

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 May 2008.

New Approvals

NADA Number: 141-285

Trade Name: Convenia®
Ingredients: Cefovecin sodium
Sponsor: Pfizer, Inc.
Approval Date: April 25, 2008
Status: Rx
Route: Subcutaneous injection
Species: Cats and dogs
Drug Form: Injectable
Concentration: Each mL of reconstituted sterile injectable lyophile contains 80 mg of cefovecin as the sodium salt.
Indications: For the treatment of skin infections (wounds and abscesses) caused by susceptible strains of *Pasteurella multocida* in cats; and the treatment of skin infections (secondary superficial pyoderma, abscesses and wounds) caused by susceptible strains of *Staphylococcus intermedius* and *Streptococcus canis* (Group G) in dogs.
Patents: 6,020,329 Expiration date: July 22, 2011
Exclusivity: 5 years

21 CFR 522.311 73 FR 29685

ANADA Number: 200-438

Trade Name: Petrem™
Pioneer Product: NADA 141-103
Ingredients: Sevoflurane
Sponsor: Minrad, Inc.
Approval Date: April 3, 2008
Status: Rx
Route: Inhalation
Species: Dogs
Drug Form: Solution
Concentration: 250 mL sevoflurane
Indications: Indicated for induction and maintenance of general anesthesia in dogs.

21 CFR 529.2150 73 FR 25507

Supplemental Approvals

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: 200-124

Trade Name: Flunixin Meglumine Injection
Ingredients: Flunixin meglumine
Sponsor: IVX Animal Health, Inc.
Approval Date: April 24, 2008

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

This supplemental application provides for intravenous use in lactating dairy cattle for control of pyrexia associated with acute bovine mastitis.

21 CFR 522970 73 FR 28036

Labeling Revisions

ANADA Number 200-326:

Trade Name: Bimectin™
Ingredients: Ivermectin
Sponsor: Cross Vetpharm Group Ltd.
Effective Date: May 23, 2008

This supplemental application provides for 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*.

NADA Number 006-084:

Trade Name: Sulmet®
Ingredients: Sulfamethazine sodium
Sponsor: Fort Dodge Animal Health, Division of Wyeth Holdings Corp.
Effective Date: May 21, 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*.”