

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were published in the Federal Register in January 2013.

Original Approvals

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

ANADA Number: 200-485

Trade Name: Meloxicam Injection
Pioneer: Metacam®
Ingredients: Meloxicam
Sponsor: Accord Healthcare, Inc.
Approval Date: December 21, 2012
Status: Rx
Route: **Dogs:** Intravenous or subcutaneous
Cats: Subcutaneous
Species: Dogs and cats
Drug Form: Sterile solution
Concentration: 5 mg/mL
Indications: **Dogs:** Meloxicam Injection 5 mg/mL Solution for Injection is indicated for the control of pain and inflammation associated with osteoarthritis.
Cats: For the control of postoperative pain and inflammation associated with orthopedic surgery, ovariohysterectomy and castration when administered prior to surgery.

21 CFR 522.1367

78 FR 5713-5715

ANADA Number: 200-491

Trade Name: Loxicom®
Pioneer: Metacam®
Ingredients: Meloxicam
Sponsor: Norbrook Laboratories, Ltd.
Approval Date: December 19, 2012
Status: Rx
Route: Intravenous or subcutaneous injection
Species: Dogs and cats
Drug Form: Solution for injection
Concentration: 5 mg/mL meloxicam solution
Indications: Loxicom® (meloxicam) 5 mg/mL Injectable sterile solution is indicated for the control of pain and inflammation associated with osteoarthritis in dogs and for the control of postoperative pain and inflammation associated with orthopedic surgery, ovariohysterectomy and castration when administered prior to surgery in cats.

21 CFR 522.1367

78 FR 5713-5715

ANADA Number: 200-496

Trade Name: AmproMed™ P for Poultry
Pioneer: AmproI®
Ingredients: Amprolium
Sponsor: Cross Vetpharm Group Ltd.
Approval Date: October 25, 2012
Status: OTC
Route: Oral
Species: Growing chickens, turkeys, and laying hens
Drug Form: Oral Solution
Concentration: 96 mg/mL (9.6%)
Indications: For the treatment of coccidiosis in growing chickens, turkeys, and laying hens.

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were published in the Federal Register in January 2013.

21 CFR 520.100

78 FR 22-25

ANADA Number: 200-543

Trade Name: Cefpodoxime Proxetil Tablets
Pioneer: SimpliceTM
Ingredients: Cefpodoxime proxetil
Sponsor: Putney, Inc.
Approval Date: December 14, 2012
Status: Rx
Route: Oral
Species: Dogs
Drug Form: Oral Tablet
Concentration: 100 mg, 200 mg
Indications: For the treatment of skin infections (wounds and abscesses) caused by susceptible strains of *Staphylococcus intermedius*, *Staphylococcus aureus*, *Streptococcus canis* (group G, β hemolytic), *Escherichia coli*, *Pasteurella multocida*, and *Proteus mirabilis*.

21 CFR 520.370

78 FR 5713-5715

Supplemental Approvals

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

NADA Number: 009-476

Trade Name: Nicarb[®] 25%
Ingredients: Nicarbazine
Sponsor: Phibro Animal Health Corp.
Approval Date: October 15, 2012

This supplement revises the nicarbazine dosage to a range consistent with the dosage approved for use in combination feeds.

21 CFR 558.366

78 FR 22-25

NADA Number: 098-378

Trade Name: Nicarb[®] 25% and bacitracin methylene disalicylate
Ingredients: Nicarbazine and bacitracin methylene disalicylate
Sponsor: Phibro Animal Health Corp.
Approval Date: October 25, 2012

This supplement revises the nicarbazine dosage to a range consistent with the dosage approved for use in combination feeds.

21 CFR 558.366

78 FR 22-25

Sponsor Address Change

Jurox Pty. Ltd.

Previous: 85 Gardiner Rd., Rutherford, NSW 2320, Australia

New: 85 Gardiner St., Rutherford, NSW 2320, Australia

21 CFR 510.600(c)

78 FR 5714