

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were completed in March 2020.

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: 200-670

Trade Name: SENERGY™
Pioneer: Revolution®
Ingredients: Selamectin
Sponsor: Chanelle Pharmaceuticals Manufacturing Ltd.
Approval Date: March 10, 2020
Status: Rx
Route: Topical
Species: Dogs and cats
Drug Form: Topical solution
Concentration: 60 mg/mL and 120 mg/mL
Indications: Recommended for use in dogs six weeks of age or older and cats eight weeks of age and older for the following parasites and indications:
Dogs: Kills adult fleas and prevents flea eggs from hatching for one month and is indicated for the prevention and control of flea infestations (*Ctenocephalides felis*), prevention of heartworm disease caused by *Dirofilaria immitis*, and the treatment and control of ear mite (*Otodectes cynotis*) infestations. It is also indicated for the treatment and control of sarcoptic mange (*Sarcoptes scabiei*) and for the control of tick infestations due to *Dermacentor variabilis*.
Cats: Kills adult fleas and prevents flea eggs from hatching for one month and is indicated for the prevention and control of flea infestations (*Ctenocephalides felis*), prevention of heartworm disease caused by *Dirofilaria immitis*, and the treatment and control of ear mite (*Otodectes cynotis*) infestations. It is also indicated for the treatment and control of roundworm (*Toxocara cati*) and intestinal hookworm (*Ancylostoma tubaeforme*) infections in cats.

ANADA Number: 200-586

Trade Name: Marboquin™
Pioneer: Zeniquin®
Ingredients: Marbofloxacin
Sponsor: Dechra Veterinary Products LLC
Approval Date: March 23, 2020
Status: Rx
Route: Oral
Species: Dogs and cats
Drug Form: Tablets
Concentration: 25 mg, 50 mg, 100 mg, and 200 mg
Indications: For the treatment of infections in dogs and cats associated with bacteria susceptible to marbofloxacin.

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: 141-322

Trade Name: Improvest®
Ingredients: Gonadotropin releasing factor analog-diphtheria toxoid conjugate
Sponsor: Zoetis Inc.
Approval Date: March 27, 2020

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were completed in March 2020.

This supplement provides for the addition of the indication for the temporary suppression of estrus in gilts intended for slaughter.

Sponsor Change

NADA Numbers: 141-481

Previous Sponsor: Kindred Biosciences, Inc.
New Sponsor: Dechra, Ltd.
Drug Labeler Code: 043264

Patent Additions

NADA Number: 141-266

Patent number: 10045940
Expiration Date: June 2, 2029

Patent Revisions

NADA Number: 141-321

Patent number: 7772194
Expiration Date: September 19, 2021

Patent number: 5496931
Expiration Date: March 5, 2013

Suitability Petitions

Number: 2020-P-0963

Petitioner: Aurora Pharmaceutical, Inc.
Date Filed: February 27, 2020
Description: The petitioner requests to file an ANADA for a generic deracoxib oral solution for use in dogs that differs from the reference listed new animal drug (RLNAD), Deramaxx™ (deracoxib) Chewable Tablets, sponsored by Elanco US Inc. under NADA 141-203. The proposed change is in dosage form and strength. The petitioner proposes a generic product that is an oral solution with a strength of 1.80% w/v (weight per volume). The RLNAD is approved as half-scored, chewable tablets in 12 mg, 25 mg, 75 mg, and 100 mg tablet strengths.

Number: 2020-P-1074

Petitioner: Akorn Animal Health Inc.
Date Filed: March 10, 2020
Description: The petitioner requests to file an ANADA for a generic polymyxin B, bacitracin, neomycin, and hydrocortisone ophthalmic ointment for use in dogs and cats that differs from the reference listed new animal drug (RLNAD), CORTISPORIN® OPHTHALMIC OINTMENT Veterinary (polymyxin B, bacitracin, neomycin, hydrocortisone), sponsored by Intervet, Inc. under NADA 065-476. The proposed change is in the strength of one of the active pharmaceutical ingredients (polymyxin B). The petitioner proposes a generic product that is an ophthalmic ointment containing 10,000 units polymyxin B sulfate/gram, 400 units bacitracin zinc/gram, 5 mg neomycin sulfate/gram, and 10 mg (1%) hydrocortisone/gram. The RLNAD is approved as an ophthalmic ointment

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were completed in March 2020.

containing 5,000 units polymyxin B sulfate/gram, 400 units bacitracin zinc/gram, 5 mg neomycin sulfate/gram, and 10 mg (1%) hydrocortisone/gram.