

## 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 June 2008.

### New Approvals

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#### NADA Number: 141-286

Trade Name: Panacur® Plus Soft Chews  
Ingredients: Ivermectin, Fenbendazole, and praziquantel  
Sponsor: Intervet, Inc.  
Approval Date: May 9, 2008  
Status: Rx  
Route: Oral  
Species: Dogs  
Drug Form: Chewable Tablets  
Concentration: 2.16 g small chews: 454 mg fenbendazole  
27 mcg ivermectin  
23 mg praziquantel  
5.4 g large chews: 1,134 mg fenbendazole  
68 mcg ivermectin  
57 mg praziquantel  
Indications: For the treatment and control of adult *Toxocara canis* (roundworm), *Ancylostoma caninum* (hookworm), *Trichuris vulpis* (whipworm), and *Dipylidium caninum* (tapeworm), and for the prevention of heartworm disease caused by *Dirofilaria immitis* in adult dogs.  
Patents: None  
Exclusivity: 3 years  
  
21 CFR 520.1200 73 FR 33692

#### ANADA Number: 200-332

Trade Name: Butorphanic™ Injection  
Pioneer Product: 135-780  
Ingredients: Butorphanol tartrate  
Sponsor: Lloyd, Inc.  
Approval Date: May 1, 2008  
Status: Rx  
Route: Intravenous Injection  
Species: Horses  
Drug Form: Solution  
Concentration: 10 mg butorphanol base per mL as butorphanol tartrate  
Indications: Butorphanic Injection is indicated for relief of pain associated with colic in adult horses and yearlings. Clinical studies in the horse have shown that Butorphanic Injection alleviates abdominal pain associated with torsion, impaction, intussusception, and tympanic colic, and postpartum pain.  
  
21 CFR 522.246 73 FR 31357

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### Supplemental Approvals

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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: 041-275**

Trade Name: Tylan® 40 Sulfa-G  
Ingredients: Tylosin phosphate and sulfamethazine  
Sponsor: Elanco Animal Health, A Division of Eli Lilly & Co.  
Approval Date: May 8, 2008

This supplement removes “bloody scours” from the indication and updates the bacterial pathogens *Serpulina* to *Brachyspira*, and *Actinomyces* to *Arcanobacterium*.

21 CFR 558.630 73 FR 34184

#### **NADA Number: 141-203**

Trade Name: Deramaxx® Chewable Tablets  
Ingredients: Deracoxib  
Sponsor: Novartis Animal Health, US, Inc.  
Approval Date: May 16, 2008

This supplement provides for the addition of a 50-mg tablet size.

21 CFR 520.538 73 FR 33691

#### **NADA Number: 033-373**

Trade Name: Vetisulid® Powder  
Ingredients: Sulfachlorpyridazine sodium  
Sponsor: Fort Dodge Animal Health, Division of Wyeth Holdings Corp.  
Approval Date: May 19, 2008

This supplement provides for a revised food safety warning statement for oral use of sulfachlorpyridazine in the milk or milk replacer of ruminating calves. The revised warning reads: “Treated, ruminating calves must not be slaughtered for food during treatment or for 7 days after the last treatment.”

21 CFR 520.2200b 73 FR 35579

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### NADA Number: 141-189

Trade Name: ProHeart® 6 Sustained Release Injectable for Dogs  
Ingredients: Moxidectin  
Sponsor: Fort Dodge Animal Health, Division of Wyeth  
Approval Date: May 23, 2008

This supplement provides for the update of the warning, precaution, adverse reactions, and post-approval experience sections of the product labeling.

21 CFR 522.1451 73 FR 32586

### ANADA Number: 200-326

Trade Name: Bimectin™ Paste 1.87%  
Pioneer Product: 134-314  
Ingredients: Ivermectin  
Sponsor: Cross Vetpharm Group Ltd.  
Approval Date: May 23, 2008

This supplement provides for new indications for use claims no longer protected by a three-year exclusivity period that expired on April 2, 2006: **Large Strongyles** – *Craterostomum acuticaudatum*; **Small Strongyles** – *Petrovinema poculatum* and *Coronocyclus* spp. including *C. coronatus*, and *C. labratus*.

The generic labeling includes an additional indication for use claim for a parasite species not protected by exclusivity, *C. labiatus*.

21 CFR 520.246 73 FR 34184

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## Labeling Revisions

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### NADA Number: 122-272

Trade Name: Sulmet® Soluble Powder  
Ingredients: Sulfamethazine sodium  
Sponsor: Fort Dodge Animal Health, Division of Wyeth Holdings Corp.  
Effective Date: June 13, 2008

The scientific name of the target pathogen for infectious coryza has been revised from “*Haemophilus gallinarum*” to “*Avibacterium paragallinarum*”. The scientific name of the target pathogen for pullorum disease has been revised from “*Salmonella pullorum*” to “*Salmonella Pullorum*.”

### NADA Number: 139-191

Trade Name: Adams™ Dog Wormer Chewable Tablets  
Ingredients: Pyrantel pamoate  
Sponsor: Farnam Companies, Inc.  
Effective Date: June 12, 2008

Proprietary name change from “D-Worm” to “Adams™”.

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