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

NADA Number: 141-251

Trade Name:	Advantage Multi™
Ingredients:	Imidacloprid + moxidectin
Sponsor:	Bayer HealthCare LLC
Approval Date:	December 20, 2006
Status:	Rx
Route:	Topical
Species:	Dogs
Dose Form:	Solution
Concentration:	Each milliliter of solution contains 100 mg imidacloprid and 25 mg moxidectin
Indications:	Prevention of heartworm disease caused by *Dirofilaria immitis*; treatment of *Ctenocephalides felis* infestations; and treatment and control of the following intestinal parasites: **Hookworms**: *Ancylostoma caninum and Uncinaria stenocephala (*Adults, immature adults and fourth stage larvae); **Roundworms***:* of *Toxocara canis* (Adults and fourth stage larvae) and *Toxascaris leonina* (Adults)*;* **Whipworms***: Trichuris vulpis* (Adults).
Exclusivity:	3 years
Patents:	6,232,328 Expiration Date: May 12, 2015 6,001,858 Expiration Date: November 27, 2015

21 CFR 524.1146

NADA Number: 141-254

Trade Name:	Advantage Multi™
Ingredients:	Imidacloprid + moxidectin
Sponsor:	Bayer HealthCare LLC
Approval Date:	January 19, 2007
Status:	Rx
Route:	Topical
Species:	Cats
Dose Form:	Solution
Concentration:	Each milliliter of solution contains 100 mg imidacloprid and 10 mg moxidectin
Indications:	Prevention of heartworm disease caused by *Dirofilaria immitis*; treatment of infestations of *Ctenocephalides felis*; treatment and control of *Otodectes cynotis* infestations; and treatment and control of the following intestinal parasites: **Hookworms**: *Ancylostoma tubaeforme* (adults, immature adults and fourth stage larvae); **Roundworms**: *Toxocara cati* (adults and fourth stage larvae).
Exclusivity:	3 years
Patents:	6,232,328 Expiration Date: May 12, 2015 6,001,858 Expiration Date: November 27, 2015

21 CFR 524.1146

NADA Number: 141-262

Trade Name:	Cerenia™
Ingredients:	Maropitant citrate
Sponsor:	Pfizer, Inc.
Approval Date:	January 29, 2007
Status:	Rx
Route:	Oral
Species:	Dogs
Dose Form:	Tablets
Concentration:	16, 24, 60, and 160 mg of maropitant as maropitant citrate per tablet
Indications:	Prevention of acute vomiting and prevention of vomiting due to motion sickness in dogs
Exclusivity:	5 years
Patents:	6,222,038 Expiration Date: April 21, 2015 6,255,320 Expiration Date: May 8, 2020

21 CFR 520.1315

New Approvals, cont.

NADA Number: 141-263

Trade Name:	Cerenia™
Ingredients:	Maropitant citrate
Sponsor:	Pfizer, Inc.
Approval Date:	January 29, 2007
Status:	Rx
Route:	Subcutaneous Injection
Species:	Dogs
Dose Form:	Solution
Concentration:	Each mL contains 10 mg of maropitant as maropitant citrate
Indications:	For the prevention and treatment of acute vomiting in dogs
Exclusivity:	3 years
Patents:	6,222,038 Expiration Date: April 21, 2015 6,255,320 Expiration Date: May 8, 2020

21 CFR 520.1315

ANADA Number: 200-448

Pioneer Product:	141-234
Trade Name:	Heifermax® 500 plus Optaflexx® and Rumensin®
Ingredients:	Melengestrol acetate, ractopamine hydrochloride, and monensin sodium
Sponsor:	Ivy Laboratories, Div. of Ivy Animal Health, Inc.
Approval Date:	January 29, 2007
Status:	OTC
Route:	Oral
Species:	Beef cattle; heifers fed in confinement for slaughter
Drug Form:	Type A Medicated Articles for use in combination for the manufacture of three-way dry and liquid Type B or Type C medicated feeds
Dose Form:	Medicated feed
Concentration:	500 mg of melengestrol acetate activity per pound of premix; 45.4 grams of ractopamine hydrochloride activity per pound of premix; 20, 30, 40, 60, 80, or 90.7 grams of monensin sodium activity per pound of premix
Indications:	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 suppression of estrus (heat) in heifers fed in confinement for slaughter for the last 28 to 42 days on feed.
Tolerance:	*21 CFR 556.380* – melengestrol acetate: 25 parts per billion (ppb) in fat *21 CFR 556.570* – ractopamine hydrochloride: 0.09 parts per million (ppm) in liver, 0.03 ppm in muscle *21 CFR 556.420* – monensin sodium: 0.05 ppm in the edible tissues
Withdrawal:	Not required

21CFR 558.500, 21 CFR 556.380, 21 CFR 556.570, and 21 CFR 556.420

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.

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.

ANADA Number: 200-346

Pioneer Product: 140-992
Trade Name: Component® TE-200 with Tylan®
Ingredients: Trenbolone acetate 200 mg and estradiol USP 20 mg with 29 mg tylosin tartrate
Sponsor: Ivy Animal Health, Inc.
Approval Date: January 26, 2007
Exclusivity: 3 years

This supplemental application provides for the addition of a 29 mg tylosin tartrate pellet as a local antibacterial to Component® TE-200 for use in steers and heifers fed in confinement for slaughter.

21CFR 522.2477 72 FR 9243

NADA Number: 140-854

Trade Name: Synanthic®
Ingredients: Oxfendazole
Status: OTC
Route: Oral
Sponsor: Fort Dodge Animal Health, Division of Wyeth
Approval Date: January 29, 2007

This supplemental application is to change the marketing status for use of the 22.5% suspension in cattle from prescription status to over-the-counter status by removing the intraruminal route of administration.

21CFR 520.1630 72 FR 10595

NADA Number: 141-258

Trade Name: Zilmax®
Ingredients: Zilpaterol hydrochloride
Sponsor: Intervet Inc.
Approval Date: January 29, 2007
This supplemental application provides for removal of the statement "Do not pellet medicated feeds containing zilpaterol." from the labeling and from 21 CFR 558.665(d)(3).

21CFR 558.665 72 FR 9245

NADA Number: 38-878

Trade Name: Coban® 60 and Coban® 90
Ingredients: Monensin, USP
Sponsor: Elanco Animal Health, A Division of Eli Lilly & Co.
Approval Date: February 7, 2007
Tolerances: Not required

This supplemental application provides for changing the active drug ingredient name to monensin, USP, changing the trade name from Elancoban® 90 to Coban® 90, and adding turkey and quail indications, use directions, and warnings for the added species.

21CFR 558.355, 21 CFR 556.420 72 FR 9244

Supplemental Approvals, cont.

NADA Number: 120-648

Trade Name: Panacur®
Ingredients: Fenbendazole
Sponsor: Intervet, Inc.
Approval Date: February 8, 2007

This supplemental application provides for updating the warning statement to read "Do not use in horses intended for human consumption."

21CFR 520.905 72 FR10595

NADA Number: 132-872

Trade Name: Safe-guard®
Ingredients: Fenbendazole
Sponsor: Intervet, Inc.
Approval Date: February 8, 2007

This supplemental application provides for updating the warning statement to read "Do not use in horses intended for human consumption." and labeling for a 92 g Safe-guard® carton.

21CFR 520.905 72 FR10595

NADA Number: 141-068

Trade Name: Baytril®
Ingredients: Enrofloxacin
Sponsor: Bayer HealthCare LLC, Animal Health Division
Approval Date: February 15, 2007

This supplemental application provides for updating the scientific name "*Pasteurella haemolytica*" to "*Mannheimia haemolytica*".

21CFR 522.812 72 FR10596

Label Revisions

NADA Number: 140-927

Trade Name: Chorulon®
Ingredients: Chorionic gonadotropin
Sponsor: Intervet Inc.
Approval Date: March 20, 2007

This supplemental application provides for updating the taxonomic names for two approved species of fish. Walleye is now *Sander vitreus* and sauger is now *Sander canadensis.*

21CFR 522.1081 No FR notice needed.

Label Revisions, cont.

NADA Number: 141-008

Trade Name: Drontal®
Ingredients: Praziquantel/pyrantel pamoate
Sponsor: Bayer HealthCare LLC
Approval Date: March 27, 2007

This supplemental application provides for updating the trade mark (™) to a registered trademark (®).

21CFR 520.1871 No FR notice needed.

Addition of Patents

NADA Number: 141-251 & 141-254

Patent Number: 6,232,328 Expiration Date: May 12, 2015
Patent Number: 6,001,858 Expiration Date: November 27, 2015

NADA Number: 141-263

Patent Number: 6,222,038 Expiration Date: April 21, 2015
Patent Number: 6,255,320 Expiration Date: May 8, 2020

NADA Number: 141-258

Patent Number: 4,900,735 Expiration Date: December 11, 2007
Patent Number: 5,731,028 Expiration Date: June 6, 2016

Addition of Patent Expiration Date

NADA Number: 141-227

Patent Number: 6,939,881 Expiration Date: May 29, 2021

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.

Notice(s)

The Food and Drug Administration (FDA) is announcing the availability of the guidance for industry (183) entitled "Guidance for Industry: Animal Drug User Fees; Fees Exceed Costs Waiver/Reduction. This guidance explains the procedures FDA expects to use to evaluate waiver requests under the fees exceed costs waiver provision of the Animal Drug User Fee Act of 2003 (ADUFA).

Submit written or electronic comments on agency guidances at any time.

Submit written requests for single copies of the guidance document to the Communications Staff (HFV-12), Center for Veterinary Medicine (CVM), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855.

FOR FURTHER INFORMATION CONTACT: Dave Newkirk, Center for Veterinary Medicine (HFV-100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6967, e-mail: david.newkirk@fda.hhs.gov.

72 FR 10768, March 9, 2007

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The Food and Drug Administration (FDA) is announcing a public meeting on the Animal Drug User Fee Act of 2003 (ADUFA) to seek public comments relative to the program's overall performance and reauthorization as directed by Congress.

The public meeting will be held on April 24, 2007, beginning at 9 a.m. at the Food and Drug Administration, 7519 Standish Pl., Third floor, Rm. A, Rockville, MD 20855.

FOR FURTHER INFORMATION CONTACT: Aleta Sindelar, Office of the Director (HFV-3), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9004, FAX 240-276-9020, e-mail: aleta.sindelar@fda.hhs.gov.

72 FR 11370, March 13, 2007

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The Food and Drug Administration (FDA) is announcing request for comment on substances prohibited from use in animal food or feed; animal proteins prohibited in ruminant feed. In the Federal Register of December 4, 2006 (71 FR 70409), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

Dates: Fax written comments on the collection of information by April 16, 2007/

Addresses: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX 202-395-6974.

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 12179, March 15, 2007

Notice(s), cont.

The Food and Drug Administration (FDA) is amending its regulations to affirm that the use of 25-hydroxyvitamin D3 is generally recognized as safe (GRAS) as a source of vitamin D3 activity in broiler chicken feeds and drinking water when used in accordance with certain limitations. This action is in response to a petition filed by Amoco BioProducts Corp. Subsequently, the sponsorship for this petition was changed to IsoGen L.L.C., Monsanto Co., Roche Vitamins, Inc. and lastly, to DSM Nutritional Products, Inc.

Dates: This rule is effective March 16, 2007

FOR FURTHER INFORMATION CONTACT: Michaela Alewynse, Center for Veterinary Medicine (HFV-228), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-453-6866, e-mail: mika.alewynse@fda.hhs.gov.

72 FR 12564, March 16, 2007

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The Food and Drug Administration (FDA) is requesting comment on focus groups as used by the Food and Drug Administration.

Dates: Submit written or electronic comments on the collection of information by May 29, 2007.

Addresses: Submit electronic comments on the collection of information to: http://www.fda.gov/dockets/ecomments. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number [Docket No. 2007N-0098].

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

72 FR 14280, March 27, 2007