

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 2007 list were published in the Federal Register in September 2007.

Original 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: 141-274

Trade Name: Etogesic® Injectable
Ingredients: Etodolac
Sponsor: Fort Dodge Animal Health, Division of Wyeth
Approval Date: September 7, 2007
Status: Rx
Route: Subcutaneous
Species: Dogs
Drug Form: Liquid solution
Concentration: 100 mg/mL
Indications: Indicated for the control of pain and inflammation associated with osteoarthritis.
Exclusivity: Three years

21 CFR 522.870

Supplemental Approvals

NADA Number: 141-267

Trade Name: Dexdomitor®
Ingredients: Dexmedetomidine hydrochloride
Sponsor: Orion Corp.
Effective Date: September 7, 2007
Exclusivity: Three years

This supplemental application provides for the addition of an indication for its use as a sedative and analgesic to facilitate clinical examination, clinical procedures, minor surgical procedures, and minor dental procedures in cats.

21 CFR 522.558 72 FR 51365

NADA Number: 141-244

Trade Name: Draxxin®
Ingredients: Tulathromycin
Sponsor: Pfizer Inc.
Effective Date: September 26, 2007
Exclusivity: Three years

This supplemental application provides for the addition of *Mycoplasma bovis* to the list of target pathogens for the control of bovine respiratory disease (BRD) in cattle at high risk.

21 CFR 522.2630 72 FR 54539

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 2007 list were published in the Federal Register in September 2007.

Supplemental Approvals, cont.

ANADA Number: 200-219

Trade Name: Phoenectin®
Ingredients: Ivermectin
Sponsor: IVX Animal Health, Inc.
Effective Date: September 20, 2007

This supplemental application provides for the incorporation of CVM requested changes to the labeling that include: adding a veal calf statement to the residue information section, revisions to the Environmental Safety and Warning sections, and the specification of *Cooperia* (*Cooperia oncophora*, *C. punctata*, *C. surnabada*) for therapeutic claims to conform to the pioneer's recent label revisions; and a sponsor name change from Phoenix Scientific, Inc. to IVX Animal Health, Inc. and corresponding changes to trade dress.

Labeling Revisions

NADA Number: 044-756

Trade Name: Butatron™
Ingredients: Phenylbutazone
Sponsor: Cross Vetpharm Group Ltd
Effective Date: September 19, 2007

This supplemental application provides for the registered trademark ® to be changed to a trademark ™.

Notice(s)

The Food and Drug Administration (FDA) is requesting nominations for voting members to serve on the Veterinary Medicine Advisory Committee (VMAC), Center for Veterinary Medicine (CVM). FDA has a special interest in ensuring that women, minority groups, and individuals with disabilities are adequately represented on advisory committees and, therefore, encourages nominations of qualified candidates from these groups.

DATES: Nominations received on or before October 30, 2007, will be given first consideration for membership on the VMAC. Nominations received after October 30, 2007, will be considered for nomination to the committee should nominees still be needed.

ADDRESSES: All nominations for membership should be sent electronically to CV@FDA.HHS.GOV, or by mail to Advisory Committee Oversight & Management Staff, 5600 Fisher Lane, HF-4, rm. 15A-12, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Aleta Sindelar, Center for Veterinary Medicine, (HFV-6), Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, 240-276-9004

72 FR 54916, September 27, 2007