Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were published in the Federal Register in September 2012.

Original Approvals

This section displays the original approval. To read the complete approval, please refer to 21 CFR Parts 500 and the related Federal Register notices.

NADA Number: 141-336

Trade Name:	Aivlosin®
Ingredients:	Tylvalosin tartrate
Sponsor:	ECO LLC
Approval Date:	July 6, 2012
Status:	Rx
Route:	Oral
Species:	Swine
Drug Form:	Water Soluble Granules
Concentration:	62.5 % (w/w) tylvalosin as tylvalosin tartrate
Indications:	Control of porcine proliferative enteropathy (PPE) associated with Lawsonia intracellularis infection in groups of swine in buildings experiencing an outbreak of PPE.
Exclusivity:	5 years

21 CFR 520.2645 *77 FR 55414-55415*

ANADA Number: 200-482

Trade Name:	AmproMed™ for Calves
Pioneer:	Corid® 9.6% Oral Solution
Ingredients:	Amprolium
Sponsor:	Cross Vetpharm Group Ltd.
Approval Date:	July 29, 2012
Status:	OTC
Route:	Oral
Species:	Cattle/calves
Drug Form:	Oral Solution
Concentration:	96 mg/mL (9.6%)
Indications:	As an aid in the treatment and prevention of coccidiosis caused by *Eimeria bovis* and *E. zuernii* in calves.

21 CFR 520.100 *77 FR 55414-55415*

Supplemental Approvals

This section displays the change(s) to the original approval. To read the complete approval, please refer to 21 CFR 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:	July 24, 2012

This supplement provides for a new indication for the control of BRD in beef and non-lactating dairy cattle at high risk of developing BRD associated with *M. haemolytica*, *P. multocida*, *H. somni* and *M. bovis*.

21 CFR 522.812 77 FR 55414-55415

Sponsor Change

ANADA Numbers: 200-258, 200-344, 200-345

Previous: Teva Animal Health, Inc.

New Sponsor: Phibro Animal Health Corp.

Drug Labeler Code: 066104

21 CFR 520.1265, 520.2220a, 520.2455 77 FR 56769-56770

Sponsor Address Change

Phibro Animal Health Corp.

Previous: 65 Challenger Rd., 3d floor, Ridgefield Park, NJ 07660

New: GlenPointe Centre East, 3d floor, 300 Frank W. Burr Blvd., suite 21, Teaneck, NJ 07666

Eka Chemicals, Inc.

Previous: 1775 West Oak Commons Ct., Marietta, GA 30062

New: 1850 Parkway Pl. SE., suite 1200, Marietta, GA 30067

21 CFR 510.600(c) 77 FR 56769-56770

Patent Additions

NADA Number: 141-036

Patent number: 6,648,851
Expiration Date: March 5, 2022

Patent Extensions

NADA Number: 141-230

Patent number: 6,541,646
Extension Period: 1 year
Expiration Date: Oct 8, 2019

Withdrawal of Approval

NADA Number: 30-525

Sponsor: Endo Pharmaceuticals Inc.
Trade Name: Numorphan
Ingredients: Oxymorphone Hydrochloride

This product is withdrawn because the product is no longer manufactured or marketed.

21 CFR 522.1642 *77 FR 55413-55414*

NADA Number: 35-825

Sponsor: Endo Pharmaceuticals Inc.
Trade Name: Narcan Injection
Ingredients: Naloxone Hydrochloride

This product is withdrawn because the product is no longer manufactured or marketed.

21 CFR 522.1462 *77 FR 55413-55414*

NADA Number: 46-822

Sponsor: United Vaccines, A Harlan Sprague Dawley, Inc.
Trade Name: Vetocin Injection
Ingredients: Oxytocin

This product is withdrawn because the product is no longer manufactured or marketed.

21 CFR 522.1680 *77 FR 55413-55414*

NADA Number: 103-090

Sponsor: United Vaccines, A Harlan Sprague Dawley, Inc.
Trade Name: Chortropin
Ingredients: Chorionic Gonadotropin

This product is withdrawn because the product is no longer manufactured or marketed.

21 CFR 522.1081 *77 FR 55413-55414*

Suitability Petitions

Number: 09-P-0162-1

Petitioner: PetMedicus Laboratories Ltd.
Date Filed: March 26, 2009
Action: Approved
Action Date: June 19, 2009
Description: The petitioner requests to file an ANADA for a generic clomipramine hydrochloride tablet that differs from the pioneer product, CLOMICALM Tablets, sponsored by Novartis Animal Health US, Inc., under NADA 141-120. The generic product will differ in dosage form and tablet strength. The pioneer product is an unscored tablet available in 5 mg, 20 mg, 40 mg, and 80 mg strengths. The proposed generic product is a unique, bi-layered, quadrisected tablet that will be available in 10 mg and 80 mg strengths.

Number: 09-P-0450-1

Petitioner: Precision Consultants, Inc.
Date Filed: September 21, 2009

Action: Denied
Action Date: May 18, 2010
Description: The petitioner requests to file an ANADA for a generic omeprazole tablet that differs from the pioneer product, ULCERGARD Oral Paste, sponsored by Merial Ltd., under NADA 141-227. The generic product will differ in strength and dosage form. The pioneer product is a 2.28 g omeprazole paste (37% w/w) that is supplied in a 4 dose oral syringe. The proposed generic product is a 570 mg omeprazole tablet (19% w/w).

Number: 10-P-0170/CP

Petitioner: Lannett Company, Inc.
Date Filed: March 23, 2010
Action: Denied
Action Date: June 15, 2010
Description: The petitioner requests to file an ANADA for a generic sulfamethoxazole and trimethoprim powder that differs from the pioneer product, TRIBRISSEN 400 Oral Paste, sponsored by Intervet, Inc., under NADA 131-918. The generic product will differ in one of the two active ingredients by substituting sulfamethoxazole for sulfadiazine and in dosage form. The petitioner also requests that FDA select TUCOPRIM Powder, sponsored by Pharmacia & Upjohn Company Division of Pfizer Inc., under ANADA 200-244, as the RLNAD for its proposed generic product.

Number: 11-P-0335-1

Petitioner: Norbrook, Inc.
Date Filed: May 6, 2011
Action: Approved
Action Date: June 22, 2011
Description: The petitioner requests to file an ANADA for a generic marbofloxacin chewable tablet that differs from the pioneer product, ZENEQUIN Tablets, sponsored by Pfizer, Inc., under NADA 141-151. The generic product will differ in dosage form. The RLNAD is a coated, single scored tablet, and the proposed generic product is a chewable tablet.

Number: 11-P-0397-1

Petitioner: NewMarket Pharmaceuticals, LLC
Date Filed: May 20, 2011
Action: Denied
Action Date: August 11, 2011
Description: The petitioner requests to file an ANADA for a generic clenbuterol hydrochloride rapidly disintegrating tablet that differs from the pioneer product, VENTIPULMIN Syrup, sponsored by Boehringer Ingelheim Vetmedica, Inc., under NADA 140-973. The generic product will differ in dosage form and concentration. The RLNAD is a syrup containing 72.5 mcg/mL and the proposed generic product is a rapidly disintegrating tablet containing 362.5 mcg/250 mg tablet.

Number: 12-P-0072-1

Petitioner: Cook Animal Health
Date Filed: January 27, 2012
Action: Denied
Action Date: May 22, 2012
Description: The petitioner requests to file an ANADA for a generic florfenicol injection that differs from the pioneer product, NUFLOR Injectable Solution, sponsored by Intervet Inc., under NADA 141-063. The generic product will differ in the formulation, elimation of one route of administration, and the removal of a class of animal from the indications. The RLNAD is formulated as a non-aqueous solution and the proposed generic product will be formulated as an aqueous solution. The sponsor proposed to remove intramuscular injection as a route of administration. The sponsor proposed to remove dairy cattle from the labeled indications.

Number: 12-P-0313-1

Petitioner:	Con Vet GmbH & Co.
Date Filed:	March 29, 2012
Action:	Denied
Action Date:	August 15, 2012
Description:	The petitioner requests to file an ANADA for a generic ivermectin impregnated, flavored, and dissolvable film strip that differs from the pioneer product, EQVALAN Oral Paste, sponsored by Merial Ltd., under NADA 134-314. The generic product will differ in the dosage form. The RLNAD is an oral paste and the proposed generic is an impregnated, flavored, dissolvable film strip.

Number: 12-P-0492-1

Petitioner:	Med-Pharmex, Inc.
Date Filed:	May 16, 2012
Action:	Approved
Action Date:	August 2, 2012
Description:	The petitioner requests to file an ANADA for a generic carprofen flavored oral paste that differs from the pioneer product, RIMADYL Chewable Tablets, sponsored by Pfizer, Inc., under NADA 141-111. The generic product will differ in the dosage form and concentration. The RLNAD is a scored chewable tablet available in 25, 75, and 100 mg tablet sizes. The propsed generic product is a flavored oral paste containing 25 mg carprofen per 1 gram of paste.

Number: 12-P-0497-1

Petitioner:	Piedmont Animal Health
Date Filed:	May 18, 2012
Action:	Approved
Action Date:	August 31, 2012
Description:	The petitioner requests to file an ANADA for a generic enrofloxacin formed soft chewable tablet that differs from the pioneer product, BAYTRIL TASTE TABS, sponsored by Bayer Healthcare LLC, Animal Health Division, under NADA 140-441. The generic product will differ in the dosage form. The RLNAD is a compressed (hard) tablet while the proposed generic product will be a soft chewable tablet, with a texture similar to semi-moist dog food.