

# Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were completed in September 2022.

## 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: 141-429

Trade Name: Stafac® and Maxiban™  
Ingredients: Virginiamycin, narasin and nicarbazin  
Sponsor: Phibro Animal Health Corp.  
Approval Date: September 6, 2022  
Status: VFD  
Route: Oral  
Species: Broiler chickens  
Drug Form: Type A medicated articles to be used in the manufacture of Type C medicated feeds  
Concentration: Stafac®: 20, 50, or 227 g/lb of virginiamycin  
Maxiban™: 36 g/lb narasin and 36 g/lb nicarbazin  
Indications: For prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to virginiamycin and for the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima* in broiler chickens.

### NADA Number: 141-462

Trade Name: Stafac® and Monteban™  
Ingredients: Virginiamycin and narasin  
Sponsor: Phibro Animal Health Corp.  
Approval Date: September 6, 2022  
Status: VFD  
Route: Oral  
Species: Broiler chickens  
Drug Form: Type A medicated articles to be used in the manufacture of Type C medicated feeds  
Concentration: Stafac®: 20, 50, or 227 g/lb of virginiamycin  
Monteban™: 45 g/lb of narasin  
Indications: For prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to virginiamycin and for the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima* in broiler chickens.

### NADA Number: 141-553

Trade Name: VALCOR™  
Ingredients: Doramectin and levamisole  
Sponsor: Zoetis Inc.  
Approval Date: September 9, 2022  
Status: Rx  
Route: Subcutaneous  
Species: Cattle: beef cattle two months of age and older and in replacement dairy heifers less than 20 months of age. Not for use in beef bulls intended for breeding over 1 year of age, dairy calves, and veal calves  
Drug Form: Injectable solution  
Concentration: 5 mg/mL doramectin and 150 mg/mL levamisole hydrochloride  
Indications: For the treatment and control of gastrointestinal roundworms (adults and fourth stage larvae) - *Ostertagia ostertagi* (including inhibited larvae), *O. lyrata*, *Haemonchus placei*, *Trichostrongylus axei*, *T. colubriformis*, *T. longispicularis*\*, *Cooperia oncophora*, *C. pectinata*\*, *C. punctata*, *C. surnabada*, *Bunostomum phlebotomum*\*, *Strongyloides papillosus*\*, *Oesophagostomum radiatum*, *Trichuris* spp.\*, and *Nematodirus helvetianus*\*; lungworms (adults and fourth stage larvae) - *Dictyocaulus viviparus*; eyeworms (adults) - *Thelazia* spp.;

## Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were completed in September 2022.

grubs (parasitic stages) - *Hypoderma bovis* and *H. lineatum*; sucking lice - *Haematopinus eurysternus*, *Linognathus vituli*, and *Solenopotes capillatus*; mange mites - *Psoroptes bovis* and *Sarcoptes scabiei*.  
\*adults only

Exclusivity: 3 years  
Patent: Patent Number 10307405      Expiration date: April 10, 2034

### ANADA Number: 200-719

Trade Name: SIMPLERA™  
Pioneer: CLARO™  
Ingredients: Florfenicol, terbinafine, and mometasone furoate  
Sponsor: Vetoquinol USA, Inc.  
Approval Date: September 28, 2022  
Status: Rx  
Route: Otic  
Species: Dogs  
Drug Form: Solution  
Concentration: 16.6 mg/mL florfenicol, 14.8 mg/mL terbinafine (equivalent to 16.6 mg/mL terbinafine hydrochloride) and 2.2 mg/mL mometasone furoate  
Indications: For the treatment of otitis externa in dogs associated with susceptible strains of yeast (*Malassezia pachydermatis*) and bacteria (*Staphylococcus pseudintermedius*).

### ANADA Number: 200-694

Trade Name: SpectoGard®  
Pioneer: Adspec®  
Ingredients: Spectinomycin sulfate  
Sponsor: Bimeda Animal Health Ltd.  
Approval Date: September 29, 2022  
Status: Rx  
Route: Injection  
Species: Cattle  
Drug Form: Injectable solution  
Concentration: 100 mg per mL  
Indications: For the treatment of bovine respiratory disease (pneumonia) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni*.

## Animal Drug Safety-Related Labeling Changes

---

### NADA Number: 141-222

Proprietary Name: MATRIX®  
Drug Product Established Name: altrenogest

#### USES:

For synchronization of estrus in sexually mature gilts that have had at least one estrous cycle. Treatment with MATRIX results in estrus (standing heat) 4 to 9 days after completion of the 14-day treatment period.

It is a violation of Federal law to use this drug product other than as directed in the labeling or as directed by your veterinarian.

#### USER SAFETY WARNINGS:

Not for use in humans. Keep out of reach of children.  
Skin contact must be avoided as MATRIX® is readily absorbed through unbroken skin, and exposure may result in serious side effects to both women and men. Always wear vinyl, neoprene, or nitrile protective gloves when handling MATRIX® or when in contact with equipment or surfaces contaminated by this product. Latex gloves are not protective.

## Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were completed in September 2022.

PREGNANT WOMEN OR WOMEN WHO MAY BE PREGNANT SHOULD NOT HANDLE MATRIX® (altrenogest). WOMEN OF CHILDBEARING AGE SHOULD EXERCISE EXTREME CAUTION WHEN HANDLING THIS PRODUCT.

Accidental absorption, such as absorption through the skin, could lead to a disruption of the menstrual cycle or prolongation of pregnancy. Wash off accidental spillage on the skin immediately with soap and water. Any equipment or surfaces that come in contact with MATRIX® should be adequately cleaned and decontaminated to prevent human exposure. Always use the MATRIX® Dosing Device to administer this product. The MATRIX® bottle is designed only for use with the MATRIX® Dosing Device. Use without the device increases the risk of human exposure.

PEOPLE WHO SHOULD NOT HANDLE MATRIX®:\*

Women who are or may be pregnant.

Anyone with blood clots or clotting disorders, or with a history of these events.

Anyone with a history of heart disease or stroke.

Women with known or suspected breast cancer.

People with known or suspected estrogen-dependent cancer.

Women with vaginal bleeding of unknown cause.

People with tumors which developed during the use of oral contraceptives or other estrogen-containing products.

Anyone with liver dysfunction or disease.

\*Based on known effects of long-term progestin use in humans.

### ACCIDENTAL EXPOSURE:

MATRIX® is readily absorbed from contact with the skin. In addition, this oil-based product can penetrate latex or other types of porous gloves.

Always wear vinyl, neoprene, or nitrile protective gloves when handling MATRIX®. Latex gloves are not protective. If MATRIX® gets inside gloves by damage or spilling, the covered skin may absorb more of the drug. Side effects after a single exposure are possible; however, continued daily exposure has the potential for more serious effects.

### IN CASE OF ACCIDENTAL EXPOSURE:

Skin exposure and/or clothing contamination: Wash skin immediately with soap and water, and launder clothing with detergent.

Eye exposure: Immediately flush with plenty of water for 15 minutes. Get medical attention. If wearing contact lenses, flush eyes immediately with water before removing lenses.

If swallowed: Do not induce vomiting. Seek medical attention immediately. MATRIX® contains an oil. Vomiting should be supervised by a physician because of possible pulmonary damage via aspiration of the oil base. If possible, bring the labeling to the physician.

### Reported HUMAN Effects from Exposure

Side effects have been reported in women and men following accidental exposure to altrenogest products, including MATRIX®, either through handling of the product or contact with contaminated surfaces.

Reproductive side effects reported in women included abnormal or absent menstrual cycles.

Reproductive side effects in men included decreased libido.

Other side effects reported in women and men included headaches, fever, abdominal pain, nausea, diarrhea, vomiting, and rashes.

## NADA Number: 141-152

Proprietary Name: revolution®

Drug Product Established Name: selamectin

### PACKAGE INSERT

#### **WARNINGS:**

*Newly added subsections. Additions are underlined.*

## Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were completed in September 2022.

### **User Safety Warnings**

**Not for human use. Keep out of reach of children.**

**In humans, Revolution may be irritating to skin and eyes.**

Reactions such as hives, itching and skin redness have been reported in humans. Individuals with known hypersensitivity to Revolution should use the product with caution or consult a health care professional. Revolution contains isopropyl alcohol and the preservative butylated hydroxytoluene (BHT).

Wash hands after use and wash off any product in contact with the skin immediately with soap and water.

If contact with eyes occurs, then flush eyes copiously with water; if wearing contact lenses, rinse the eyes first then remove contact lenses and continue to rinse for 5-10 minutes and seek medical attention.

In case of ingestion by a human, contact a physician immediately.

The safety data sheet (SDS) provides more detailed occupational safety information. To obtain a SDS contact Zoetis at 1-888-963-8471 or [www.zoetisus.com](http://www.zoetisus.com).

Flammable - Keep away from heat, sparks, open flames or other sources of ignition.

### **Animal Safety Warnings**

**Do not use in sick, debilitated or underweight animals** (see **TARGET ANIMAL SAFETY**).

### **CONTACT INFORMATION:**

*Newly added section.*

### **CONTACT INFORMATION:**

Contact Zoetis at 1-888-963-8471 or [www.zoetis.com](http://www.zoetis.com). To report suspected adverse drug experiences, contact Zoetis at 1-888-963-8471. For additional information about reporting adverse drug experiences for animal drugs, contact FDA at 1-888-FDA-VETS or [www.fda.gov/reportanimalae](http://www.fda.gov/reportanimalae).

### **ADVERSE REACTIONS:**

*Updated Post-Approval Experience subsection.*

### **Post-Approval Experience (2021):**

The following adverse events are based on post-approval adverse drug experience reporting for Revolution. 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 this data.

The following adverse events reported for **dogs** are listed in decreasing order of reporting frequency:

Lethargy, vomiting, diarrhea, anorexia, generalized pruritus, seizures, application site reactions (including alopecia, lesions, erythema, pruritis, and inflammation), tremors, ataxia, death, and dermatitis.

The following adverse events reported for **cats** are listed in decreasing order of reporting frequency:

Application site reactions (including alopecia, lesions, erythema, pruritus, inflammation, vesicles, blisters, and excoriations), lethargy, anorexia, vomiting, death, generalized pruritus, diarrhea, ataxia, fever, generalized alopecia, tremors, hypersalivation, dermatitis, and seizures.

### **CARTON**

*Revised Dosage and Administration section on carton to update bathing information for cats. Revisions underlined.*

Puppy/kitten carton:

However, bathing or immersing your puppy in water 2 hours after application, and kittens 24 hours after application, will not reduce the effectiveness of this treatment.

Cat carton:

However, bathing or immersing your pet in water 24 hours after application will not reduce the effectiveness of this treatment.

## Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were completed in September 2022.

### Sponsor Change

---

#### NADA Number: 039-583

Previous Sponsor: Mylan Institutional, Inc.  
New Sponsor: Cronus Pharma Specialities India Private Ltd.

### Sponsor Name Change

---

Previous Name: Akorn Operating Company LLC (dba Akorn Animal Health Inc)  
New Name: Akorn Operating Company LLC  
New Address: 5605 Centerpoint Court, Suite A, Gurnee, IL 60031

### Patent Additions

---

#### NADA Number: 141-509

Patent number: 8859540  
Expiration Date: December 18, 2025

### Withdrawal of Approval

---

#### NADA Number: 140-908

Sponsor: Lloyd, Inc.  
Trade Name: Veta-Meth™  
Ingredients: Sulfamethazine

This product is withdrawn because the product is no longer manufactured or marketed.

#### NADA Number: 136-214

Sponsor: Ridley USA Inc.  
Trade Name: Enproal Bloat Blox  
Ingredients: Polyoxyethylene 23 Lauryl Ether

This product is withdrawn because the product is no longer manufactured or marketed.

### Suitability Petitions

---

#### Number: 2022-P-2076

Petitioner: Noble Pharma, LLC  
Date Filed: August 31, 2022  
Description: The petitioner requests to file an ANADA for a generic maropitant citrate tablet for use in dogs that differs from the reference listed new animal drug (RLNAD), Cerenia® (maropitant citrate) Tablets, sponsored by Zoetis Inc. under NADA 141-262. The proposed change is in dosage form from a compressed, scored tablet (RLNAD) to an extruded, chicken liver-flavored, and scored soft chewable tablet (proposed generic product).

#### Number: 2022-P-1049

Petitioner: Noble Pharma, LLC

## **Actions Taken by FDA Center for Veterinary Medicine**

The following corrections or additions to the list were completed in September 2022.

Date Filed: June 7, 2022  
Action: Approved  
Action Date: September 8, 2022  
Description: The petitioner requests to file an ANADA for a generic firocoxib tablet for use in dogs that differs from the reference listed new animal drug (RLNAD), Previcox® (firocoxib) Chewable Tablets, sponsored by Boehringer Ingelheim Animal Health USA, Inc. under NADA 141-230. The proposed change is in dosage form from a compressed, barbecue-flavored, and half-scored chewable tablet (RLNAD) to an extruded, chicken liver-flavored, and half-scored soft chewable tablet (proposed generic product).