

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were completed in November 2016.

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: 141-474

Trade Name: Itrafungol™
Ingredients: Itraconazole
Sponsor: Elanco US Inc.
Approval Date: November 10, 2016
Status: Rx
Route: Oral
Species: Cats
Drug Form: Oral solution
Concentration: 10 mg/mL
Indications: For the treatment of dermatophytosis caused by *Microsporum canis* in cats.
Exclusivity: Five years

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: 141-443

Trade Name: onsior™
Ingredients: Robenacoxib
Sponsor: Elanco US Inc.
Approval Date: November 16, 2016
Status: Rx
Route: Subcutaneous injection
Species: Dogs
Drug Form: Injection
Concentration: 20 mg/mL
Indications: For the control of postoperative pain and inflammation associated with soft tissue surgery in dogs \geq 4 months of age; for up to a **maximum of 3 days**.
Exclusivity: Three years

Sponsor Change

NADA Number: 141-110

Previous Sponsor: Elanco US Inc.
New Sponsor: Phibro Animal Health
Drug Labeler Code: 066104

Sponsor Name Change

Previous Name: ivaoes Animal Health
New Name: Ivaoes Animal Health

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were completed in November 2016.

Patent Addition:

Patent Number: 6107306
Expiration Date: December 4, 2016