HFV-305

Date of Approval: JAN 2 9 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

2007-140-854

FOIS 2

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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

NDC 0856-0881-80

Synanthic®

OXFENDAZOLE

Bovine Dewormer Suspension, 22.5%

For Animal Use Only

Manufactured by a non-sterilizing process.

FORT DODGE®

Each mL contains 225 mg of oxfendazole. Shake well before use. Avoid freezing. Protect from excessive heat. Store at temperatures not to exceed 104°F (40°C).

Consult a veterinarian for assistance in the diagnosis, treatment and control of parasitism.

INDICATIONS: Synanthic Bovine Dewormer Suspension, 22.5%, is a broad-spectrum anthelmintic effective for the removal and control of the following parasites in cattle: lungworms, roundworms (including inhibited forms of *Ostertagia ostertagi*) and tapeworms, as indicated below:

Lungworms:	*Dictyocaulus viviparus* (Adult, L4)
Stomach Worms	
Barberpole Worms	*Haemonchus contortus* (Adult) *Haemonchus placei* (Adult)
Small Stomach Worms	*Trichostrongylus axei* (Adult)
Brown Stomach Worms	*Ostertagia ostertagi* (Adult, L4, inhibited L4)
Intestinal Worms	
Nodular Worms	*Oesophagostomum radiatum* (Adult)
Hookworms	*Bunostomum phlebotomum* (Adult)
Small Intestinal Worms	*Cooperia punctata* (Adult, L4) *Cooperia oncophora* (Adult, L4) *Cooperia mcmasteri* (Adult, L4)
Tapeworms	*Moniezia benedeni* (Adult)

ADMINISTRATION AND DOSAGE: Synanthic Bovine Dewormer Suspension, 22.5%, is supplied in 500 mL packages containing 225 mg of oxfendazole per mL. The recommended dose for cattle is 2.05 mg/lb (4.5 mg/kg) of body weight. Synanthic Bovine Dewormer Suspension, 22.5%, should be administered orally by accurate dose syringe at the rate of 1 mL per 110 lb (50 kg) of body weight. This product should be shaken well immediately prior to use.

Remove Cap and Protective Seal and Replace with Blue Cap Prior to Use. Do Not Squeeze Sides of Bottle.

WARNING: Cattle must not be slaughtered until 7 days after treatment. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age.

SAFETY: There are no contraindications for the use of Synanthic Bovine Dewormer Suspension, 22.5%, in cattle.

DIRECTIONS: Determine the proper dose according to estimated body weight. Administer orally. The recommended dose of 2.05 mg/lb (4.5 mg/kg) is achieved when 1 mL of the suspension is given for each 110 lb (50 kg) of body weight.

EXAMPLES:

CATTLE WEIGHT	DOSE
110 lb (50 kg)	1.0 mL
220 lb (100 kg)	2.0 mL
330 lb (150 kg)	3.0 mL
440 lb (200 kg)	4.0 mL
550 lb (250 kg)	5.0 mL
660 lb (300 kg)	6.0 mL
770 lb (350 kg)	7.0 mL
880 lb (400 kg)	8.0 mL
990 lb (450 kg)	9.0 mL
1100 lb (500 kg)	10.0 mL

Treatment may be repeated in 4–6 weeks.

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

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NET CONTENT: 500 mL

(treats 110 cattle weighing approximately 500 lbs each)

NADA 140-854, Approved by FDA

U.S. Patent No. 3,929,821; 4,080,461; and others.

Fort Dodge Animal Health
Fort Dodge, Iowa 50501 USA

01426

0134D

INDICATIONS: Synanthic Bovine Dewormer Suspension, 22.5%, is a broad-spectrum anthelmintic effective for the removal and control of the following parasites in cattle: lungworms, roundworms (including inhibited forms of *Ostertagia ostertagi*) and tapeworms, as indicated below:

Lungworms:	*Dictyocaulus viviparus* (Adult, L_4)
Stomach Worms	
Barberpole Worms	*Haemonchus contortus* (Adult) *Haemonchus placei* (Adult)
Small Stomach Worms	*Trichostrongylus axei* (Adult)
Brown Stomach Worms	*Ostertagia ostertagi* (Adult, L_4, inhibited L_4)
Intestinal Worms	
Nodular Worms	*Oesophagostomum radiatum* (Adult)
Hookworms	*Bunostomum phlebotomum* (Adult)
Small Intestinal Worms	*Cooperia punctata* (Adult, L_4) *Cooperia oncophora* (Adult, L_4) *Cooperia mcmasteri* (Adult, L_4)
Tapeworms	*Moniezia benedeni* (Adult)

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110 lb (50 kg)	1.0 mL
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880 lb (400 kg)	8.0 mL
990 lb (450 kg)	9.0 mL
1100 lb (500 kg)	10.0 mL

Treatment may be repeated in 4–6 weeks.

U.S. Patent No. 3,929,821; 4,080,461; and others.

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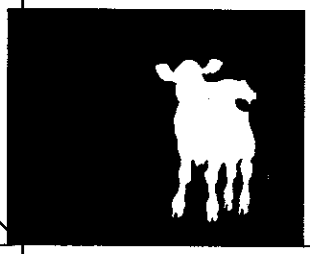
Fort Dodge Animal Health
Fort Dodge, Iowa 50501 USA

Lot:
Exp. Date:

Synanthic
OXFENDAZOLE
Bovine Dewormer Suspension, 22.5%

22.5%



Bovine Dewormer Suspension, 22.5%

Synanthic
OXFENDAZOLE

For Animal Use Only

FORT DODGE

7 26287 10138 3

WARNING: Cattle must not be slaughtered until 7 days after treatment. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age.

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

Shake well before use. Avoid freezing. Protect from excessive heat. Store at temperatures not to exceed 104°F (40°C).

NET CONTENT: 500 mL

22.5%

Bovine Dewormer Suspension, 22.5%

NDC 0856-0691 00

Synanthic®
OXFENDAZOLE

For Animal Use Only

Manufactured by a non-sterilizing process.

FORT DODGE

Each mL contains 225 mg of oxfendazole.

Consult a veterinarian for assistance in the diagnosis, treatment and control of parasites.

Shake well before use. Avoid freezing. Protect from excessive heat. Store at temperatures not to exceed 104°F (40°C).

NET CONTENT: 500 mL

(treats 110 cattle weighing approximately 990 lbs each)

NADA 140-934, Approved by FDA

22.5%

Bovine Dewormer Suspension, 22.5%

Synanthic
OXFENDAZOLE

For Animal Use Only

Manufactured by a non-sterilizing process.

FORT DODGE

Each mL contains 225 mg of oxfendazole.

Consult a veterinarian for assistance in the diagnosis, treatment and control of parasites.

SAFETY: There are no contraindications for the use of Synanthic Bovine Dewormer Suspension 22.5%, in cattle.

Shake well before use. Avoid freezing. Protect from excessive heat. Store at temperatures not to exceed 104°F (40°C).

NET CONTENT: 500 mL

NDC 0856-0881-81

Synanthic®

OXFENDAZOLE

Bovine Dewormer Suspension, 22.5%

For Animal Use Only

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FORT DODGE®

INDICATIONS: Synanthic Bovine Dewormer Suspension, 22.5%, is a broad-spectrum anthelmintic effective for the removal and control of the following parasites in cattle: lungworms, roundworms (including inhibited forms of *Ostertagia ostertagi*) and tapeworms, as indicated below:

Lungworms:	*Dictyocaulus viviparus* (Adult, L_4)
Stomach Worms	
Barberpole Worms	*Haemonchus contortus* (Adult) *Haemonchus placei* (Adult)
Small Stomach Worms	*Trichostrongylus axei* (Adult)
Brown Stomach Worms	*Ostertagia ostertagi* (Adult, L_4, inhibited L_4)
Intestinal Worms	
Nodular Worms	*Oesophagostomum radiatum* (Adult)
Hookworms	*Bunostomum phlebotomum* (Adult)
Small Intestinal Worms	*Cooperia punctata* (Adult, L_4) *Cooperia oncophora* (Adult, L_4) *Cooperia mcmasteri* (Adult, L_4)
Tapeworms	*Moniezia benedeni* (Adult)

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Remove Cap and Protective Seal and Replace with Blue Cap Prior to Use. Do Not Squeeze Sides of Bottle.

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

NET CONTENT: 1000 mL (one Liter)

(treats 220 cattle weighing approximately 500 lbs each)

NADA 140-854, Approved by FDA

WARNING: Cattle must not be slaughtered until 7 days after treatment. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age.

SAFETY: There are no contraindications for the use of Synanthic Bovine Dewormer Suspension, 22.5%, in cattle.

DIRECTIONS: Determine the proper dose according to estimated body weight. Administer orally. The recommended dose of 2.05 mg/lb (4.5 mg/kg) is achieved when 1 mL of the suspension is given for each 110 lb (50 kg) of body weight.

EXAMPLES:

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U.S. Patent No. 3,929,821; 4,080,461; and others.

Fort Dodge Animal Health
Fort Dodge, Iowa 50501 USA

01426 0135D

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Small Stomach Worms	*Trichostrongylus axei* (Adult)
Brown Stomach Worms	*Ostertagia ostertagi* (Adult, L_4, inhibited L_4)
Intestinal Worms	
Nodular Worms	*Oesophagostomum radiatum* (Adult)
Hookworms	*Bunostomum phlebotomum* (Adult)
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Treatment may be repeated in 4–6 weeks.

U.S. Patent No. 3,929,821; 4,080,461; and others.

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Fort Dodge Animal Health
Fort Dodge, Iowa 50501 USA

Lot:
Exp Date:

Synanthic
OXFENDAZOLE
Bovine Dewormer Suspension, 22.5%

22.5%

Bovine Dewormer Suspension, 22.5%

Synanthic
OXFENDAZOLE

FORT DODGE®

For Animal Use Only

WARNING: Cattle must not be slaughtered until 7 days after treatment. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age.

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

Shake well before use. Avoid freezing. Protect from excessive heat. Store at temperatures not to exceed 104°F (40°C).

NET CONTENT: 1000 mL (one Liter)

22.5%

Bovine Dewormer Suspension, 22.5%

NDC 0856-0851-01

Synanthic®
OXFENDAZOLE

FORT DODGE®

For Animal Use Only

Manufactured by a non-sterilizing process.

Each mL contains 225 mg of oxfendazole.

Consult a veterinarian for assistance in the diagnosis, treatment and control of parasitism.

Shake well before use. Avoid freezing. Protect from excessive heat. Store at temperatures not to exceed 104°F (40°C).

NET CONTENT: 1000 mL (one Liter)
(treats 220 cattle weighing approximately 500 lbs each)
NADA 140-864, Approved by FDA

22.5%

Bovine Dewormer Suspension, 22.5%

Synanthic
OXFENDAZOLE

FORT DODGE®

For Animal Use Only

Manufactured by a non-sterilizing process.

Each mL contains 225 mg of oxfendazole.

Consult a veterinarian for assistance in the diagnosis, treatment and control of parasitism.

SAFETY: There are no contraindications for the use of Synanthic Bovine Dewormer Suspension, 22.5%, in cattle.

Shake well before use. Avoid freezing. Protect from excessive heat. Store at temperatures not to exceed 104°F (40°C).

NET CONTENT: 1000 mL (one Liter)