Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were completed in October 2021.

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: 200-691

Trade Name:	RAC™ 45 CATTLE
Pioneer:	Optaflexx™ 45
Ingredients:	Ractopamine hydrochloride
Sponsor:	Virbac AH, Inc.
Approval Date:	October 1, 2021
Status:	OTC
Route:	Oral
Species:	Cattle fed in confinement for slaughter
Drug Form:	Type A medicated article to be used in the manufacture of Type B and Type C medicated feeds
Concentration:	45.4 g per lb (100 g per 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. **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: 200-604

Trade Name:	Amoxicillin and Clavulanate Potassium for Oral Suspension
Pioneer:	CLAVAMOX®
Ingredients:	Amoxicillin and clavulanate potassium
Sponsor:	Dechra Veterinary Products LLC
Approval Date:	October 20, 2021
Status:	Rx
Route:	Oral
Species:	Dogs and cats
Drug Form:	Suspension
Concentration:	Each mL of suspension contains 50 mg of amoxicillin activity as the trihydrate and 12.5 mg of clavulanic acid activity as the potassium salt.
Indications:	For the treatment of the following: **Dogs**: Skin and soft tissue infections such as wounds, abscesses, cellulitis, superficial/juvenile and deep pyoderma due to susceptible strains of the following organisms: β-lactamase-producing *Staphylococcus aureus*, non-β-lactamase-producing *Staphylococcus aureus*, *Staphylococcus* spp., *Streptococcus* spp., and *E. coli*. Periodontal infections due to susceptible strains of both aerobic and anaerobic bacteria. **Cats**: Skin and soft tissue infections such as wounds, abscesses, and cellulitis/dermatitis due to susceptible strains of the following organisms: β-lactamase-producing *Staphylococcus aureus*, non-β-lactamase-producing *Staphylococcus aureus*, *Staphylococcus* spp., *Streptococcus* spp., *E. coli*, *Pasteurella multocida*, and *Pasteurella* spp. Urinary tract infections (cystitis) due to susceptible strains of *E. coli*.

ANADA Number: 200-588

Trade Name:	FLORFENICOL INJECTION
Pioneer:	Nuflor®
Ingredients:	Florfenicol
Sponsor:	Sparhawk Laboratories, Inc.
Approval Date:	October 28, 2021
Status:	Rx
Route:	Intramuscular or subcutaneous

Species:	Beef and non-lactating dairy cattle
Drug Form:	Injectable solution
Concentration:	300 mg/mL
Indications:	For treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni*, and for the treatment of bovine interdigital phlegmon (foot rot, acute interdigital necrobacillosis, infectious pododermatitis) associated with *Fusobacterium necrophorum* and *Bacteroides melaninogenicus*. Also, it is indicated for the control of respiratory disease in cattle at high risk of developing BRD associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni*.

ANADA Number: 200-628

Trade Name:	ENROFLOXACIN 100
Pioneer:	Baytril® 100
Ingredients:	Enrofloxacin
Sponsor:	Sparhawk Laboratories, Inc.
Approval Date:	October 29, 2021
Status:	Rx
Route:	Intramuscular or subcutaneous
Species:	Beef cattle, non-lactating dairy cattle, and swine
Drug Form:	Injectable solution
Concentration:	100 mg/mL
Indications:	**Cattle - Single-Dose Therapy**: For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni* and *Mycoplasma bovis* in beef and non-lactating dairy cattle; and for the control of BRD in beef and nonlactating dairy cattle at high risk of developing BRD associated with *M. haemolytica*, *P. multocida*, *H. somni* and *M. bovis*. **Cattle - Multiple-Day Therapy**: For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida* and *Histophilus somni* in beef and nonlactating dairy cattle. **Swine**: For the treatment and control of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Haemophilus parasuis*, *Streptococcus suis*, *Bordetella bronchiseptica* and *Mycoplasma hyopneumoniae*. It is also indicated for the control of colibacillosis in groups or pens of weaned pigs where colibacillosis associated with *Escherichia coli* has been diagnosed.

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: 141-348

Trade Name:	SYNOVEX® ONE Grower
Ingredients:	Trenbolone acetate and estradiol benzoate
Sponsor:	Zoetis Inc.
Approval Date:	October 29, 2021

This supplement provides for approval of the indication for increased rate of weight gain for up to 200 days in growing beef steers and heifers fed in confinement for slaughter.

Sponsor Change

(A)NADA Numbers: 200-322, 200-408

Previous Sponsor:	Elanco US Inc.
New Sponsor:	Dechra Veterinary Products LLC

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were completed in October 2021.

(A)NADA Numbers: 047-955, 047-956

Previous Sponsor: Elanco US Inc.

New Sponsor: Dechra, Ltd.

Patent Extensions

NADA Numbers: 141-508, 141-512, 141-514

Patent number: 6730792
Extension Period: 1 year
Expiration Date: July 9, 2022

Suitability Petitions

Number: 2021-P-1085

Petitioner: Ray Law Firm, PLLC
Date Filed: October 19, 2021
Description: The petitioner requests to file an ANADA for a generic robenacoxib tablet for use in dogs that differs from the reference listed new animal drug (RLNAD). Onsior™ (robenacoxib) tablets, sponsored by Elanco US Inc. under NADA 141-463, is the RLNAD. The proposed change is the addition of an unscored 5 mg tablet strength. The RLNAD is approved as unscored tablets in 10 mg, 20 mg, and 40 mg tablet strengths.

Number: 2021-P-1173

Petitioner: Felix Pharmaceuticals Pvt. Ltd.
Date Filed: October 27, 2021
Description: The petitioner requests to file an ANADA for a generic pimobendan oral suspension for use in dogs that differs from the reference listed new animal drug (RLNAD), Vetmedin® (pimobendan) Chewable Tablets, sponsored by Boehringer Ingelheim Animal Health USA, Inc. under NADA 141-273. The proposed change is for an oral suspension (2.5 mg/mL strength); the RLNAD is approved as scored, chewable tablets in 1.25 mg, 2.5 mg, 5 mg, and 10 mg tablet strengths.

Number: 2021-P-1174

Petitioner: Felix Pharmaceuticals Pvt. Ltd.
Date Filed: October 27, 2021
Description: The petitioner requests to file an ANADA for a generic methimazole oral solution for use in cats that differs from the reference listed new animal drug (RLNAD), FELIMAZOLE® COATED TABLETS (methimazole), sponsored by Dechra, Ltd. under NADA 141-292. The proposed change is for an oral solution (5 mg/mL strength); the RLNAD is approved as unscored, coated tablets in 2.5 mg and 5 mg tablet strengths.

Number: 2021-P-1175

Petitioner: Felix Pharmaceuticals Pvt. Ltd.
Date Filed: October 27, 2021
Description: The petitioner requests to file an ANADA for a generic levothyroxine sodium oral solution for use in dogs that differs from the reference listed new animal drug (RLNAD), Thyro-Tabs® Canine (levothyroxine sodium tablets), USP, sponsored by Lloyd, Inc. under NADA 141-448. The proposed change is for an oral solution (200 µg/mL and 400 µg/mL strengths); the RLNAD is approved as

scored, color-coded tablets in 0.1 mg, 0.2 mg, 0.3 mg, 0.4 mg, 0.5 mg, 0.6 mg, 0.7 mg, 0.8 mg, and 1.0 mg tablet strengths.