Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 2008 list were published in the Federal Register in February 2008.

New Approvals

NADA Number: 141-276

Trade Name:	Zilmax®, Rumensin®, and Tylan®
Ingredients:	Zilpaterol hydrochloride, monensin USP, and tylosin phosphate
Sponsor:	Intervet, Inc.
Approval Date:	January 10, 2008
Status:	OTC
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 C medicated feeds
Concentration:	Zilpaterol hydrochloride: 6.8 g/ton (as fed) Monensin USP: 10 – 40 g/ton (as fed) Tylosin phosphate: 8 -10 g/ton (as fed)
Indications:	Provides for use of zilpaterol, and monensin, and tylosin Type A medicated articles to make dry and liquid three-way combination Type B and Type C medicated feeds used in cattle fed in confinement for slaughter during the last 20 to 40 days on feed 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*.
Withdrawal Time:	3 days
Tolerance:	Cattle: Zilpaterol freebase - 12 parts per billion (ppb) in liver (*21 CFR 556.765*); monensin USP - 0.05 parts per million (ppm) in muscle, kidney, & fat, - 0.10 ppm in liver (*21 CFR 556.420*); tylosin phosphate - 0.2 ppm in muscle, kidney, fat, & liver (*21 CFR 556.740*).

21 CFR 558.355; 558.625; 558.665

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: 141-244

Trade Name:	Draxxin® Injectable Solution
Ingredients:	Tulathromycin
Sponsor:	Pfizer Inc.
Approval Date:	December 28, 2007
Exclusivity:	3 years

This supplemental application provides for the addition of a new indication the treatment of infectious bovine keratoconjunctivitis associated with *Moraxella bovis*, and for the addition of *Mycoplasma hyopneumoniae* to the list of target pathogens for the swine respiratory disease indication.

21 CFR 522.2630 73 FR 6017

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 February 2008.

NADA Number: 131-310

Trade Name: Regu-Mate®
Ingredients: Altrenogest
Sponsor: Intervet, Inc.
Approval Date: January 18, 2008

This supplemental application provides for labeling revisions including updating the Warning statement to include "Do not use in horses intended for human consumption" and other labeling changes.

21 CFR 520.48 73 FR 9455

NADA Number: 091-818

Trade Name: Phenylbutazone Tablets, USP
Ingredients: Phenylbutazone
Sponsor: IVX Animal Health, Inc.
Approval Date: January 17, 2008
Species: Horses

This supplemental application provides for the revision of the food safety warning statements to read: "Do not use in horses intended for human consumption. Federal law prohibits the use of this drug in female dairy cattle 20 months of age or older." and updating of the sponsor name.

21 CFR 520.1720(a) 73 FR 8192

NADA Number: 094-170

Trade Name: Phenylbutazone Tablets, USP
Ingredients: Phenylbutazone
Sponsor: IVX Animal Health, Inc.
Approval Date: January 17, 2008
Species: Dogs

This supplemental application provides for the updating of the sponsor name.

21 CFR 520.1720(a) 73 FR 8192

NADA Number: 110-048

Trade Name: Valbazen®
Ingredients: Albendazole
Sponsor: Pfizer, Inc.
Approval Date: January 24, 2008
Tolerance: Goat: the tolerance for the 2-aminosulfone metabolite of albendazole (marker residue) in liver (target tissue) is 0.25 parts per million (ppm) *(21 CFR 556.34)*
Withdrawal time: 7 days
Exclusive Marketing Rights: 7 years

This supplemental application provides for use of albendazole oral suspension in non-lactating goats for the treatment of adult liver flukes (*Fasciola hepatica*) and qualifies the product for an additional exclusivity period of 7 years because the new animal drug has been declared a designated drug by the FDA under section 573(a) of the Act. Limitations: Do not administer to does during the first 30 days of pregnancy or for 30 days after removal of bucks.

21 CFR 520.45a , 21 CFR 556.34 73 FR 11026

ANADA Number: 200-202

Pioneer Product: 140-439
Trade Name: Phoenectin®
Ingredients: Ivermectin
Sponsor: IVX Animal Health, Inc.
Approval Date: January 24, 2008

This supplemental application provides for the addition of indications for use claims for additional parasite species no longer protected by exclusivity (*Craterostomum acuticaudatum*, *Petrovinema poculatum*, and *Coronocyclus* spp. including *C. coronatus* and *C. labratus*) and some currently-approved parasite genera that were revised to add corresponding species; the separation of the listing of adult small strongyle species from their related fourth stage larvae; and changes to reflect updated nomenclature.

21 CFR 520.1195 73 FR 9455

Change of Sponsor

ANADA Numbers: 200-073

From: Veterinary Research Associates, Inc.

To: Putney, Inc.
400 Congress Street, suite 200,
Portland, ME 04101.

Drug Labeler Code: 026637

73 FR 8191

Correction of Patent Information

NADA Number: 141-068

Patent Number. 5,756,506
Corrected Expiration Date: June 27, 2015

NADA Number: 141-188

Patent No. 5,883,095
Corrected Expiration Date: March 31, 2017

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 February 2008.

Patent Number Addition

NADA Number: 141-152

Patent No. 6,797,701
Expiration Date: November 18, 2019

NADA Number: 141-276

Patent No.	Expiration Date
4,900,735	December 11, 2008
5,731,028	June 6, 2016
7,207,289	May 20, 2025

Labeling Revisions

NADA Number: 131-538

Trade Name: Disal®
Ingredients: Furosemide
Sponsor: Boehringer Ingelheim Vetmedica, Inc.
Effective Date: February 28, 2008

This supplemental application provides for the trademark ™ to be changed to a registered trademark ®.

NADA Number: 141-257

Trade Name: IVERHART MAX®
Ingredients: Ivermectin/pyrantel pamoate/praziquantel
Sponsor: Virbac Animal Health, Inc.
Effective Date: February 13, 2008

This supplemental application provides for the trademark ™ to be changed to a registered trademark ®.

Notices

The Food and Drug Administration (FDA) is announcing the final rule amending the animal drug regulations to correct an error in the indications for use for spectinomycin oral solution in swine. FDA notes that the animal drug regulations do not reflect the approved indications for use for spectinomycin oral solution in swine. FDA is also amending the regulations for other oral dosage forms of spectinomycin (tablets and powder) to reflect current format. These actions are being taken to improve the accuracy and readability of the animal drug regulations.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV-6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9019, e-mail: george.haibel@fda.hhs.gov

21 CFR 520.2123(a)(b)(c) 73 FR 6607