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 May 2007.

New Approvals

NADA Number: 141-273

Trade Name:	Vetmedin®
Ingredients:	Pimobendan
Sponsor:	Boehringer Ingelheim Vetmedica, Inc.
Approval Date:	April 30, 2007
Status:	Rx
Route:	Oral
Species:	Dogs
Drug Form:	Chewable tablet
Concentration:	1.25, 2.5, and 5 mg pimobendan per tablet
Indications:	For the management of the signs of mild, moderate, or severe (modified NYHA Class II, III, or IV) congestive heart failure in dogs due to atrioventricular valvular insufficiency (AVVI) or dilated cardiomyopathy (DCM); for use with concurrent therapy for congestive heart failure (e.g., furosemide, etc.) as appropriate on a case-by-case basis.
Exclusivity:	5 years
Patent:	5,364,646 Expiration Date: November 15, 2011

21 CFR 520.1780

ANADA Number: 200-460

Pioneer Product:	130-435
Trade Name:	Tetroxy® Aquatic
Ingredients:	Oxytetracycline hydrochloride
Sponsor:	Cross Vetpharm Group Ltd.
Approval Date:	April 20, 2007
Status:	OTC
Route:	Immersion water
Species:	Finfish
Drug Form:	Soluble powder
Concentration:	366 mg/g of powder
Indications:	To mark skeletal tissues, most often the otoliths, of all finfish fry and fingerlings for subsequent identification,

21 CFR 529.1660, and 21 CFR 556.500

New Approvals, cont.

ANADA Number: 200-437

Pioneer Product:	128-409
Trade Name:	Noromectin®
Ingredients:	Ivermectin
Sponsor:	Norbrook Laboratories, Ltd.
Approval Date:	April 20, 2007
Status:	OTC
Route:	Injection
Species:	Cattle (exception: not approved for use in female dairy cattle of breeding age and pre-ruminant calves); Swine; Reindeer; American Bison
Drug Form:	Sterile Solution
Concentration:	10 mg/mL
Indications:	For treatment and control of gastrointestinal roundworms (including inhibited *Ostertagia ostertagi*), lungworms, grubs, sucking lice, and mange mites in cattle; for the treatment and control of gastrointestinal roundworms, lungworms, lice, and mange mites in swine; for the treatment and control of warbles (*Oedemagena tarandi*) in reindeer; and for the treatment and control of grubs (*Hypoderma bovis*) in American Bison.
Tolerance:	*21 CFR 556.344* - The tolerance established for the pioneer product applies to the generic product. Tolerances of 100 parts per billion (ppb) and 10 ppb are established for 22, 23-dihydroavermectin B_1a (marker residue) residues in the liver (target tissue) and muscle, respectively, of cattle under 21 CFR 556.344. A tolerance of 20 parts per billion (ppb) is established for 22, 23-dihydroavermectin B_1a residues in the liver and muscle of swine under 21 CFR 556.344. Tolerances of 15 parts per billion (ppb) are established for 22, 23-dihydroavermectin B_1a residues in the liver of reindeer and American bison under 21 CFR 556.344.
Withdrawal:	Cattle 35 days; Swine 18 days; Reindeer and American Bison 56 days.

21CFR 522.1192, 21 CFR 556.344 and 21 CFR 522.1192

ANADA Number: 200-436

Pioneer Product:	140-833
Trade Name:	Noromectin®
Ingredients:	Ivermectin and clorsulon
Sponsor:	Norbrook Laboratories, Ltd.
Approval Date:	April 23, 2007
Status:	OTC
Route:	Injection
Species:	Cattle (exception: not approved for use in female dairy cattle of breeding age and pre-ruminant calves)
Drug Form:	Sterile Solution
Concentration:	10 mg/mL (1%) Ivermectin and 100 mg/mL (10%) clorsulon
Indications:	For treatment and control of gastrointestinal roundworms (including inhibited *Ostertagia ostertagi*), lungworms, grubs, sucking lice, and mange mites in cattle
Tolerance:	*21 CFR 556.344* - The tolerance established for the pioneer product applies to the generic product. Tolerances of 100 parts per billion (ppb) and 10 ppb are established for 22, 23-dihydroavermectin B_1a (marker residue) residues in the liver (target tissue) and muscle, respectively, of cattle under 21 CFR 556.344. Tolerances of 1 part per million (ppm) and 0.1 ppm are established for parent clorsulon (marker residue) in the kidney (target tissue) and muscle, respectively, of cattle under 21 CFR 556.163.
Withdrawal:	Cattle 49 days

21CFR 522.1193, 21 CFR 556344, 21 CFR 556.163, and 21 CFR 522.1193

New Approvals, cont.

ANADA Number: 200-408

Pioneer Product:	141-047
Trade Name:	Butorphanol Tartrate Injection (2 mg/mL)
Ingredients:	Butorphanol tartrate
Sponsor:	IVX Animal Health, Inc.
Approval Date:	April 20, 2007
Status:	Rx
Route:	Subcutaneous injection
Species:	Cats
Drug Form:	Injection
Concentration:	Each mL contains 2 mg butorphanol base (as butorphanol tartrate, USP)
Indications:	For the relief of pain caused by major or minor trauma, or pain associated with surgical procedures in cats.

21 CFR 522.246

ANADA Number: 200-333

Pioneer Product:	091-818
Trade Name:	Superiorbute®
Ingredients:	phenylbutazone
Sponsor:	Superior Equine Pharmaceuticals, Inc.
Approval Date:	April 20, 2007
Status:	Rx
Route:	Oral
Species:	Horses
Drug Form:	Powder
Concentration:	Each 1.15 grams contains 1.0 grams of phenylbutazone
Indications:	For the relief of inflammatory conditions associated with the musculoskeletal system in horses.

21 CFR 520.1720e

ANADA Number: 200-398

Pioneer Product:	135-940
Trade Name:	Clindamycin Hydrochloride Oral Drops
Ingredients:	Clindamycin Hydrochloride
Sponsor:	First Priority, Inc.
Approval Date:	March 19, 2007
Status:	Rx
Route:	Oral
Species:	Dogs and cats
Drug Form:	Liquid
Concentration:	Each mL contains clindamycin hydrochloride equivalent to 25 mg clindamycin
Indications:	For treatment of infected wounds, abscesses, and dental infections in dogs and cats, and the treatment of osteomyelitis in dogs

21 CFR 520.447

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 May 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: 200-299

Pioneer Product:	140-841
Trade Name:	IVER-ON™
Ingredients:	Ivermectin
Sponsor:	Med-Pharmex, Inc.
Approval Date:	May 7, 2007
Status:	OTC
Tolerance:	*21 CFR 556.344* - The tolerance established for the pioneer product applies to the generic product. Tolerances of 100 parts per billion (ppb) and 10 ppb are established for 22, 23-dihydroavermectin B_1a (marker residue) residues in the liver (target tissue) and muscle, respectively, of cattle
Withdrawal:	48 days

This supplemental application provides for the addition of persistent activity claims to the generic labeling that are no longer protected by three years marketing exclusivity and incorporate additional CVM requested labeling changes to the Environmental Safety section, Disposal statement, and Residue Information.

21 CFR 524.1193, 21 CFR 556.344, and 21 CFR 524.1193

Regulatory Labeling Supplements

NADA Number: 141-230

Trade Name:	Previcox®
Ingredients:	Firocoxib
Sponsor:	Merial Ltd.
Approval Date:	May 11, 2007

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

21CFR 520.928

Sponsor Information Change

Change of Address:

Alpharma, Inc. One Executive Dr. Fort Lee, NJ 07024	**to**	Alpharma, Inc. 440 Rte. 22 Bridgewater, NJ 08807
Modern Veterinary Therapeutics, LLC 18301 SW. 86th Ave Miami, FL 33157	**to**	Modern Veterinary Therapeutics, LLC 1550 Madruga Ave Suite 329 Coral Gables, FL 33146

21 CFR 510.600 (c)

Sponsor Information Change, cont.

Change of Sponsor Name and Address:

American Pharmaceutical Partners, Inc
2045 North Cornell Ave.
Melrose Park, IL 60160

to

Abraxis Pharmaceuticals Products
A Div. of Abraxis Bioscience
6133 River Rd
Suite 500
Rosemont, IL 60018

21 CFR 510.600 (c)

Patent Information Correction

NADA 141-262

In the May update to the 2007 Green Book, the following patent numbers were incorrectly attributed to NADA 141-262:

Patent Number:	5,134,127	Expiration Date:	January 23, 2010
Patent Number:	5,376,645	Expiration Date:	January 23, 2010

In the May update to the 2007 Green Book, the following patent number was omitted for NADA 141-262

Patent Number:	6,255,320	Expiration Date:	May 8, 2020

Suitability Petition(s)

2007P-0177/CP1

Norbrook Laboratories Limited

Request permission to file an ANADA for a generic new animal drug meloxicam which differs from the pioneer product, Metacam® 1.5 mg/mL Oral Suspension, Boehringer Ingelheim, NADA 141-213 by the following characteristics. The generic will differ in dosage form (chewable tablets) and different strength.

Filed: May 2, 2007

2007P-0175

Norbrook Laboratories Limited

Request permission to file an ANADA for a generic new animal drug ivermectin// pyrantel pamoate chewable tablet which differs from the pioneer product, Heartgard-30® Plus, Merial Limited, NADA 140-971 by the following characteristics. The generic will differ in dosage form. The generic product will be a compressed tablet, whereas the pioneer's product is an extruded tablet.

Filed: May 2, 2007

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 May 2007.

Notice(s)

The Food and Drug Administration (FDA) is reopening to June 8, 2007, the comment period for the notice of availability that appeared in the Federal Register of February 12, 2007 (72 FR 6572). In the notice, FDA requested comments on the draft compliance policy guide on voluntary self-inspection of medicated feed manufacturing facilityes. The agency is taking this action in respons to requests for an extension to allow interested persons additional time to submit comments.

Submit written and electronic comments by June 8, 2007 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.

FOR FURTHER INFORMATION CONTACT: Paul Bachman, Center for Veterinary Medicine (HFV-230), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-267-9225, e-mail: Paul.Bachman@fda.hhs.gov.

72 FR 26135, May 8, 2007

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The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry (83) entitled ``Chemistry, Manufacturing, and Control Changes to an Approved NADA or ANADA.'' This guidance is intended to provide recommendations to holders of new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) on how they should report certain changes to such applications, in accordance with the final regulation, 21 CFR 514.8, which was issued in the Federal Register of December 13, 2006 (71 FR 74766).

Submit written requests for single copies of the guidance document 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. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document. Submit written comments on the guidance document 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

FOR FURTHER INFORMATION CONTACT: Dennis Bensley, Jr., Center for Veterinary Medicine (HFV-140), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-6956, e-mail: dennis.bensley@fda.hhs.gov.

72 FR 30386, May 31, 2007