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 March 2008.

New Approvals

NADA Number: 141-278

Trade Name:	Zilmax® and Rumensin®
Ingredients:	Zilpaterol hydrochloride and monensin U.S.P.
Sponsor:	Intervet, Inc.
Approval Date:	February 15, 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 Monensin USP: 10 – 40 g/ton
Indications:	Provides for use of zilpaterol and monensin Type A medicated articles to make two-way combination Type B and Type C medicated feeds used for increased rate of weight gain, improved feed efficiency, increased carcass leanness, and prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii* in cattle fed in confinement for slaughter during the last 20 to 40 days on feed.
Withdrawal Time:	3 days
Tolerance:	Cattle: Zilpaterol freebase (liver) - 12 parts per billion (ppb) *(21 CFR 556.765)*; Monensin USP (muscle, kidney, & fat) - 0.05 parts per million (ppm), (liver) - 0.10 ppm *(21 CFR 556.420)*

21 CFR 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: 108-114

Trade Name:	Cefa-Dri®
Ingredients:	Cephapirin benzathine
Sponsor:	Fort Dodge Animal Health, Division or Wyeth
Approval Date:	February 7, 2008

This supplemental application provides for minor labeling changes including the addition of the phrase "including penicillin-resistant strains."

21 CFR 526.363

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 2008.

NADA Number: 065-110

Trade Name: PEN-G-MAX®
Ingredients: Penicillin G procaine
Sponsor: IVX Animal Health, Inc.
Approval Date: February 12, 2008

This supplemental application provides for revision of the target pathogen for erysipelas from "*Erysipelothrix insidiosa*" to "*Erysipelothrix rhusiopathiae*", the trademark ™ to be changed to a registered trademark ®, and revision of the Residue Warning statement in regards to veal. The last two sentences in the Residue Warning section will read "A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal."

21 CFR 522.1696

NADA Number: 141-143

Trade Name: Tetradure™ 300
Ingredients: Oxytetracycline
Sponsor: Norbrook Laboratories, Inc.
Approval Date: February 8, 2008

This supplemental application provides for the changing the scientific name of one of the target pathogens from *Haemophilus* spp. to *Histophilus* spp.

21 CFR 522.1660b

New Sponsor

Pharmacosmos, Inc,
776 Mountain Blvd.
Watchung, NJ 07069

Drug Labeler Code: 042552

73 FR14384, March 18, 2008

Change of Sponsor

NADA Numbers: 106-772, 134-708

From: Boehringer Ingelheim Vetmedica, Inc.

To: Animal Health Pharmaceuticals, LLC
1805 Oak Ridge Circle, Suite 101
St. Joseph, MO 64506

Drug Labeler Code: 068718

73 FR 12634, March 10, 2008

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 March 2008.

NADA Numbers: 106-772, 134-708

From: Animal Health Pharmaceuticals, LLC

To: Pharmacosmos, Inc,
776 Mountain Blvd.
Watchung, NJ 07069

Drug Labeler Code: 042552

73 FR14384, March 18, 2008

Patent Number Extension

NADA Number(s): 141-051, 141-087, 141-099, 141-216, 141-220, 141-247, 141-18

Patent number: 4,916,154
Extension Period: 1 year
Expiration Date: April 10, 2009

Labeling Revisions

NADA Number: 141-222

Trade Name: Matrix®
Ingredients: Altrenogest
Sponsor: Intervet Inc.
Effective Date: March 31, 2008

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

NADA Number: 065-495

Trade Name: Biomox®
Ingredients: Amoxicillin
Sponsor: Virbac AH, Inc..
Effective Date: March 5, 2008

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

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 2008.

Proposed Rule

The Food and Drug Administration (FDA) is proposing to amend the implementing regulations of the Minor Use and Minor Species Animal Health Act of 2004 (MUMS act). In response to Congress' charge to the agency to further define minor use; this amendment proposes a specific "small number of animals" for each of the seven major animal species to be used in determining whether any particular intended use in a major species is a minor use.

DATES: Submit written or electronic comments on the proposed rule by July 16, 2008. Submit comments regarding information collection by April 17, 2008 to OMB

ADDRESSES: You may submit comments, identified by Docket No. 2008N-0011 and RIN number 0910-AG03, by any of the following methods:
Electronic Submissions. Submit electronic comments in the following way:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Written Submissions. Submit written submissions in the following ways:

FAX: 301-827-6870.

Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]:
Division of Dockets Management (HFA-305), Food and Drug Administration,
5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described previously.

FOR FURTHER INFORMATION CONTACT: Margaret Oeller, Center for Veterinary Medicine (HFV-50), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9005, e-mail: Margaret.Oeller@fda.hhs.gov.

73 FR 14411 March 18, 2008

Notice (Technical Amendment)

The FDA is amending its animal drug regulations to correct an inadvertent omission in the list of concentrations of pyrantel tartrate Type A medicated articles approved for use by Philbro Animal Health.

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.