

## Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 2007 list were published in the Federal Register in August 2007.

### Original Approvals

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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: 141-275

Trade Name: Profender®  
Ingredients: Emodepside and praziquantel  
Sponsor: Bayer HealthCare LLC.  
Approval Date: June 29, 2007  
Status: Rx  
Route: Topical  
Species: Cats  
Drug Form: Solution  
Concentration: Each mL contains 21.4 mg emodepside and 85.7 mg praziquantel  
Indications: Indicated for the treatment and control of hookworm infections caused by *Ancylostoma tubaeforme* (adults, immature adults, and fourth stage larvae), roundworm infections caused by *Toxocara cati* (adults and fourth stage larvae), and tapeworm infections caused by *Dipylidium caninum* (adults) and *Taenia taeniaeformis* (adults).  
Exclusivity: Three years  
Patents: 5,514,773 Expires: May 7, 2013  
5,589,503 Expires: January 4, 2015

21 CFR 524.775

#### ANADA Number: 200-452

Pioneer: 008-963  
Trade Name: OxyTet™10  
Ingredients: Oxytetracycline hydrochloride  
Sponsor: Norbrook Laboratories, Inc.  
Approval Date: June 27, 2007  
Status: OTC  
Route: Injectable  
Species: Beef cattle, beef calves, non-lactating dairy cattle, and dairy calves  
Drug Form: Solution  
Concentration: 100 mg/mL  
Indications: The use of OxyTet™ 10 Injection is indicated in beef cattle, beef calves, non-lactating dairy cattle and dairy calves for the treatment of the following disease conditions caused by one or more of the oxytetracycline sensitive pathogens listed as follows: bacterial pneumonia and shipping fever complex associated with *Pasteurella* spp.; bacterial enteritis (scours) caused by *Escherichia coli*; necrotic pododermatitis (foot rot) and calf diphtheria caused by *Fusobacterium necrophorum*; wooden tongue caused by *Actinobacillus lignieresii*; and wound infections, acute metritis and traumatic injury caused by susceptible strains of streptococcus and staphylococcus organisms.  
Tolerance: Tolerances are established for the sum of residues of tetracycline including oxytetracycline in uncooked edible tissues as follows: 2 parts per million (ppm) in muscle, 6 ppm in liver, 12 ppm in fat and kidney for beef cattle, beef calves, non-lactating dairy cattle, and dairy calves (21 CFR 556.500(b)). The Acceptable Daily Intake for oxytetracycline is 25 micrograms per kilogram of body weight per day.  
Withdrawal Time: withdrawal period of at least 22 days prior to slaughter in beef cattle, beef calves, non-lactating dairy cattle, and dairy calves.

21 CFR 522.1662a, 21 CFR 556.500(b)

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### Voluntary Withdrawal

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#### NADA Number: 128-550

Trade Name: Anchor Zinc Bacitracin  
Ingredients: Bacitracin zinc  
Sponsor: Pennfield Oil Co.  
Effective Date: August 28, 2007

21 CFR 558.78

### Removal of Patent

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#### NADA Number: 141-258

Patent Number: 6,001,858

### Notice(s)

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The Food and Drug Administration (FDA) is announcing the rates and payment procedures for fiscal year (FY) 2008 animal drug user fees. The Federal Food, Drug, and Cosmetic Act (the act), as amended by the Animal Drug User Fee Act of 2003 (ADUFA), authorizes FDA to collect user fees for certain animal drug applications, on certain animal drug products, on certain establishments where such products are made, and on certain sponsors of such animal drug applications and/or investigational animal drug submissions. This notice establishes the fee rates for FY 2008.

For FY 2008, the animal drug user fee rates are: \$172,500 for an animal drug application; \$86,250 for a supplemental animal drug application for which safety or effectiveness data is required; \$4,125 for an annual product fee; \$52,700 for an annual establishment fee; and \$43,900 for an annual sponsor fee. FDA will issue invoices for FY2008 product, establishment and sponsor fees by December 30, 2007, and these invoices will be due and payable by January 31, 2008.

FOR FURTHER INFORMATION CONTACT: Roxanne Schweitzer, Center for Veterinary Medicine, (HFV-10), Food and Drug Administration, 7529 Standish Place, Rockville, MD 20855, 301-276-9705

72 FR 42419, August 2, 2007

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The FDA is announcing opportunity for public comment FDA's current Good Manufacturing Practice (cGMP) regulations for Type A medicated articles.

DATES: Submit written or electronic comments on the collection of information by October 15, 2007.

ADDRESSES: Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/ecomments>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1472.

72 FR 46089, August 16, 2007

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

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### **Notice(s), cont.**

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The FDA is announcing opportunity for public comment FDA's current Good Manufacturing Practice (cGMP) regulations for medicated feeds.

**DATES:** Submit written or electronic comments on the collection of information by October 15, 2007.

**ADDRESSES:** Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/ecomments>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Denver Presley, Jr., Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1472.

72 FR 46090, August 16, 2007

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

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