Actions Taken by FDA Center for Veterinary Medicine

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

NADA Number: 141-539

Trade Name:	ThyroKare™
Ingredients:	Levothyroxine sodium
Sponsor:	Neogen Corp.
Approval Date:	January 15, 2021
Status:	Rx
Route:	Oral
Species:	Dogs
Drug Form:	Tablet
Concentration:	0.1 mg, 0.2 mg, 0.3 mg, 0.4 mg, 0.5 mg, 0.6 mg, 0.7 mg, 0.8 mg, or 1.0 mg of levothyroxine sodium per tablet
Indications:	For replacement therapy for diminished thyroid function in dogs.
Exclusivity:	3 years

ANADA Number: 200-676

Trade Name:	Optigrid® and Monovet® and Tylovet®
Pioneer:	Optaflexx™ and Rumensin™ and Tylan™
Ingredients:	Ractopamine hydrochloride, monesin, and tylosin phosphate
Sponsor:	Huvepharma EOOD
Approval Date:	January 12, 2021
Status:	VFD
Route:	Oral
Species:	Cattle fed in confinement for slaughter
Drug Form:	Type A medicated articles to be used in the manufacture of Type B and Type C medicated feeds.
Concentration:	Optigrid®: 45.4 g/lb (100 g/kg) of ractopamine hydrochloride Monovet®: 90.7 g/lb of monensin Tylovet®: 40 g/lb and 100 g/lb of tylosin
Indications:	1) For increased rate of weight gain, improved feed efficiency, prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii* and reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium* (*Actinomyces*) *pyogenes* in cattle fed in confinement for slaughter for the last 28 to 42 days on feed. 2) For increased rate of weight gain, improved feed efficiency, increased carcass leanness, prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii* and reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium* (*Actinomyces*) *pyogenes* in cattle fed in confinement for slaughter for the last 28 to 42 days on feed. 3) For increased rate of weight gain, improved feed efficiency, prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii* and reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium* (*Actinomyces*) *pyogenes* in cattle fed in confinement for slaughter for the last 28 to 42 days on feed.

ANADA Number: 200-677

Trade Name:	Optigrid® and Monovet® and MGA®
Pioneer:	Optaflexx™ and Rumensin™ and MGA®
Ingredients:	Ractopamine hydrochloride, monesin, and melengestrol acetate
Sponsor:	Huvepharma EOOD
Approval Date:	January 12, 2021
Status:	VFD
Route:	Oral
Species:	Heifers fed in confinement for slaughter

Drug Form:	Type A medicated articles to be used in the manufacture of Type C medicated feeds.
Concentration:	Optigrid®: 45.4 g/lb (100 g/kg) of ractopamine hydrochloride Monovet®: 90.7 g/lb of monensin MGA®: 200 mg/lb and 500 mg/lb of melengestrol acetate
Indications:	For increased rate of weight gain, improved feed efficiency, increased carcass leanness, prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*; and suppression of estrus (heat) in heifers fed in confinement for slaughter during the last 28 to 42 days on feed.

ANADA Number: 200-678

Trade Name:	Optigrid® and Monovet® and Tylovet® and MGA®
Pioneer:	Optaflexx™ and Rumensin™ and Tylan™ and MGA®
Ingredients:	Ractopamine hydrochloride, monesin, tylosin phosphate, and melengestrol acetate
Sponsor:	Huvepharma EOOD
Approval Date:	January 12, 2021
Status:	VFD
Route:	Oral
Species:	Heifers fed in confinement for slaughter
Drug Form:	Type A medicated articles to be used in the manufacture of Type C medicated feeds.
Concentration:	Optigrid®: 45.4 g/lb (100 g/kg) of ractopamine hydrochloride Monovet®: 90.7 g/lb of monensin Tylovet®: 40 g/lb and 100 g/lb of tylosin MGA®: 200 mg/lb and 500 mg/lb of melengestrol acetate
Indications:	For increased rate of weight gain, improved feed efficiency, increased carcass leanness, prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii* and reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium* (*Actinomyces*) *pyogenes*; and suppression of estrus (heat) in heifers fed in confinement for slaughter for the last 28 to 42 days on feed.

ANADA Number: 200-675

Trade Name:	Optigrid® and Monovet®
Pioneer:	Optaflexx™ and Rumensin™
Ingredients:	Ractopamine hydrochloride and monesin
Sponsor:	Huvepharma EOOD
Approval Date:	January 12, 2021
Status:	VFD
Route:	Oral
Species:	Cattle fed in confinement for slaughter
Drug Form:	Type A medicated articles to be used in the manufacture of Type B and Type C medicated feeds.
Concentration:	Optigrid®: 45.4 g/lb (100 g/kg) of ractopamine hydrochloride Monovet®: 90.7 g/lb of monensin
Indications:	1) For increased rate of weight gain, improved feed efficiency and prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii* in cattle fed in confinement for slaughter during the last 28 to 42 days on feed. 2) For increased rate of weight gain, improved feed efficiency, increased carcass leanness and prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii* in cattle fed in confinement for slaughter during the last 28 to 42 days on feed. 3) For increased rate of weight gain and improved feed efficiency; and for prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii* in cattle fed in confinement for slaughter during the last 28 to 42 days on feed.

Conditional 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.

Actions Taken by FDA Center for Veterinary Medicine

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

Application Number: 141-526

Trade Name:	LAVERDIA™-CA1
Ingredients:	Verdinexor
Sponsor:	Anivive Lifesciences, Inc.
Approval Date:	January 11, 2021
Status:	Rx
Route:	Oral
Species:	Dogs
Drug Form:	Coated tablet
Concentration:	Three tablet sizes containing 2.5 mg, 10 mg, or 50 mg of verdinexor per tablet
Indications:	Conditionally approved for the treatment of lymphoma in dogs.
Exclusivity:	7 years

Patent:

Patent Number	Expiration date:
9079865	July 26, 2032
9206158	July 26, 2032
9714226	July 26, 2032
10173987	July 26, 2032
10544108	July 26, 2032
16696702	Pending

Application Number: 141-544

Trade Name:	KBroVet®-CA1
Ingredients:	Potassium bromide
Sponsor:	Pegasus Laboratories, Inc.
Approval Date:	January 14, 2021
Status:	Rx
Route:	Oral
Species:	Dogs
Drug Form:	Chewable tablets
Concentration:	250 or 500 mg per tablet
Indications:	Conditionally approved for the control of seizures associated with idiopathic epilepsy in dogs.

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: 141-336

Trade Name:	Aivlosin®
Ingredients:	62.5% w/w tylvalosin as tylvalosin tartrate
Sponsor:	ECO LLC
Approval Date:	January 7, 2021

This supplement provides for the addition of *Mycoplasma hyopneumoniae* to the list of pathogens in the indication for control of swine respiratory disease.

Post Approval Experience Labeling Changes

NADA Number: 141-440

Proprietary Name: Claro®
Drug Product Established Name: Florfenicol, terbinafine, mometasone furoate

The following safety-related changes were made to the labeling:

1. The statement **'Do Not Use in Cats'** was added to the product identification.

2. The following statements and graphic were added to the Dosage and Administration section:

Wear eye protection when administering CLARO®. (see **Human Warnings, Precautions, Post Approval Experience**).

Splatter may occur if the dog shakes its head following administration. Persons near the dog during administration should also take steps to avoid ocular exposure.

Verify the tympanic membrane is intact prior to administration. (see **Contraindications, Precautions, Post Approval Experience).**

Restrain the dog to minimize post application head shaking to reduce potential for splatter of product and accidental eye exposure in people and dogs (see **Post Approval Experience**).

3. **Human Warnings**
(Additions and/or revisions underlined)

Human Warnings:
CLARO® may cause eye injury and irritation (see **Precautions, Post Approval Experience)**.
If contact with eyes occurs, flush copiously with water for at least 15 minutes. If irritation persists, contact a physician.
Humans with known hypersensitivity to any of the active ingredients in CLARO® should not handle this product.
Not for use in humans. Keep this and all drugs out of the reach of children. Avoid skin contact. In case of accidental ingestion by humans, contact a physician immediately.

4. **Precautions**
(Additions and/or revisions underlined)

Precautions:
For use in dogs only. Do not use in cats (see **Post Approval Experience).**

Wear eye protection when administering CLARO® and restrain the dog to minimize post application head shaking. Reducing the potential for splatter of product will help prevent accidental eye exposure in people and dogs and help to prevent ocular injury (see **Dosage and Administration, Human Warnings, Post Approval Experience**).
Proper patient selection is important when considering the benefits and risks of using CLARO®.
The integrity of the tympanic membrane should be confirmed before administering the product.

CLARO® has been associated with rupture of the tympanic membrane. Reevaluate the dog if hearing loss or signs of vestibular dysfunction are observed during treatment.

Signs of internal ear disease such as head tilt, vestibular signs, ataxia, nystagmus, facial paralysis, and keratoconjunctivitis sicca have been reported (see **Post Approval Experience**) with the use of CLARO®.

Do not administer orally.

Use of topical otic corticosteroids has been associated with adrenocortical suppression and iatrogenic hyperadrenocorticism in dogs (see **Animal Safety**).

Use with caution in dogs with impaired hepatic function (see **Animal Safety**).

The safe use of CLARO® in dogs used for breeding purposes, during pregnancy, or in lactating bitches, has not been evaluated.

5. The following Post-Approval Experience section was added to the labeling:

Post Approval Experience Section (2019):

The following adverse events are based on post-approval adverse drug experience reporting for CLARO®. Not all adverse events are reported to FDA/CVM. It is not always possible to reliably estimate the adverse event frequency or establish a causal relationship to product exposure using these data.

In **humans**, accidental exposure leading to corneal ulcers and other ocular injuries such as eye irritation and redness have been reported. Exposure occurred when the dog shook its head after application of CLARO®. Skin irritation has also been reported.

In **dogs**, the adverse events reported are presented below in decreasing order of reporting frequency:

Ear discharge, head shaking, ataxia, internal ear disorder (head tilt and vestibular), deafness, emesis, nystagmus, pinnal irritation and ear pain, keratoconjunctivitis sicca, vocalization, corneal ulcer, cranial nerve disorder (facial paralysis), tympanic membrane rupture.

CLARO® is not approved for use in **cats**. The adverse events reported following extra-label use in **cats** are presented below in decreasing order of reporting frequency:

Ataxia, anorexia, internal ear disorder (head tilt and vestibular), Horner's syndrome (third eyelid prolapse and miosis), nystagmus, lethargy, anisocoria, head shake, emesis, tympanic rupture, and deafness.

To report suspected adverse drug events and/or obtain a copy of the Safety Data Sheet (SDS) or for technical assistance, contact Bayer HealthCare at 1-800-422-9874.
For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or online at http://www.fda.gov/reportanimalae.

6. The following Information for Dog Owners section was added to the labeling:

Information for Dog Owners:

Owners should be aware that adverse reactions may occur following administration of CLARO® and should be instructed to observe the dog for signs such as ear pain and irritation, vomiting, head shaking, head tilt, incoordination, eye pain and ocular discharge (see **Post Approval Experience**). Owners should be advised to contact their veterinarian if any of the above signs are observed.

Owners should also be informed that splatter may occur if the dog shakes its head following administration of CLARO® which may lead to ocular exposure. Eye injuries, including corneal ulcers, have been reported in humans and dogs associated with head shaking and splatter following administration. Owners should be careful to avoid ocular exposure (see **Precautions, Post Approval Experience**).

In addition, the following safety-related changes were made to the language on the packaging.

1. The statement '**Do Not Use in Cats**' was added.

2. The statement 'Wear eye protection when administering CLARO®' was added.

Suitability Petitions

Number: 2020-P-2234

Petitioner: Ray Law Firm, PLLC
Date Filed: November 24, 2020
Action: Filed
Description: The petitioner requests to file an ANADA for generic cefpodoxime proxetil tablets for the treatment of skin infections (wounds and abscesses) in dogs caused by susceptible strains of *Staphylococcus pseudintermedius*, *Staphylococcus aureus*, *Streptococcus canis* (group G, ß hemoltyic), *Escherichia coli*, *Pasteurella multocida*, and *Proteus mirabilis* that differ from the reference listed new animal drug (RLNAD), SIMPLICEF® (cefpodoxime proxetil tablets), sponsored by Zoetis Inc. under NADA 141-232. The proposed changes are the addition of a 50 mg tablet strength and the removal of scoring from the 100 and 200 mg tablet strengths. The RLNAD is approved as scored tablets in 100 mg and 200 mg tablet strengths.

Number: 2020-P-2102

Petitioner: Aurora Pharmaceutical, Inc.
Date Filed: October 20, 2020
Action: Approved
Action Date: January 13, 2021
Description: The petitioner requests to file an ANADA for a generic firocoxib oral solution for use in horses that differs from the reference listed new animal drug (RLNAD), Equioxx® (firocoxib) Oral Paste, sponsored by Boehringer Ingelheim Animal Health USA Inc. under NADA 141-253. The proposed generic product would differ from the RLNAD in dosage form and strength. The petitioner proposes a generic product that is an oral solution with a strength of 0.9% w/v (weight per volume). The RLNAD is approved as an oral paste; the strength of the RLNAD is 8.2 mg/g.

Number: 2021-P-0086

Petitioner: Felix Pharmaceuticals Pvt. Ltd.
Date Filed: January 15, 2021
Action: Filed
Description: The petitioner requests to file an ANADA for a generic clindamycin tablet for use in dogs that differs from the reference listed new animal drug (RLNAD), Antirobe® (clindamycin hydrochloride capsules, USP), sponsored by Zoetis Inc. under NADA 120-161. The proposed change is in dosage form from a capsule (RLNAD) to a tablet (proposed generic product).