Supplemental Approval(s)

This section displays the change(s) to the original approval. To read the complete approval, please refer to 21CFR Parts 500 and the related Federal Register notices.

NADA Number: 131-675

Trade Name: SafeGuard® Dewormer 20% Type A Medicated Article
Ingredients: Fenbendazole
Sponsor: Intervet, Inc.
Approval Date: September 5, 2008
Exclusivity: 3 year

This supplemental approval provides use of the product to manufacture a free choice, liquid Type C medicated feed for use in dairy and beef cattle for removal and control of lungworm (*Dictyocaulus viviparus*) in addition to existing indications for the following parasites: Stomach worms: Barberpole worms (*Haemonchus contortus*), brown stomach worms (*Ostertagia ostertagi*), small stomach worms (*Trichostrongylus axei*). Intestinal worms: Hookworms (*Bunostomum phlebotomum*), thread-necked intestinal worms (*Nematodirus helvetianus*), small intestinal worms (*Cooperia punctata* and *C. oncophora*). Bankrupt worms (*Trichostrongylus colubriformis*). Nodular worms (*Oesophagostomum radiatum*).

The three year exclusivity period applies only to the newly added indication, the removal and control of lungworm (*Dictyocaulus viviparous*).

21 CFR 558.258 73 FR 58873

NADA Number: 141-209

Trade Name: Excede™ Sterile Suspension
Ingredients: Ceftiofur Crystalline Free Acid
Sponsor: Pharmacia & Upjohn Co. a Division of Pfizer, Inc.
Approval Date: August 15, 2008
Exclusivity: 3 year

This supplemental approval provides for the treatment of bovine foot rot (interdigital necrobacillosis) associated with *Fusobacterium necrophorum* and *Porphyromonas levii* in beef, non-lactating dairy, and lactating dairy cattle.

The three year exclusivity period applies only to the newly added indication, the treatment of bovine foot rot associated with *Fusobacterium necrophorum* and *Porphyromonas levii*.

21 CFR 522.313a 73 FR 58871

NADA Number: 141-244

Trade Name: Draxxin® Injectable Solution
Ingredients: Tulathromycin
Sponsor: Pfizer, Inc.
Approval Date: August 28, 2008
Exclusivity: 3 year

This supplemental approval provides for the treatment of bovine foot rot (interdigital necrobacillosis) associated with *Fusobacterium necrophorum* and *Porphyromonas levii* in beef and non-lactating dairy cattle.

The three year exclusivity period applies only to the newly added indication, the treatment of bovine foot rot associated with *Fusobacterium necrophorum* and *Porphyromonas levii*.

21 CFR 522.2630 73 FR 58872

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 2008 list were published in the Federal Register in October 2008.

NADA Number: 141-230

Trade Name: Previcox® Chewable Tablets
Ingredients: Firocoxib
Sponsor: Merial Ltd.
Approval Date: September 23, 2008
Exclusivity: 3 year

This supplemental approval provides for the control of post-operative pain and inflammation associated with orthopedic surgery in dogs.

The three year exclusivity period applies only to the newly added indication, the control of post-operative pain and inflammation associated with orthopedic surgery in dogs.

21 CFR 520.928 73 FR64885

Patent Information

NADA Number: 107-957

Patent Number: 5,496,931
Expiration Date: March 5, 2013

Minor Labeling Supplement(s)

NADA Number: 065-506

Trade Name: Combi-Pen-48®
Ingredients: Penicillin G benzathine and penicillin G procaine
Sponsor: Cross Vetpharm Group Ltd.

The effect of the supplement is that the scientific name of the organism *Corynebacterium pyrogenes* has been changed to *Actinomyces pyogenes* in the package insert.

NADA Number: 006-677

Trade Name: 20% Sulfaquinoxaline Sodium Solution
Ingredients: Sodium sulfaquinoxaline
Sponsor: IVX Animal Health, Inc.

The effect of the supplement is that the label is changed, to better to reflect the existing CFR wording:

1) under the “Indications” sections for “Chickens”, “Turkeys”, and “Chickens and Turkeys”, the phrase “For the control of…” has been changed to “As an aid in the control of outbreaks of…”;

2) under the “Indications” section for “Chickens and Turkeys”, the acute fowl cholera and fowl typhoid references have been reversed so that the acute fowl cholera indication now appears before the fowl typhoid indication; and

3) under the “Residue Warnings section,” the statement “Do not give to laying chickens or laying turkeys in production for food” has been replaced with “Do not medicate chickens or turkeys producing eggs for human consumption.”