Date of Approval: September 4, 2003

FREEDOM OF INFORMATION SUMMARY

ANADA 200-330

ANIMAX Cream
(nystatin-neomycin sulfate-thiostrepton-triamcinolone acetonide cream)

Dogs and Cats

Indications: Topical dermatologic disorders characterized by inflammation and dry or exudative dermatitis, particularly associated with bacterial or candidal (*Candida albicans*) infections for use in cats and dogs only.

Sponsored by:
Altana Inc.
Melville, NY 11747

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

a. File Number:	ANADA 200-330
b. Sponsor:	Altana Inc. 60 Baylis Road Melville, NY 11747 Labeler Code: 025463
c. Established Name:	Nystatin, neomycin sulfate, thiostrepton, and triamcinolone acetonide
d. Proprietary Name:	ANIMAX Cream
e. Dosage Form:	Topical Cream
f. How Supplied:	7.5 and 15 gram tubes
g. How Dispensed:	Rx
h. Amount of Active Ingredients:	Each gram contains: nystatin-100,000 units, neomycin sulfate-2.5 mg, thiostrepton-2,500 units, triamcinolone acetonide-1.0 mg
i. Route of Administration:	Topical
j. Species/Class:	Dogs and cats
k. Recommended Dosage:	Application may range from once daily to once a week. For severe condition, apply 2 to 3 times daily**,** if necessary**.**
l. Pharmacological Category:	Anti-inflammatory, antipruritic, antifungal, and antibacterial
m. Indications:	Topical dermatologic disorders characterized by inflammation and dry or exudative dermatitis, particularly associated with bacterial or candidal infections.
n. Pioneer Product:	PANOLOG Cream; NADA 096-676; Fort Dodge Animal Health

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) an Abbreviated New Animal Drug Application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). New target animal safety and effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily, the ANADA sponsor is required to show that the generic product is bioequivalent to the pioneer, which has been shown to be safe and effective. If bioequivalence is demonstrated through a clinical endpoint study, then a tissue residue study to establish the withdrawal time for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from the requirement of an *in vivo* bioequivalence study. (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based upon the formulation characteristics of the generic product, Altana Inc. was granted a waiver on August 25, 1998, from the requirement for an *in vivo* bioequivalence study for ANIMAX Cream. The generic and pioneer products contain the same active and inactive ingredients in similar formulations. The pioneer product, PANOLOG, the subject of Fort Dodge Animal Health's NADA 96-676, was approved on July 11, 1978.

3. HUMAN SAFETY:

This drug is indicated for use in dogs and cats, which are non-food animals. Because this new animal drug is not intended for use in food-producing animals, data on human safety pertaining to drug residues in food were not required for approval of this ANADA.

Human Warning is provided on the product label as follows:
"Not for Ophthalmic Use"

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 ANIMAX Cream, when used under its proposed conditions of use, is safe and effective for its labeled indications.

5. ATTACHMENTS:

Facsimile generic labeling and currently approved pioneer labeling are attached:

Pioneer Labeling for NADA 96-676:
PANOLOG-7.5 and 15 gram tubes
Insert

Generic Labeling for ANADA 200-330
ANIMAX Cream- 7.5 and 15 gram tubes
Insert