamazoo, Michigan 49001

FREEDOM OF INFORMATION SUMMARY

1. General Information

ANADA:	200-244
Sponsor:	Pharmacia & Upjohn Co. 7000 Portage Road Kalamazoo, Michigan 49001
Trade Name:	TUCOPRIM® Powder
Generic Name:	trimethoprim/sulfadiazine powder
Dosage Form:	TUCOPRIM Powder is a formulation of 333 mg sulfadiazine and 67 mg trimethoprim per gram in a calcium carbonate (limestone) base.
How Dispensed:	Rx
Route of Administration:	Orally in the feed
Species:	Equine
Indications for Use:	For control of bacterial infections of horses during treatment of acute strangles, respiratory tract infections, acute urogenital infections, wound infections, and abscesses.
Labeled Dosage:	The recommended dosage is 3.75 g TUCOPRIM Powder per 110 lbs (50 kg) body weight. This provides 250 mg of trimethoprim and 1250 mg of sulfadiazine per 110 lbs body weight. The product should be administered once daily in a small amount of palatable feed for five to seven days or for two or three days after clinical symptoms have subsided.
Pioneer Product:	UNIPRIM Powder, manufactured by Macleod Pharmaceuticals, Inc. (ANADA 200-033)

2. Target Animal Safety and Drug Effectiveness

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act (GADPTRA, 53 FR 50460, 15 December 1988, First GADPTRA Policy Letter), an abbreviated new animal drug application (ANADA) may be submitted for a generic version of an approved new animal drug. New target animal safety, drug effectiveness data, and human food safety data are not required. The sponsor relies on the efficacy and target animal safety of the pioneer product, based on established bioequivalence between the two formulations. In this case, a waiver from the requirement to conduct an *in vivo* bioequivalence study (fifth GADPTRA Policy Letter: Bioequivalence Guideline, 12 April 1990) was granted based on the chemical similarity of the products. The generic product contains the same active and inactive ingredients, all in the same concentration as the pioneer product. The generic product is also the same dosage form, an oral powder, as the pioneer product.

3. Human Safety

This product has the following WARNING statements on the label, "Not for human use. Keep out of reach of children. Not for use in horses intended for food".

Human food safety data are not required.

4. Agency Conclusions

This ANADA submitted under section 512(b) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the Act and demonstrates that when Tucoprim® Powder (sulfadiazine and trimethoprim oral powder) is used under the proposed conditions of use, it is safe and effective for its labeled indications.

Attachments:
generic product labeling
pioneer product labeling