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 April 2008.

New Approvals

NADA Number: 141-280

Trade Name:	Zilmax®, Rumensin®, Tylan®, and MGA®
Ingredients:	Zilpaterol hydrochloride monensin U.S.P., tylosin phosphate, and melengestrol acetate
Sponsor:	Intervet, Inc.
Approval Date:	February 29, 2008
Status:	OTC
Route:	Oral
Species:	Heifers 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: 21.77 gram/pound Monensin USP: 80 g/pound Tylosin phosphate: 40 and 100 g/pound Melengestrol acetate: 200 and 500 mg/pound
Indications:	Provides for use of zilpaterol hydrochloride, monensin USP, tylosin phosphate, and melengestrol acetate Type A medicated articles to make dry and liquid four-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*; and for reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium (Actinomyces) pyogenes* and suppression of estrus (heat) in heifers 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), and (liver) 0.10 ppm *(21 CFR 556.420)*; tylosin (muscle, kidney, & fat) 0.2 ppm *(21 CFR 556.740)*; melengestrol acetate (fat) 25 ppb *(21 CFR 556.380)*.
Patents:	4,900,735 Expiration date(s): December 11, 2008 5,731,028 June 6, 2016 7,207,289 May 20, 2025

21 CFR 558.342, 558.665 73 FR 18958

NADA Number: 141-282

Trade Name:	Zilmax®, Rumensin®, and MGA®
Ingredients:	Zilpaterol hydrochloride, monensin USP, and melengestrol acetate
Sponsor:	Intervet, Inc.
Approval Date:	February 22, 2008
Status:	OTC
Route:	Oral
Species:	Heifers 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: 21.77 g/pound Monensin USP: 80 g/pound Melengestrol acetate: 200 and 500 mg/pound
Indications:	Provides for use of zilpaterol hydrochloride monensin USP, and melengestrol acetate Type A medicated articles to make dry and liquid three-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*; and suppression of estrus (heat) in heifers 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), and (liver) 0.10 ppm *(21 CFR 556.420)*; melengestrol acetate (fat) 25 ppb *(21 CFR 556.380)*.

21 CFR 558.665 73 FR 19432

New Approvals, cont.

NADA Number: 141-265

Trade Name:	Nuflor Gold ™
Ingredients:	Florfenicol
Sponsor:	Schering-Plough Animal Health Corp.
Approval Date:	March 21, 2008
Status:	Rx
Route:	Subcutaneous in the neck
Species:	Cattle/beef and non-lactating dairy
Drug Form:	Injectable solution
Concentration:	300 mg/mL
Indications:	Indicated for treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica, Pasteurella multocida,* and *Histophilus somni* in beef and non-lactating dairy cattle.
Withdrawal Time:	44 days
Tolerance:	Cattle: Liver (the target tissue). The tolerance for florfenicol amine (the marker residue) is 3.7 parts per million (ppm) *(21 CFR 556.283)*.
Exclusivity:	3 years

21 CFR 522.955 73 FR 21041

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: 141-068

Trade Name:	Baytril® 100
Ingredients:	Enrofloxacin
Sponsor:	Bayer HealthCare, LLC. Animal Health Division
Approval Date:	February 13, 2008
Exclusivity:	3 years

This supplemental application provides for the use of enrofloxacin injectable solution in female dairy cattle less than 20 months of age.

21 CFR 522.812 73 FR 17890

NADA Number: 141-236

Trade Name:	Vetsulin®
Ingredients:	Porcine insulin zinc
Sponsor:	Intervet, Inc.
Approval Date:	March 24, 2008
Exclusivity:	3 years

This supplemental application provides for a new recommended initial dose in dogs and adds an indication for use in cats with diabetes mellitus for the reduction of hyperglycemia and hyperglycemia-associated clinical signs..

21 CFR 522.1160 73 FR 21042

Supplemental Approvals, cont.

NADA Number: 141-068

Trade Name: Baytril® 100
Ingredients: Enrofloxacin
Sponsor: Bayer HealthCare, LLC. Animal Health Division
Approval Date: March 14, 2008
Exclusivity: 3 years

This supplemental application provides for a new indication, the use of enrofloxacin injectable solution for the treatment and control of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Haemophilus parasuis*, and *Streptococcus suis* in swine.

21 CFR 522.812, 556.228 73 FR 21819

Change of Sponsor's Name

From: Halocarbon Laboratories, Division of Halocarbon Products Corp

To: Halocarbon Products Corp.

Drug Labeler Code: 012164

73 FR 23066, April 29, 2008

Labeling Revisions

NADA Number 141-210:

Trade Name: Genesis®
Ingredients: Triamcinolone acetonide
Sponsor: RMS Laboratories, Inc.
Effective Date: April 3, 2008

This supplemental application provides for the trademark ™ to be changed to 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 April 2008.

Technical Amendment Withdrawal of Approval

The Food and Drug Administration (FDA) is amending the animal drug regulations by removing those portions that reflect approval of seven new NADAs because FDA is withdrawing approval of the NADAs. The following sponsors have requested that FDA withdraw approval of the following seven NADAs because the products are no longer manufactured or marketed:

NADA number:	Sponsor:	Product:
065-063	Eon Labs Manufacturing, Inc.	Tetracycline capsules
065-345	Eon Labs Manufacturing, Inc.	Chloramphenicol capsules
065-465	G.C. Hanford Manufacturing Co.	Aqua-Mast (penicillin G procaine)
095-551	International Nutrition, Inc.	Tylan 5 Premix (tylosin phosphate)
109-688	International Nutrition, Inc.	Hygromix 2.4 Premix (hygromycin B)
109-816	International Nutrition, Inc.	Tylan 10 Sulfa-G Premix (tylosin phosphate & sulfamethazine)
103-758	Pfizer, Inc.	Teramix-10 Premix (oxytetracycline)

FOR FURTHER INFORMATION CONTACT: Pamela K. Esposito, Center for Veterinary Medicine (HFV-212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9067; e-mail: Pamela.esposito@fda.hhs.gov .

73 FR 18441 April 4, 2008

Direct Final Rule Withdrawal

The FDA is withdrawing a direct final rule that published in the Federal Register of December 4, 2007 (72 FR 68064), to amend certain regulations as the first phase of an incremental approach to modernize or clarify some of the current good manufacturing practice (CGMP) regulations for finished pharmaceuticals, as well as harmonize some of the CGMP requirements with those of other foreign regulators and other FDA regulations. The comment period closed February 19, 2008. FDA is withdrawing the direct final rule because the agency received significant adverse comments. FDA will consider the comments received under our usual procedures for notice and comment in connection with the notice of proposed rulemaking that was published in the Federal Register of December 4, 2007, as a companion to the direct final rule (72 FR 68113).

DATES: The direct final rule published at 72 FR 68064 on December 4, 2007, is withdrawn as of April 4, 2008.

FOR FURTHER INFORMATION CONTACT: Dennis Bensley, Center for Veterinary Medicine (HFV-140), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8268, or
Mary Malarkey, Center for Biologics Evaluation and Research (HFM-600), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6190, or
Brian Hasselbalch, Center for Drug Evaluation and Research (HFD-320), Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-3279.

73 FR 18440 April 4, 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 April 2008.

Final Rule

The FDA is amending the agency's regulations to prohibit the use of certain cattle origin materials in food or feed of all animals. These materials include the following: The entire carcass of bovine spongiform encephalopathy (BSE)-positive cattle; the brains and spinal cords from cattle 30 months of age and older; the entire carcass of cattle not inspected and passed for human consumption that are 30 months of age or older from which brains and spinal cords were not removed; tallow that is derived from BSE-positive cattle; tallow that is derived from other materials prohibited by this rule that contains more than 0.15 percent insoluble impurities; and mechanically separated beef that is derived from the materials prohibited by this rule. These measures will further strengthen existing safeguards against BSE.

DATES: This final rule is effective April 27, 2009.

FOR FURTHER INFORMATION CONTACT: Burt Pritchett, Center for Veterinary Medicine (HFV-222), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-453-6860; e-mail: burt.pritchett@fda.hhs.gov .

73 FR 22719 April 27, 2008

Technical Amendment

The Food and Drug Administration (FDA) noticed during the codifying of the approval of a new animal drug application (NADA) for the use of Type A medicated articles containing zilpaterol hydrochloride, monensin USP, tylosin phosphate, and melengestrol acetate in four-way combination Type B and Type C medicated feeds for heifers fed in confinement for slaughter that the codified indications for use of tylosin in combination with melengestrol and lasalocid were not consistent with the conditions of use approved for an abbreviated new animal drug application (ANADA) (71 FR 39204), July 2l, 2006). The indications for use are revised to include the pathogens associated with this ANADA.

FOR FURTHER INFORMATION CONTACT: Gerald L. Rushin, Center for Veterinary Medicine (HFV-126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8103; e-mail: Gerald.rushin@fda.hhs.gov .

73 FR 18958 April 8, 2008

Notices

The FDA is announcing an opportunity for public comment with respect to the reporting and recordkeeping requirements for "New Animal Drugs for Investigational Use."

DATES: Submit written or electronic comments on the collection of information by June 9, 2008.

Submit electronic comments to: http://www.regulations.gov.
Submit written comments 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: FDA-2008-N-0172.

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.

73 FR 19073 April 8, 2008

Notices, cont.

The FDA is announcing the availability of a guidance for industry (181) entitled "Blue Bird Medicated Feed Labels." This guidance provides NADA sponsors with the Center for Veterinary Medicine's current thinking on what constitutes recommended content and format of representative labels for new animal drugs intended for use in the manufacture of medicated feeds.

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

Person with access to the Internet may obtain the guidance at either http://www.fda.gov/cvm or http://www.regulations.gov .
Submit written requests for single copies of the guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl,, Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your request.

Submit written comments on this guidance 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.regulations.gov.

FOR FURTHER INFORMATION CONTACT: Dragan Momcilovic, Center for Veterinary Medicine (HFV-220), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-453-6856, e-mail: dragan.momcilovic@fda.hhs.gov .

73 FR 19513 April 10, 2008