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 April 2007.

New Approvals

NADA Number: 141-261

Trade Name:	WORMXPLUS™ Virbantel™
Ingredients:	Pyrantel pamoate/Praziquantel
Sponsor:	Virbac AH, Inc.
Approval Date:	March 13, 2007
Status:	OTC
Route:	Oral
Species:	Dogs
Drug Form:	Chewable tablet
Concentration:	Small size: 30 milligrams pyrantel pamoate and 30 milligrams praziquantel Large size; 114 milligrams pyrantel pamoate and 114 milligrams praziquantel
Indications:	For treatment and control of roundworms (*Toxocara canis, Toxascaris leonina*); hookworms (*Ancylostoma caninum, Ancylostoma braziliense, Uncinaria stenocephala*), and tapeworms (*Dipylidium caninum, Taenia pisiformis*) in dogs and puppies.
Exclusivity:	3 years

21 CFR 520.1871

NADA Number: 141-268

Trade Name:	Protazil™
Ingredients:	Diclazuril
Sponsor:	Schering-Plough Animal Health Corp.
Approval Date:	March 29, 2007
Status:	Rx
Route:	Oral
Species:	Horses
Drug Form:	Pellets
Concentration:	1.56% (w/w) diclazuril
Indications:	For the treatment of equine protozoal myeloencephalitis (EPM) caused by *Sarcocystis neurona* in horses
Exclusivity:	3 years
Patents:	4,631,278 Expiration Date: August 1, 2007 5,830,893 Expiration Date: April 23, 2017 5,883,095 Expiration Date: August 7, 2017

21 CFR 520.606

ANADA Number: 200-418

Pioneer Product:	140-839
Trade Name:	Muricin™
Ingredients:	Mupirocin
Sponsor:	Altana Inc.
Approval Date:	March 8, 2007
Status:	Rx
Route:	Topical
Species:	Dogs
Drug Form:	Ointment
Concentration:	Each gram contains 20 milligrams of mupirocin
Indications:	For the topical treatment of canine bacterial infections of the skin, including superficial pyoderma caused by susceptible strains of *Staphylococcus aureus* and *Staphylococcus intermedius.*

21CFR 524.1465

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 March 2007.

New Approvals, cont.

ANADA Number: 200-451

Pioneer Product:	140-288
Trade Name:	HeifermaX® 500 plus Bovatec®
Ingredients:	Melengestrol acetate plus lasalocid sodium
Sponsor:	Ivy Laboratories, Div. of Ivy Animal Health, Inc.
Approval Date:	March 12, 2007
Status:	OTC
Route:	Oral
Species:	Heifers fed in confinement for slaughter
Drug Form:	Type A medicated articles for use in combination for the manufacture of two-way dry and liquid Type B or Type C medicated feeds
Dose Form:	Medicated feeds
Concentration:	500 mg of melengestrol acetate activity per pound of premix; 68 g/lb (15%), 91 g/lb (20%), 150 g/lb (33.1%), or Liquid 90.7 g/lb (20%) as lasalocid sodium
Indications:	For increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat) in heifers fed in confinement for slaughter.
Tolerance:	*21 CFR 556.380* – melengestrol acetate: 25 parts per billion (ppb) in fat *21 CFR 556.347* – lasalocid sodium: 0.7 parts per million (ppm) in liver
Withdrawal:	Not required

21CFR 558.342, 21 CFR 556.380, and 21 CFR 556.347

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: 141-246

Trade Name:	Aquaflor®
Ingredients:	Florfenicol
Sponsor:	Schering-Plough Animal Health Corp.
Approval Date:	March 19, 2007
Status:	VFD
Exclusivity:	7 years
Tolerance:	*21 CFR 556.283* – florfenicol: 1 parts per million (ppm) in muscle/skin
Withdrawal:	Feeds containing Aquaflor® (florfenicol) must be withdrawn 15 days prior to slaughter.

This supplemental application provides for the addition of the indication for the control of mortality in freshwater-reared salmonids due to coldwater disease associated with *Flavobacterium psychrophilum.*

21CFR 556.283, 21 CFR 558.261, and 21 CFR 558.4

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 April 2007.

Label Revisions

NADA Number: 141-227

Trade Name: UlcerGard®
Ingredients: Omeprazole
Sponsor: Merial Ltd.
Approval Date: April 18, 2007

This supplemental application provides for changing the trademark symbol from ™ to ® which allows compliance with their approved legal authorization.

21CFR 520.1615 No FR notice needed.

Addition of Patents

NADA Number: 141-268

Patent Number:	4,631,278	Expiration Date:	August 1, 2007
Patent Number:	5,830,893	Expiration Date:	April 23, 2017
Patent Number:	5,883,095	Expiration Date:	August 7, 2017

NADA Number: 141-263 and 141-262

Patent Number:	6,222,038	Expiration Date:	April 21, 2015
Patent Number:	5,939,433	Expiration Date:	May 31, 2011
Patent Number:	5,538,982	Expiration Date:	July 23, 2013
Patent Number:	5,134,127	Expiration Date:	January 23, 2010
Patent Number:	5,376,645	Expiration Date:	January 23, 2010

NADA Number: 141-258

Patent Number:	7,207,289	Expiration Date:	May 20, 2025
Patent Number:	6,001,858	Expiration Date:	November 27, 2015

Extension of Patent Term

NADA Numbers: 141-099, 141-087, 141-051, 141-189, 141-216, 141-220, and 141-247

Patent Number:	4,916,154	Expiration Date:	April 10, 2008

Removal of Patent

NADA Numbers: 140-999

Patent Number: 4,783,477

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 March 2007.

Addition of Exclusivity Period

NADA Number: 141-263 and 141-262

3 years granted Expiration Date: January 29, 2010

Voluntary Withdrawals

NADA Number: 141-040 and 141-041

Ingredient: Estradiol benzoate
Date of Withdrawal: September 29, 2006
Sponsor: PR Pharmaceuticals, Inc.

NADA Number: 121-200

Ingredient: Tylosin phosphate
Date of Withdrawal: April 30, 2007
Sponsor: Custom Feed Services Corp.

NADA Number: 129-159

Ingredient: Tylosin phosphate and sulfamethazine
Date of Withdrawal: April 30, 2007
Sponsor: Custom Feed Services Corp.

NADA Number: 137-484

Ingredient: Pyrantel tartrate
Date of Withdrawal: April 30, 2007
Sponsor: Custom Feed Services Corp.

72 FR 19665, April 19, 2007

Removal of Sponsor

PR Pharmaceuticals, Inc.
Drug Labeler Code: 067210

Custom Feed Services Corp.
Drug Labeler Code: 017473

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 April 2007.

Technical Amendment

The Food and Drug Administration (FDA) is amending a final rule that appeared in the FEDERAL REGISTER of January 4, 2007 (72 FR 263, revising the animal drug regulations to reflect approval of an original new animal drug application (NADA). The document incorrectly listed the amount of drug per milliliter of Dexmedetomidine hydrochloride injectable solution.

Sec. 522.558 Dexmedetomidine (a) Specifications. Each milliliter of solution contains 0.5 milligram (mg) of Dexmedetomidine hydrochloride.

FOR FURTHER INFORMATION CONTACT: George Haibel, Center for Veterinary Medicine (HFV-6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-267-9019, e-mail: george.haibel@fda.hhs.gov.

72 FR 19796, April 20, 2007