

# Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were published in the Federal Register in January 2010.

---

## Original Approvals

---

This section displays the change(s) to the original approval. To read the complete approval, please refer to 21CFR Parts 500 and the related Federal Register notices.

### ANADA Number: 200-467

Trade Name: Sevoflurane  
Pioneer: Sevoflo®  
Ingredients: Sevoflurane  
Sponsor: Halocarbon Products Corp.  
Approval Date: November 27, 2009  
Status: Rx  
Route: Inhalation  
Species: Dogs  
Drug Form: Liquid  
Concentration: 250 mL sevoflurane  
Indications: For induction and maintenance of general anesthesia in dogs.

21 CFR 529.2150 75 FR 1021

### NADA Number: 141-299

Trade Name: Resflor Gold®  
Ingredients: Florfenicol and flunixin meglumine  
Sponsor: Intervet, Inc.  
Approval Date: November 23, 2009  
Status: Rx  
Route: Subcutaneous  
Species: Cattle/beef and non-lactating dairy  
Drug Form: Injectable solution  
Concentration: 300 mg florfenicol and 16.5 mg flunixin (27.37 mg flunixin meglumine) per mL.  
Indications: For treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni*, and control of BRD-associated pyrexia in beef and non-lactating dairy cattle.  
Patent: 6,790,867, expires January 24, 2023  
Exclusivity: 3 years

21 CFR 522.956 75 FR 1274

### NADA Number: 141-298

Trade Name: Surolan® Otic Suspension  
Ingredients: miconazole nitrate, polymyxin B sulfate, and prednisolone acetate  
Sponsor: Janssen Pharmaceutica NV  
Approval Date: November 23, 2009  
Status: Rx  
Route: Otic  
Species: Dogs  
Drug Form: Suspension  
Concentration: 23 mg/mL miconazole nitrate, 0.5293 mg/mL polymyxin B sulfate, 5 mg/mL prednisolone acetate  
Indications: For treatment of canine otitis externa associated with susceptible strains of yeast (*Malassezia pachydermatis*) and bacteria (*Staphylococcus pseudintermedius*).  
Exclusivity: 3 years

21 CFR 524.1445 75 FR 4692

## Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were published in the Federal Register in January 2010.

### Supplemental Approvals

---

This section displays the change(s) to the original approval. To read the complete approval, please refer to 21CFR Parts 500 and the related Federal Register notices.

#### **NADA Number: 122-578**

Trade Name: Hyvisc® Sterile Injection  
Ingredients: Hyaluronate sodium  
Sponsor: Anika Therapeutics, Inc.  
Approval Date: December 11, 2009

This supplement provides for changing the Warning statement to “Do not use in horses intended for human consumption”.

*21 CFR 522.1145 75 FR 1274*

#### **NADA Number: 141-221**

Trade Name: Optaflexx 45 Type A medicated article  
Ingredients: ractopamine hydrochloride  
Sponsor: Elanco Animal Health, a Div. of Eli Lilly & Co.  
Approval Date: December 11, 2009

This supplement provides for feeding ractopamine hydrochloride Type C medicated feed as a top dress.

*21 CFR 558.500 75 FR 1275*

#### **NADA Number: 141-209**

Trade Name: Excede® Sterile Suspension  
Ingredients: Ceftiofur crystalline free acid  
Sponsor: Pharmacia & Upjohn Co., a Division of Pfizer, Inc.  
Approval Date: December 16, 2009  
Exclusivity: Three years

This supplement provides for provides for a new indication, for the treatment of lower respiratory tract infections in horses caused by susceptible strains of *Streptococcus equi ssp. zooepidemicus*.

*21 CFR 522.313a 75 FR 4692*

#### **NADA Number: 48-480**

Trade Name: Chloratet™ 90 and Chloratet™ 100  
Ingredients: Chlortetracycline  
Sponsor: ADM Alliance Nutrition  
Approval Date: January 7, 2010

There are two separate supplements that provides for two new Type A medicated article formulation containing 90 grams and a second providing for 100 grams chlortetracycline per pound.

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

The following corrections or additions to the list were published in the Federal Register in January 2010.

### **Sponsor Name and Address Change**

---

Previous Sponsor Name: Fort Dodge Animal Health, A Division of Wyeth Holdings Corp.  
P.O. Box 1339  
Fort Dodge, IA 50501

New Sponsor Name: Fort Dodge Animal Health, Division of Wyeth Holdings Corp., a wholly owned subsidiary of  
Pfizer Inc.  
235 East 42<sup>nd</sup>. St.  
New York, NY 10017

*21 CFR 510.600, 75 FR 3159*