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 January 2007.

New Approvals

NADA Number: 141-267

Trade Name:	Dexdomitor®
Ingredients:	Dexmedetomidine hydrochloride
Sponsor:	Orion Corp.
Approval Date:	December 1, 2006
Status:	Rx
Route:	Intravenous or intramuscular
Species:	Dogs
Drug Form:	Sterile solution
Concentration:	0.5 mg/mL
Indications:	For use as a sedative and analgesic in dogs to facilitate clinical examinations, clinical procedures, minor surgical procedures, and minor dental procedures. Also, indicated for use as a preanesthetic to general anesthesia.
Exclusivity:	THREE years.
Patents:	4,910,214 Date of Expiration: July 15, 2008

21CFR 522.558

NADA Number: 141-260

Trade Name:	Slentrol™
Ingredients:	Dirlotapide
Sponsor:	Pfizer Inc.
Approval Date:	December 12, 2006
Status:	Rx
Route:	Oral
Species:	Dogs
Drug Form:	Oral solution
Concentration:	5 mg/mL
Indications:	For the management of obesity in dogs.
Exclusivity:	FIVE years.
Patents:	6,720,351 Date of Expiration: October 12, 2022

21CFR 520.666

ANADA Number: 200-435

Pioneer Product:	034-879
Trade Name:	Respiram™
Ingredients:	Doxapram hydrochloride
Sponsor:	Modern Veterinary Therapeutics, LLC
Approval Date:	November 21, 2006
Status:	Rx
Route:	Intravenous, subcutaneous, sublingual or umbilical vein
Species:	Dogs, cats, and horses
Drug Form:	Sterile solution
Concentration:	20 mg/mL
Indications:	To stimulate respirations during and after general anesthesia. To speed awakening and return of reflexes after anesthesia. For neonate dogs and cats: Initiate respirations following cesarean section or dystocia. To stimulate respirations following dystocia or cesarean section.

21CFR 522.775

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: 141-033

Trade Name: Antisedan®
Ingredients: Atipamezole hydrochloride
Sponsor: Orion Corp
Approval Date: December 1, 2006
Exclusivity: 3 years

This supplemental application provides for the additional indication for the reversal of the sedative and analgesic effects of Dexdomitor® (dexmedetomidine hydrochloride).

This supplemental application lists two U.S. Patents:

Patent Number	Expiration Date
4,689,339	August 6, 2010
4,933,359	May 14, 2007

21CFR 522.147

NADA Number: 009-782

Trade Name: Nolvasan®
Ingredients: Chlorhexidine acetate
Sponsor: Fort Dodge Animal Health, Division of Wyeth
Approval Date: November 28, 2006

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

21CFR 524.402

NADA Number: 141-120

Trade Name: Clomicalm®
Ingredients: Clomipramine hydrochloride
Sponsor: Novartis Animal Health US, Inc.
Approval Date: November 22, 2006

This supplemental application provides for the addition of a 5 mg tablet size.

21CFR 520.455

NADA Number: 141-206

Trade Name: Nuflor®
Ingredients: Florfenicol
Sponsor: Schering-Plough Animal Health Corp.
Approval Date: December 8, 2006

This application provides for removal of the "Type 2" designation from "*Streptococcus suis* Type 2," replacement of the black box from the "Residue Warnings" to compressed arrows, and additional minor label changes.

21CFR 520.955

NADA Number: 095-735

Trade Name: Rumensin® 80
Ingredients: Monensin
Sponsor: Elanco Animal Health, A Division of Eli Lilly & Co.
Approval Date: December 1, 2006

This supplemental application provides for an increase in the upper dose limit of monensin to 40 g/ton (480 mg/hd/day) in cattle being fed in confinement for slaughter for (1) improved feed efficiency and (2) prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii*.

21CFR 558.355

New Sponsor

Modern Veterinary Therapeutics, LLC
18301 SW. 86th Ave.
Miami, FL 33157
Drug Labeler Code: 015914

Change of Sponsor

NADA Numbers: 048-480, 065-256, 091-582, 107-957, 108-484, 110-045, 110-439, 118-877, 128-411, 131-956, 131-957, 132-448, 133-490, and 140-842

From: ADM Animal Health and Nutrition Division

To: ADM Alliance Nutrition, Inc.
1000 North 30th St.
Quincy, IL 62305-3115

Drug Labeler Code: 021930

21 CFR 510.600(c), 21 CFR 520.445B, 21 CFR 558.95, 21 CFR 558.128, 21 CFR 558.274, 21 CFR 558.485, 21 CFR 558.625, and 21 CFR 558.630

Regulatory Labeling Supplements

NADA Number: 200-344

Trade Name: TiaGard™
Ingredients: Tiamulin
Sponsor: IVX Animal Health
Approval Date: December 19, 2006

This supplemental application provides for a change in trade name and trade dress.

21CFR 520.2455

Actions Taken by FDA Center for Veterinary Medicine

NADA Number: 141-084

Trade Name: Sentinel® Flavor Tabs™
Ingredients: Milbemycin Oxime/Lufenuron
Sponsor: Novartis Animal Health US, Inc.
Approval Date: January 9, 2007

This supplemental application provides for the "®" behind Flavor Tabs has changed to a "™" in all sizes except the 26-50 lbs dog cartons, the package insert has the addition of ® after Capstar, and other minor labeling changes.

21CFR 520.1446

Notice(s)

The Food and Drug Administration (FDA) is announcing the availability of, and is requesting comment on, a draft risk assessment on animal cloning. FDA's Center for Veterinary Medicine (CVM) developed this draft risk assessment to evaluate the health risks to animals involved in the process of cloning and to evaluate the food consumption risks that may result from edible products derived from animal clones or their progeny. FDA is also announcing the availability of, and is requesting comment on, a proposed risk management plan for animal clones and their progeny. The proposed risk management plan takes into account the risks identified in the draft risk assessment and sets out proposed measures that FDA might use to manage those risks. In addition, FDA is announcing availability of draft guidance for industry 179 for public comment. This draft guidance describes FDA's recommendations regarding the use of edible products from animal clones and their progeny in human food or in animal feed.

Submit written or electronic comments on the draft risk assessment document, the proposed risk management plan, and the draft guidance for industry by April 3, 2007. FDA will accept comments, data, and information after the deadline, but to ensure consideration by the agency in any final documents, comments must be received by this date. Comments on agency guidance documents are welcome at any time.

Submit written comments on the draft risk assessment, proposed risk management plan, or draft guidance for industry to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit electronic comments to http://www.fda.gov/dockets/ecomments.

Comments submitted regarding this assessment should include the following Docket Number: 2003N-0573.

For further information contact Larisa Rudenko, Center for Veterinary Medicine (HFV-100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-453-6842, e-mail: clones@cvm.fda.gov.

72 FR 137, January 3, 2007

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