Date of Approval: January 29, 2007

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION

NADA 140-854

SYNANTHIC (oxfendazole) Bovine Dewormer Suspension, 22.5%

To change the marketing status for use of the 22.5% suspension in cattle from prescription status to over-the-counter status.

Sponsored by:

Fort Dodge Animal Health

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I. GENERAL INFORMATION:

A. File Number:	NADA 140-854
B. Sponsor:	Fort Dodge Animal Health Division of Wyeth 800 Fifth St. NW. Fort Dodge, IA 50501 Drug Labeler Code: 000856
C. Proprietary Name:	SYNANTHIC (oxfendazole) Bovine Dewormer Suspension, 22.5%
D. Established Name:	Oxfendazole
E. Pharmacological Category:	Antiparasitic
F. Dosage Form:	Oral suspension
G. Amount of Active Ingredient:	225 mg/mL and 90.6 mg/mL This supplemental approval only affects the 225 mg/mL suspension.
H. How Supplied:	500 mL and 1000 mL bottles (22.5% bovine suspension) 1000 mL and 4000 mL bottles (9.06% bovine suspension) 1000 mL bottle (9.06% equine suspension)
I. How Dispensed:	OTC
J. Dosage:	Cattle: 4.5 mg oxfendazole/kg body weight (2.05 mg/lb)
K. Route of Administration:	Oral
L Species/Classes:	Bovine and Equine. This supplemental approval only affects cattle.

M. Indications: For the removal and control of the following parasites in cattle:

Lungworms:

Dictyocaulus viviparus (Adult, L4)

Stomach worms:
Barberpole worms - *Haemonchus contortus* (Adult) and
Haemonchus placei (Adult)
Small Stomach Worms – *Trichostrongylus axei* (Adult)
Brown Stomach Worms – *Ostertagia ostertagi*
(Adult, L4,and inhibited L4)

Intestinal Worms:
Nodular Worms – *Oesophagostomum radiatum* (Adult)
Hookworms – *Bunostomum phlebotomum* (Adult)
Small Intestinal Worms – *Cooperia punctata* (Adult, L4),
Cooperia oncophora (Adult, L4), and
Cooperia mcmasteri (Adult, L4)
Tapeworms – *Moniezia benedeni* (Adult)

N. Effects of Supplement: This supplement provides for a change in marketing status from prescription (Rx) to over-the-counter (OTC) by removing the intraruminal route of administration on the 22.5% suspension.

II. EFFECTIVENESS:

A. Dosage Characterization:

This supplemental approval does not change the previously approved 4.5 mg oxfendazole/kg body weight dosage. The FOI Summary for the original approval of NADA 140-854 dated September 17, 1990, contains dosage characterization information for cattle.

B. Substantial Evidence:

CVM did not require effectiveness studies for this supplemental approval. The FOI Summary for the original approval of NADA 140-854 dated September 17, 1990, contains a summary of studies that demonstrate effectiveness of the drug for cattle. In the original approval of the 22.5% suspension, the marketing status was prescription due to the intraruminal route of administration, in addition to the oral route. The intraruminal route is being removed from the label, thus the marketing status is changed to over-the-counter as adequate directions for use are written and likely to be followed in practice for the lay person.

III. TARGET ANIMAL SAFETY:

CVM did not require additional target animal safety data for this supplemental approval. The FOI Summary for the original approval of NADA 140-854 dated September 17, 1990, contains a summary of target animal safety studies for cattle.

IV. HUMAN FOOD SAFETY:

A. Toxicology:

CVM did not require toxicology studies for this supplemental approval. The FOI Summary for the original approval of NADA 140-854 dated September 17, 1990, contains a summary of all toxicology studies.

B. Residue Chemistry:

CVM did not require residue chemistry studies for this supplemental approval. The FOI Summary for the original approval of NADA 140-854 dated September 17, 1990, contains a summary of residue chemistry studies for cattle.

C. Microbial Food Safety:

CVM considered the impact of the use of 4.5 mg/kg body weight SYNANTHIC (oxfendazole) Bovine Dewormer Suspension, 22.5% for the removal of various internal parasites in cattle on antimicrobial resistance development in bacteria of public health concern. A microbial food safety assessment was not necessary at this time.

D. Analytical Method for Residues:

The FOI Summary for the original approval of NADA 140-854 dated September 17, 1990, contains the analytical method summaries for SYNANTHIC (oxfendazole) Bovine Dewormer Suspension, 22.5% in cattle.

V. USER SAFETY:

The product labeling contains the following information regarding safety to humans handling, administering, or exposed to SYNANTHIC (oxfendazole) Bovine Dewormer Suspension, 22.5%:

CAUTION: Use only as directed. Keep out of reach of children. Not for human use.

To request a material safety data sheet, call 1-800-211-2573.

VI. AGENCY CONCLUSIONS:

The data submitted in support of this NADA satisfy the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act and 21 CFR Part 514. The data demonstrate that SYNANTHIC (oxfendazole) Bovine Dewormer Suspension, when administered according to the label, is safe and effective for removal and control of various internal parasites. Additionally, data demonstrate that residues in food products derived from cattle treated with SYNANTHIC (oxfendazole) Bovine Dewormer Suspension will not represent a public health concern when the product is used according to the label.

A. Marketing Status:

The Agency has concluded that this product shall have over-the-counter marketing status because adequate directions for use have been written for the layperson and the conditions of use prescribed on the label are likely to be followed in practice.

B. Exclusivity:

This approval does not qualify for marketing exclusivity under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act.

C. Supplemental Applications:

This supplemental NADA did not require a reevaluation of the safety or effectiveness data in the original NADA (21 CFR §514.106(b)(2)(viii)).

D. Patent Information:

The sponsor did not submit any patent information with this application.

VII. ATTACHMENTS:

Facsimile Labeling:

A. 500 mL bottle label
B. 500 mL carton label
C. 1000 mL bottle label
D. 1000 mL carton label