# Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were completed in May 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: 200-679

| | |
|---|---|
| Trade Name: | Optigrid® 45 |
| Pioneer: | Optaflexx™ 45 |
| Ingredients: | Ractopamine hydrochloride |
| Sponsor: | Huvepharma EOOD |
| Approval Date: | May 14, 2020 |
| Status: | OTC |
| Route: | Oral |
| Species: | Cattle fed in confinement for slaughter |
| Drug Form: | Type A medicated article for use in the manufacture of Type B and Type C medicated feeds |
| Concentration: | 45.4 g/lb (100 g/kg) |
| Indications: | **Complete Feed**: For increased rate of weight gain, improved feed efficiency and increased carcass leanness in cattle fed in confinement for slaughter during the last 28 to 42 days on feed.<br>**Top Dress Feed**: For increased rate of weight gain and improved feed efficiency in cattle fed in confinement for slaughter during the last 28 to 42 days on feed. |

### ANADA Number: 200-680

| | |
|---|---|
| Trade Name: | Enrofloxacin Flavored Tablets |
| Pioneer: | Baytril® Taste Tabs® |
| Ingredients: | Enrofloxacin |
| Sponsor: | Felix Pharmaceuticals Pvt. Ltd. |
| Approval Date: | May 21, 2020 |
| Status: | Rx |
| Route: | Oral |
| Species: | Dogs and cats |
| Drug Form: | Flavored Tablet |
| Concentration: | 22.7 mg, 68 mg, and 136 mg enrofloxacin per tablet |
| Indications: | For the management of diseases associated with bacteria susceptible to enrofloxacin in dogs and cats. |

### ANADA Number: 200-638

| | |
|---|---|
| Trade Name: | IMOXI™ Topical Solution for Cats |
| Pioneer: | Advantage Multi® for Cats |
| Ingredients: | Imidacloprid and moxidectin |
| Sponsor: | Vetoquinol USA, Inc. |
| Approval Date: | May 27, 2020 |
| Status: | Rx |
| Route: | Topical |
| Species: | Cats |
| Drug Form: | Topical solution |
| Concentration: | 100 mg/mL (10%) imidacloprid and 10 mg/mL (1%) moxidectin |
| Indications: | For the prevention of heartworm disease caused by *Dirofilaria immitis*. Kills adult fleas (*Ctenocephalides felis*) and is indicated for the treatment of flea infestations. It is also indicated for the treatment and control of ear mite (*Otodectes cynotis*) infestations and the following intestinal parasites: adult, immature adult, and fourth stage larvae in hookworms (*Ancylostoma tubaeforme*); and adult and fourth stage larvae in roundworm (*Toxocara cati*). |

# Actions Taken by FDA Center for Veterinary Medicine

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

## Post Approval Experience Labeling Changes

### NADA Number: 141-331

The following changes were made to the package insert:

- The Warnings section was revised to include: Dogs have eaten Prascend tablets that were placed in food intended for horses or dropped during administration of the tablets to the horses. Adverse reactions may occur if animals other than horses ingest Prascend tablets (see Post Approval Experience).
- A Post-Approval Experience section was added:
  Post Approval Experience (2019):
  The following adverse events are based on post approval adverse drug experience reporting for Prascend. Not all adverse events are reported. It is not always possible to reliably estimate the adverse event frequency or establish a causal relationship to product exposure using these data.

  The following adverse events in horses are categorized in order of decreasing reporting frequency by body system and in decreasing order of reporting frequency within each body system:

  **General**: anorexia, lethargy, weight loss
  **Gastrointestinal**: diarrhea, abdominal pain/colic
  **Dermatological**: alopecia, hyperhidrosis, dermatitis
  **Musculoskeletal**: laminitis, muscle stiffness/soreness
  **Neurological**: ataxia, seizure, muscle tremors
  **Behavioral**: aggression (to other horses and humans), hyperactivity (anxiety, agitation), other behavioral changes (stud-like behavior, spooky, unpredictable, confused)
  **Clinical pathology**: anemia, elevated liver enzymes, thrombocytopenia

  The above adverse events have been reported in horses after initial dosing, or after a dose increase.

  Death (including euthanasia) has been reported.

  Adverse events have been reported in dogs following ingestion of tablets prepared for administration to horses.

## Suitability Petitions

### Number: 2020-P-0963

| | |
|---|---|
| Petitioner: | Aurora Pharmaceutical, Inc. |
| Date Filed: | February 27.2020 |
| Action: | Approved |
| Action Date: | May 14, 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. |