Section 7.0 - Suitability Petition Action

Number	Petitioner	Description	Action	Date
89P-0191/CP1	Fermenta Animal Health Co.	Request to substitute sulfathiazole for sulfamethazine in a Type A medicated feed article for use in feed for beef cattle.	Denied	07/13/1989
89P-0191/PRC1	Fermenta Animal Health Co.	Request to reconsider proposal to substitute sulfathiazole for sulfamethazine in a Type A medicated feed article for use in feed for beef cattle.	Denied	12/06/1989
89P-0446/CP1	Boehringer Ingelheim Vetmedica, Inc.	Request to differ the dosage form and strength in a Type A medicated feed article.	Approved	12/29/1989
89P-0509/CP1	Cheminex Laboratories, Inc.	Request to change dosage form in NADA 131-918 (Tribrissen 400 Oral Paste) from paste to a powder mixed with feed.	Approved	01/24/1990
90P-0051/CP1	Beecham Laboratories	Request to change Nemex Tabs from two tablet strengths, 22.7 and 113.5 milligrams per tablet to four tablet strengths, 22.7, 45.4, 90.8, and 136.2 milligrams per tablet.	Approved	03/21/1990
90P-0073/CP1	A. L. Laboratories	Request to revoke approval of petition 89P-0446/CP approved in 1989 for Boehringer Ingelheim Animal Health, Inc.	Denied	04/12/1990
90P-0181/CP1	American Cyanamid, Division AHP Corp.	Request permission to file ANADA for change of dosage form of CSP500 and CSP250 Type A medicated feed articles containing chlortetracycline, sulfathiazole and penicillin.	Approved	07/31/1990
90P-0213/CP1	Micrel Limited, Inc.	Request permission to file an ANADA containing a change in dosage form to provide microencapsulation (microspheres) of the active ingredient in an injectable form of RALGRO (NADA 038-233).	Denied	08/21/1990
90P-0213/PRC1	Micrel Limited, Inc.	Request reconsideration to file an ANADA containing a change in dosage form to provide microencapsulation (microspheres) of the active ingredient in an injectable form of RALGRO (NADA 038-233).	Denied	10/16/1990
90P-0434/CP1	Sanofi Animal Health, Inc.	Request permission to substitute a different salt form of one active ingredient in a lincomycin spectinomycin combination. Pioneer product is NADA 046-109.	Approved	02/27/1991
91P-0048/CP1	Sanofi Animal Health, Inc.	Request permission to change the dosage form for Sulfaquinoxaline sodium solution. The pioneer NADA is 006-677.	Denied	03/21/1991
91P-0048/CP1	Sanofi Animal Health, Inc.	Request permission to change the dosage form for Sulfaquinoxaline sodium solution. The pioneer NADA is 006-677.	Acknowledged	03/21/1991

Number	Petitioner	Description	Action	Date
91P-0277/CP1	The Upjohn Co.	Request permission to file an ANADA for a different dosage form of neomycin soluble powder. The pioneer product is NADA 011-315. *The petition was approved but the applicant may not file an ANADA until the pioneer product has been DESI finalized and approved.	Approved	09/03/1991
91P-0277/CP1	The Upjohn Co.	Request permission to file an ANADA for a different dosage form of neomycin soluble powder. The pioneer product is NADA 011-315. *The petition was approved but the applicant may not file an ANADA until the pioneer product has been DESI finalized and approved.	Approved	09/03/1992
91P-0316/CP1	Vet-A-Mix, Inc.	Request permission to file an ANADA for a different strength of sulfamethazine oblets. The pioneer is NADA 122-271.	Filed	09/11/1991
91P-0316/CP1	Vet-A-Mix, Inc.	Request permission to file an ANADA for a different strength of sulfamethazine oblets. The pioneer is NADA 122-271.	Approved	09/11/1991
91P-0071/CP1	Fermenta Animal Health Co.	Request permission to change strength of oxytetracycline in a generic product referencing NADA 113-232. *Note: The original approval of this petition was revised to require labeling changes of the generic product to be consistent with that of the pioneer product. See 91P-0285/CP1 for details.	Approved	12/02/1991
91P-0071/CP1	Fermenta Animal Health Co.	Request permission to change strength of oxytetracycline in a generic product referencing NADA 113-232. *Note: The original approval of this petition was revised to require labeling changes of the generic product to be consistent with that of the pioneer product. See 91P-0285/CP1 for details.	Acknowledged	06/01/1992

Number	Petitioner	Description	Action	Date
91P-0285/CP1	Pfizer, Inc.	Request that FDA require bioequivalence testing of generic oxytetracycline animal drug products referencing Pfizer's Liquamycin LA-200. The petition also requested that FDA deny Fermenta Animal Health Company's ANADA for an oxytetracycline product. Pfizer pointed out that the Fermenta ANADA does not contain tissue residue studies for calculation of a withdrawal period. *Note: Six points raised in the petition were addressed. The Agency agreed that demonstration of in vivo bioequivalence between the Fermenta and Pfizer formulations is essential to the approval of Fermenta's ANADA. The Agency did not agree that tissue residue studies necessarily would be required. The pharmacokinetic profiles of both formulations will be evaluated to determine bioequivalence and could be used in lieu of a tissue residue study in assigning a withdrawal period. The Agency agreed that bioequivalence studies would be required in more than one species but it does not intend to require demonstration of bioequivalence in all classes of animals within a species. Bioequivalence studies in the Fermenta ANADA will be required in swine and in one class of adult ruminating nonlacting cattle. The Agency agreed that the Fermenta product, although a different strength, must be labeled to deliver the same dose of oxytetracycline base to the animal. The Agency retracted a statement made in approving the Fermenta suitability petition requesting that the generic product be labeled at 9.3 milligrams per pound of body weight. Fermenta will be instructed to label their generic product at 9 milligrams per pound of body weight. The Agency pointed out that although different salts of oxytetracycline are used in the manufacture of the two products, the finished form of active ingredient in both cases is magnesium chelated oxytetracycline. Some technical issues regarding labeling and notification of the patent holder were also addressed in the Agency's response.	See note*	12/02/1991
91P-0421/CP1	Arthur A. Checci, Inc.	Request permission to file an ANADA for a Tolnaftate 1% in an oil base that differs from the pioneer product Tolnaftate 1% cream. The pioneer is NADA 037-502. Prior to making a decision, CVM requested additional information on the formulation of the proposed generic product, including information on a patent and information on the rationale for each ingredient in the formulation.	Pending	01/03/1992
91P-0437/CP1	Specialty Biologicals, Inc.	Request permission to file an ANADA for a drug product, Ovagen, that differs from the pioneer (FSH-P) in the method of assay. The pioneer product is NADA 009-505. Submitted in 1991.	Denied	01/22/1992
91P-0489/CP1	RMS Laboratories, Inc.	Request permission to file an ANADA for a product having a different dosage form than the pioneer, Vetalog Cream (triamcinolone acetonide). The pioneer is NADA 046-146. The proposed product would be a non-aerosol pump spray rather than a cream. Received in 1991.	Approved	02/13/1992

Number	Petitioner	Description	Action	Date
92P-0057/CP1	The Upjohn Co.	Request permission to file an ANADA for a different dosage form for neomycin sulfate from a soluble powder to a liquid. The pioneer product is NADA 011-315.	Approved	04/03/1992
92P-0157/CP1	Pfizer, Inc.	Request permission to file an ANADA for a different dosage form for neomycin sulfate from a soluble powder to a Type A medicated article. The pioneer product is NADA 011-315.	Approved	05/12/1992
91P-0255/CP1	Sanofi Animal Health	Request permission to file an ANADA for an oral dosage form for neomycin solution in place of the pioneer's soluble powder form. The pioneer product is NADA 011-315.	Approved	08/04/1992
92P-0254/CP1	Halocarbon Products Corp.	Request permission to file an ANADA for the use of a different dosage form and a lesser strength for topical application of fluocinolone acetonide. The pioneer product is NADA 015-152.	Denied	09/02/1992
92P-0363/CP1	IVX Animal Health, Inc.	Request permission to file an ANADA for the use of a different oral dosage form (liquid) and strength for neomycin sulfate. The pioneer product is NADA 011-315.	Approved	10/01/1992
92P-0366/CP1	The Upjohn Co.	Request permission to file an ANADA for the use of a different oral dosage form (bolus) for neomycin sulfate. The pioneer product is NADA 011-315, and is a soluble powder.	Approved	11/04/1992
92P-0399/CP1	Sanofi Animal Health, Inc.	Request permission to file an ANADA for a different dosage form (bolus) for a neomycin sulfate product. The pioneer product is NADA 011-315, a soluble powder.	Approved	11/23/1992
92P-0402/CP1	Arkansas Micro Specialties, Inc.	Request approval to file an ANADA for the use of a different oral dosage form (liquid) and strength for neomycin sulfate. The pioneer product is NADA 011-315, a soluble powder.	Approved	11/23/1992
92P-0498/CP1	Fermenta Animal Health Co.	Request permission to change dosage form from a powder to a solution and file an ANADA for neomycin sulfate. The pioneer NADA is 011-315.	Approved	01/29/1993
92P-0511/CP1	Fermenta Animal Health Co.	Request permission to change dosage form from a powder to a bolus and file an ANADA for neomycin sulfate. The pioneer NADA is 011-315.	Approved	01/29/1993
92P-0490/CP1	Norbrook Laboratories Ltd.	Request permission to file an ANADA for an injectable solution containing 300 milligrams oxytetracycline base per milliliter. The proposed product brand name is Noromycin LA 300. The pioneer NADA is 113-232.	Denied	04/12/1993
93P-0294/CP1	IVX Animal Health, Inc.	Request permission to file an ANADA for a change in strength of gentamicin sulfate oral solution in a pump dispenser from 4.35 milligrams per milliliter to 5.0 milligrams per milliliter. The delivery volume would also change from 1.15 milliliter per pump to 1.0 milliliter per pump. The pioneer product is NADA 130-464.	Approved	11/03/1993

Number	Petitioner	Description	Action	Date
93P-0422/CP1	Wildlife Pharmaceuticals	Request permission to file an ANADA for a change in strength of etorphine hydrochloride parenteral solution from 1 milligrams per milliliter to 5 milligrams per milliliter. The pioneer product is NADA 095-017.	Denied	02/16/1994
94P-0039/CP1	Akzo Intervet, Inc.	Request permission to file an ANADA for a change in strength of the implant component of the product. The pioneer product, NADA 134-930, sponsored by Sanofi Animal Health, Inc., is a two component drug consisting of an implant containing 6 milligrams norgestomet and an injectable solution containing 3 milligrams norgestomet and 5 milligrams estradiol valerate per 2 milliliter. The proposed ANADA would change the strength of the implant from 6 milligrams to 3 milligrams of norgestomet. The injectable solution would stay the same.	Approved	03/21/1994
94P-0159/CP1	Sanofi Sante Animale, Canada Inc.	Request permission to file an ANADA for a change in strength of the active ingredient, neomycin base, to 56.9% instead off 50% as in the pioneer. The pioneer product is NADA 011-315 sponsored by the Upjohn Co.	Approved	06/29/1994
94P-0408/CP1	Macleod Pharmaceuticals, Inc.	Request permission to file an ANADA for a generic new animal drug containing trimethoprim and sulfadiazine whose strength, dosage form, and inactive ingredient composition differ from the pioneer product. The proposed generic product contains 40 milligrams per milliliter trimethoprim and 200 milligrams per milliliter sulfadiazine. The trimethoprim in the proposed generic product is in solution whereas the pioneer product is in suspension. The proposed generic product contains an innovative active ingredient, N-methylpyrrolidone. The pioneer product is NADA 106-965 sponsored by Cooper Animal Health.	Denied	01/12/1995
95P-0036/CP1	Norbrook Laboratories Ltd.	Request permission to file an ANADA (hybrid application) for a generic new animal drug with a dosage form different from the pioneer product. The pioneer product, NADA 055-089, sponsored by Beecham Laboratories, is a powder formulation containing 25 milligrams amoxicillin per vial for reconstitution with Water for Injection USP, to an oil-based suspension with a nominal concentration of 250 milligrams amoxicillin base per milliliter. The Norbrook formulation is an oil-based suspension containing 250 milligrams amoxicillin base per milliliter. The pioneer product is indicated for intramuscular or subcutaneous administration, while the generic product will be indicated only for intramuscular administration.	Denied	04/24/1995
95P-0350/CP1	IVX Animal Health, Inc.	Request permission to file an ANADA for a generic new animal drug which differs from that of the pioneer product only by the addition of 1.5% benzyl alcohol to the formula. The pioneer product is Ivomex 1% Injection, NADA 128-409, sponsored by Merck Research Laboratories.	Not required	01/15/1996

Number	Petitioner	Description	Action	Date
96P-0098/CP1	Equi Aid Products, Inc.	Request permission to file an ANADA for a generic new animal drug which differs from that of the pioneer product in two ways: 1) the generic product would be a palatable product to mix with cat food instead of the tablet dosage form of the pioneer product; and 2) pyrantel pamoate would be the only active ingredient instead of pyrantel pamoate and praziquantel. The pioneer product is Drontal Tablets, NADA 141-008, sponsored by Bayer Corp., Agriculture Division, Animal Health.	Denied	04/15/1996
96P-0098/PRC1	Equi Aid Products, Inc.	Filed for reconsideration: Request permission to file an ANADA for a generic new animal drug which differs from that of the pioneer product in two ways: 1) the generic product would be a palatable product to mix with cat food instead of the tablet dosage form of the pioneer product; and 2) pyrantel pamoate would be the only active ingredient instead of pyrantel pamoate and praziquantel. The pioneer product is Drontal Tablets, NADA 141-008, sponsored by Bayer Corp., Agriculture Division, Animal Health.	Denied	07/15/1996
96P-0438/CP1	Pharmacia & Upjohn Co.	Request permission to file an ANADA for a generic new animal drug which differs from that of the pioneer product only in the formulation and method of oral administration. The product would be formulated as a powder and administered orally once per day in a small amount of palatable feed. The pioneer product is Tribrissen 400 Oral Paste, NADA 131-918, sponsored by Mallinckrodt Veterinary, Inc.	Approved	01/10/1997
97P-0072/CP1	Bioniche Animal Health USA, Inc.	Request permission to file an ANADA for a generic new animal drug, Butequine™ Paste (phenylbutazone paste) which differs from the pioneer product, Butazolidin Paste, Coopers Animal Health, NADA 116-087 by the following characteristics: Butequine™ Paste: 20 grams of phenylbutazone per 60 milliliter syringe of paste (1 gram per 3 milliliter). Butezolidin Paste (pioneer): 12 grams of phenylbutazone per 60 gram syringe of paste (1 gram per 5 grams). The dosage (1-2 grams of phenylbutazone per 500 pounds body weight) is the same in both products. However, in the generic product, the dosage would be given as 3-6 milliliters as opposed to 5-10 grams of the pioneer product.	Approved	04/11/1997
97P-0473/CP1	Macleod Pharmaceuticals, Inc.	Request permission to file an ANADA for a generic new animal drug, Unibute Paste (phenylbutazone paste) which differs from the pioneer product, Butazolidin Paste, Mallinckrodt Veterinary, Inc, NADA 116-087 by the following characteristics: Unibute Paste: 20 grams of phenylbutazone per 60 grams of paste. Butazolidin Paste (pioneer): 12 grams of phenylbutazone per 60 grams of paste. The dosage (1-2 grams of phenylbutazone per 500 pounds body weight) is the same in both products.	Approved	01/30/1998

Number	Petitioner	Description	Action	Date
97P-0474/CP1	Macleod Pharmaceuticals, Inc.	Request permission to file an ANADA for a generic new animal drug, Uniprim Paste (trimethoprim and sulfadiazine) which differs from the pioneer product, Tribrissen 400 Oral Paste, Mallinckrodt Veterinary, Inc, NADA 131-918 by the following characteristics: Uniprim Paste: 56 grams of trimethoprim and 278 milligrams of sulfadiazine per gram. Uniprim Paste: 67 grams of trimethoprim and 333 milligrams of sulfadiazine per gram. The dosage (1-2 grams of phenylbutazone 500 pounds body weight) is the same in both products.	Approved	01/30/1998
98P-0159/CP1	IVX Animal Health, Inc.	Request permission to file an ANADA for a generic Ivermectin Chewable Tablet which differs from the pioneer product, Heartgard-30®, Merial Limited NADA 140-886 by the following characteristics: Ivermectin generic is a compressed chewable tablet and Heartgard is an 'extruded' chewable tablet.	Approved	06/18/1998
98P-0190/CP1	Blue Ridge Pharmaceuticals, Inc.	Request permission to file an ANADA for a generic new animal drug ivermectin/pyrantel pamoate which differs from the pioneer product, Heartgard-30® Plus, Merial Limited, NADA 140-971, by the following characteristic: Ivermectin/pyrantel pamoate generic is a compressed chewable tablet and Heartgard-30® Plus is an 'extruded' tablet.	Approved	06/22/1998
98P-0232/CP1	Virbac, Inc.	Request permission to file an ANADA for a generic new animal drug miconazole nitrate which differs from the pioneer product, Conofite® Lotion 1%, Schering-Plough Animal Health Corporation, NADA 095-184, by the following characteristics: Miconazole 2% is formulated as a leave-on conditioner and Conofite® Lotion 1% is formulated as a topical lotion and a different strength.	Denied	07/08/1998
98P-0862/CP1	IVX Animal Health, Inc.	Request permission to file an ANADA for a generic new animal drug ivermectin/pyrantel which differs from the pioneer product, Heartgard™ Plus (ivermectin/pyrantel), Merial Limited, NADA 140-971 by the following characteristic: Ivermectin/pyrantel generic is a compressed chewable tablet and Heartgard™ Plus is an 'extruded' chewable tablet.	Filed	10/01/1998
98P-0862/CP1	IVX Animal Health, Inc.	Request permission to file an ANADA for a generic new animal drug ivermectin/pyrantel which differs from the pioneer product, Heartgard™ Plus (ivermectin/pyrantel), Merial Limited, NADA 140-971 by the following characteristic: Ivermectin/pyrantel generic is a compressed chewable tablet and Heartgard™ Plus is an 'extruded' chewable tablet.	Approved	12/18/1998

Number	Petitioner	Description	Action	Date
98P-0927/CP1	Heska Corporation	Request permission to file an ANADA for a generic new animal drug ivermectin/pyrantel which differs from the pioneer product, Heartgard™ Plus (ivermectin/pyrantel), Merial Limited, NADA 140-971 by the following characteristic: Ivermectin/pyrantel generic is a compressed chewable tablet and Heartgard™ Plus is an 'extruded' chewable tablet.	Filed	10/21/1998
98P-0927/CP1	Heska Corporation	Request permission to file an ANADA for a generic new animal drug ivermectin/pyrantel which differs from the pioneer product, Heartgard™ Plus (ivermectin/pyrantel), Merial Limited, NADA 140-971 by the following characteristic: Ivermectin/pyrantel generic is a compressed chewable tablet and Heartgard™ Plus is an 'extruded' chewable tablet.	Approved	12/18/1998
98P-0580/CP1	Delmarva Laboratories, Inc.	Request permission to file an ANADA for a generic new animal drug clindamycin hydrochloride which differs from the pioneer product, Antirobe® Capsules, Pharmacia & Upjohn Co., NADA 120-161, by the following characteristics: Clindamycin hydrochloride generic is a tablet and Antirobe® is a capsule.	Approved	10/30/1998
98P-1037/CP1	IVX Animal Health, Inc.	Request permission to file an ANADA for a generic new animal drug trimethoprim/ sulfadiazine which differs from the listed product, trimethoprim/sulfadiazine (Uniprim), Macleod Pharmaceuticals, Inc., ANADA 200-033 by the following characteristic: Trimethoprim/sulfadiazine generic differs in dosage form from the listed product.	Filed	11/23/1998
98P-1037/CP1	IVX Animal Health, Inc.	Request permission to file an ANADA for a generic new animal drug trimethoprim/ sulfadiazine which differs from the listed product, trimethoprim/sulfadiazine (Uniprim), Macleod Pharmaceuticals, Inc., ANADA 200-033 by the following characteristic: Trimethoprim/sulfadiazine generic differs in dosage form from the listed product.	Approved	03/03/1999
98P-1196/CP1	IVX Animal Health, Inc.	Request permission to file an ANADA for a generic new animal drug propofol which differs from the pioneer product, propofol (Rapinovet®) Schering-Plough Animal Health Corp., NADA 141-070, by the following characteristics: Propofol generic differs in concentration and the addition of a preservative from the pioneer product.	Filed	12/17/1998
98P-1196/CP1	IVX Animal Health, Inc.	Request permission to file an ANADA for a generic new animal drug propofol which differs from the pioneer product, propofol (Rapinovet®) Schering-Plough Animal Health Corp., NADA 141-070, by the following characteristics: Propofol generic differs in concentration and the addition of a preservative from the pioneer product.	Denied	03/26/1999

Number	Petitioner	Description	Action	Date
98P-1231/CP1	Superior Equine Pharmaceuticals, Inc.	Request permission to file an ANADA for a generic new animal drug phenylbutazone which differs from the pioneer product, phenylbutazone, Anthony Products, Co., NADA 049-187 by the following characteristics: Phenylbutazone generic is a powder dosage form where as the pioneer product is a tablet.	Filed	12/29/1998
98P-1231/CP1	Superior Equine Pharmaceuticals, Inc.	Request permission to file an ANADA for a generic new animal drug phenylbutazone which differs from the pioneer product, phenylbutazone, Anthony Products, Co., NADA 049-187 by the following characteristics: Phenylbutazone generic is a powder dosage form where as the pioneer product is a tablet.	Approved	03/03/1999
99P-0627/CP1	IVX Animal Health, Inc.	Request permission to file an ANADA for a generic new animal drug clorsulon which differs from the pioneer product, ivermectin/ clorsulon (Ivomec® F Injection for Cattle), Merial Ltd, NADA 140-833, by the following characteristics: Clorsulon generic is a single ingredient product where as the pioneer product is a combination product.	Filed	03/22/1999
99P-0627/CP1	IVX Animal Health, Inc.	Request permission to file an ANADA for a generic new animal drug clorsulon which differs from the pioneer product, ivermectin/ clorsulon (Ivomec® F Injection for Cattle), Merial Ltd, NADA 140-833, by the following characteristics: Clorsulon generic is a single ingredient product where as the pioneer product is a combination product.	Denied	05/27/1999
99P-0794/CP1	Veterinary Research Associates, Inc.	Request permission to file an ANADA for a generic new animal drug propofol which differs from the pioneer product, propofol (PropoFlo™), Abbott Laboratories, NADA 141-098, by the following characteristics: Propofol generic differs in concentration, dosage form, and inactive ingredients from the pioneer product.	Filed	03/31/1999
99P-0794/CP1	Veterinary Research Associates, Inc.	Request permission to file an ANADA for a generic new animal drug propofol which differs from the pioneer product, propofol (PropoFlo™), Abbott Laboratories, NADA 141-098, by the following characteristics: Propofol generic differs in concentration, dosage form, and inactive ingredients from the pioneer product.	Denied	11/05/1999
99P-0923/CP1	Nycomed US, Inc.	Request permission to file an ANADA for a generic new animal drug miconazole nitrate which differs from the pioneer product, Conofite ® Cream 2%, Schering-Plough Animal Health Corporation, NADA 095-183, by the following characteristics: The generic will provide for a product containing 20 milligrams miconazole nitrate per gram of cream as opposed to the pioneer product which contains 23 milligrams miconazole nitrate per gram of cream.	Filed	04/02/1999

Number	Petitioner	Description	Action	Date
99P-0923/CP1	Nycomed US, Inc.	Request permission to file an ANADA for a generic new animal drug miconazole nitrate which differs from the pioneer product, Conofite ® Cream 2%, Schering-Plough Animal Health Corporation, NADA 095-183, by the following characteristics: The generic will provide for a product containing 20 milligrams miconazole nitrate per gram of cream as opposed to the pioneer product which contains 23 milligrams miconazole nitrate per gram of cream.	Approved	06/28/1999
99P-2733/CP1	Wildlife Laboratories, Inc.	Request permission to file an ANADA for a generic new animal drug, ketamine hydrochloride, which differs from the pioneer product, Vetalar, Fort Dodge Animal Health, Div. Of AHP Corp., NADA 045-290 by the following characteristic: the generic product will provide a product containing 200 milligrams per milliliter ketamine hydrochloride whereas the pioneer product contains 100 milligrams per milliliter ketamine hydrochloride.	Filed	08/12/1999
99P-2733/CP1	Wildlife Laboratories, Inc.	Request permission to file an ANADA for a generic new animal drug, ketamine hydrochloride, which differs from the pioneer product, Vetalar, Fort Dodge Animal Health, Div. Of AHP Corp., NADA 045-290 by the following characteristic: the generic product will provide a product containing 200 milligrams per milliliter ketamine hydrochloride whereas the pioneer product contains 100 milligrams per milliliter ketamine hydrochloride.	Denied	11/05/1999
99P-4167/CP1	A & G Pharmaceuticals, Inc.	Request permission to file an ANADA for a generic new animal drug, phenylbutazone, which differs from the pioneer product, Phenylbute ™, Phoenix Scientific Inc., NADA 091-818 by the following characteristic: the proposed generic product will have the dosage form of powder, as opposed to the pioneer product which is a tablet.	Filed	09/20/1999
99P-4167/CP1	A & G Pharmaceuticals, Inc.	Request permission to file an ANADA for a generic new animal drug, phenylbutazone, which differs from the pioneer product, Phenylbute ™, Phoenix Scientific Inc., NADA 091-818 by the following characteristic: the proposed generic product will have the dosage form of powder, as opposed to the pioneer product which is a tablet.	Approved	12/07/1999
99P-5328/CP1	Tyler Group, Inc	Request permission to file an ANADA for a generic new animal drug, prednisolone, which differs from the pioneer product, PrednisTab®, Lloyd, Inc., NADA 140-921 by the following characteristics: the proposed generic product will have a dosage form as a palatable chewable tablet as opposed to the pioneer product which is a tablet.	Filed	12/03/1999

Number	Petitioner	Description	Action	Date
99P-5328/CP1	Tyler Group, Inc	Request permission to file an ANADA for a generic new animal drug, prednisolone, which differs from the pioneer product, PrednisTab®, Lloyd, Inc., NADA 140-921 by the following characteristics: the proposed generic product will have a dosage form as a palatable chewable tablet as opposed to the pioneer product which is a tablet.	Approved	03/21/2000
99P-5329/CP1	Tyler Group, Inc.	Request permission to file an ANADA for a generic new animal drug, furosemide, which differs from the pioneer product, Lasix®, Hoechst Roussel Vet, NADA 034-621 by the following characteristics: the proposed generic product will have a dosage form as a palatable chewable tablet as opposed to the pioneer product which is a tablet.	Filed	12/03/1999
99P-5329/CP1	Tyler Group, Inc.	Request permission to file an ANADA for a generic new animal drug, furosemide, which differs from the pioneer product, Lasix®, Hoechst Roussel Vet, NADA 034-621 by the following characteristics: the proposed generic product will have a dosage form as a palatable chewable tablet as opposed to the pioneer product which is a tablet.	Approved	03/20/2000
99P-5330/CP1	Tyler Group, Inc.	Request permission to file an ANADA for a generic new animal drug, enalapril maleate, which differs from the pioneer product, Enacard® Tablets, Merial Ltd., NADA 141-015 by the following characteristics: the proposed generic product will have a dosage form as a palatable chewable tablet as opposed to the pioneer product which is a tablet.	Filed	12/03/1999
99P-5330/CP1	Tyler Group, Inc.	Request permission to file an ANADA for a generic new animal drug, enalapril maleate, which differs from the pioneer product, Enacard® Tablets, Merial Ltd., NADA 141-015 by the following characteristics: the proposed generic product will have a dosage form as a palatable chewable tablet as opposed to the pioneer product which is a tablet.	Approved	03/20/2000
99P-2733/PRC1	Wildlife Laboratories, Inc.	Request permission for reconsideration to file an ANADA for a generic new animal drug, ketamine hydrochloride, which differs from the pioneer product, Vetalar, Fort Dodge Animal Health, Division AHP Corp., NADA 045-290 by the following characteristic: The generic product will provide for a product containing 200 milligrams per milliliter ketamine hydrochloride whereas the pioneer product contains 100 milligrams per milliliter ketamine hydrochloride.	Filed	12/10/1999

Number	Petitioner	Description	Action	Date
99P-2733/PRC1	Wildlife Laboratories, Inc.	Request permission for reconsideration to file an ANADA for a generic new animal drug, ketamine hydrochloride, which differs from the pioneer product, Vetalar, Fort Dodge Animal Health, Division AHP Corp., NADA 045-290 by the following characteristic: The generic product will provide for a product containing 200 milligrams per milliliter ketamine hydrochloride whereas the pioneer product contains 100 milligrams per milliliter ketamine hydrochloride.	Denied	03/20/2000
99P-5331/CP1	PharmX, Inc	Request permission to file an ANADA for a generic new animal drug, phenylbutazone, which differs from the pioneer product, PhenylBute™, Phoenix Scientific Inc., NADA 091-818 by the following characteristics: the proposed generic product will have a dosage form as palatable pellets as opposed to the pioneer product which is a tablet.	Filed	12/13/1999
99P-5331/CP1	PharmX, Inc	Request permission to file an ANADA for a generic new animal drug, phenylbutazone, which differs from the pioneer product, PhenylBute™, Phoenix Scientific Inc., NADA 091-818 by the following characteristics: the proposed generic product will have a dosage form as palatable pellets as opposed to the pioneer product which is a tablet.	Approved	03/07/2000
00P-0117/CP1	IVX Animal Health, Inc.	Request permission to file an ANADA for a generic new animal drug, lincomycin hydrochloride and spectinomycin dihydrochloride pentahydrate, which differs from the pioneer product, Pharmacia & Upjohn Co., NADA 046-109 by the following characteristics: The generic product will provide for a product containing spectinomycin dihydrochloride pentahydrate whereas the pioneer product contains spectinomycin sulfate tetrahydrate.	Filed	01/01/2000
00P-0117/CP1	IVX Animal Health, Inc.	Request permission to file an ANADA for a generic new animal drug, lincomycin hydrochloride and spectinomycin dihydrochloride pentahydrate, which differs from the pioneer product, Pharmacia & Upjohn Co., NADA 046-109 by the following characteristics: The generic product will provide for a product containing spectinomycin dihydrochloride pentahydrate whereas the pioneer product contains spectinomycin sulfate tetrahydrate.	Approved	03/09/2000
00P-0444/CP1	IVX Animal Health, Inc.	Request permission to file an ANADA for a generic new animal drug, spectinomycin dihydrochloride pentahydrate, which differs from the pioneer product, spectinomycin sulfate tetrahydrate (Adspec™ Sterile Solution), Pharmacia & Upjohn Co., NADA 141-077, by the following characteristic: The generic product differs in the salt form of the active drug substance.	Filed	02/04/2000

Number	Petitioner	Description	Action	Date
00P-0444/CP1	IVX Animal Health, Inc.	Request permission to file an ANADA for a generic new animal drug, spectinomycin dihydrochloride pentahydrate, which differs from the pioneer product, spectinomycin sulfate tetrahydrate (Adspec™ Sterile Solution), Pharmacia & Upjohn Co., NADA 141-077, by the following characteristic: The generic product differs in the salt form of the active drug substance.	Denied	03/22/2000
00P-0596/CP1	IVX Animal Health, Inc.	Request permission to file an ANADA for a generic new animal drug, phenylbutazone, which differs from the pioneer product, phenylbutazone (Phoenix Scientific, Inc.), NADA 091-818, by the following characteristic: The generic product will consist of a different physical form, powder, whereas the pioneer approved product is a tablet.	Filed	02/14/2000
00P-0596/CP1	IVX Animal Health, Inc.	Request permission to file an ANADA for a generic new animal drug, phenylbutazone, which differs from the pioneer product, phenylbutazone (Phoenix Scientific, Inc.), NADA 091-818, by the following characteristic: The generic product will consist of a different physical form, powder, whereas the pioneer approved product is a tablet.	Not required	05/05/2000
00P-1225/CP1	Equi Aid Products, Inc.	Request permission to file an ANADA for a generic new animal drug, ivermectin, which differs from the pioneer product, ivermectin (Eqvalan), Merial Ltd., NADA 140-439 by the following characteristics: the generic product will consist of a different dosage form (Type A Medicated Article), different route of administration (via feed), and different strength (5%) from the pioneer.	Filed	03/31/2000
00P-1225/CP1	Equi Aid Products, Inc.	Request permission to file an ANADA for a generic new animal drug, ivermectin, which differs from the pioneer product, ivermectin (Eqvalan), Merial Ltd., NADA 140-439 by the following characteristics: the generic product will consist of a different dosage form (Type A Medicated Article), different route of administration (via feed), and different strength (5%) from the pioneer.	Denied	06/30/2000
00P-1342/CP1	IVX Animal Health, Inc.	Request permission to file an ANADA for a generic new animal drug , pyrantel pamoate, which differs from the pioneer product, Strongid® P, Pfizer Inc., NADA 129-831, by the following characteristic: The generic product will contain a different concentration, 19.13% w/w active ingredient whereas the pioneer product contains 15.25% w/w active ingredient.	Filed	06/15/2000
00P-1342/CP1	IVX Animal Health, Inc.	Request permission to file an ANADA for a generic new animal drug , pyrantel pamoate, which differs from the pioneer product, Strongid® P, Pfizer Inc., NADA 129-831, by the following characteristic: The generic product will contain a different concentration, 19.13% w/w active ingredient whereas the pioneer product contains 15.25% w/w active ingredient.	Approved	08/15/2000

Number	Petitioner	Description	Action	Date
00P-1486/CP1	Equi Aid Products, Inc.	Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, ivermectin (Eqvalan®), Merial Ltd., NADA 134-314 by the following characteristics: the generic product will consist of a different dosage form ('chewable') and strength (22.7 milligrams per 'chewable') from the pioneer.	Filed	08/29/2000
00P-1486/CP1	Equi Aid Products, Inc.	Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, ivermectin (Eqvalan®), Merial Ltd., NADA 134-314 by the following characteristics: the generic product will consist of a different dosage form ('chewable') and strength (22.7 milligrams per 'chewable') from the pioneer.	Denied	07/26/2001
00P-1519/CP1	Smart Drug Systems, Inc.	Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, ivermectin (Heartgard-30®), Merial Ltd., NADA 140-886 by the following characteristics: Ivermectin generic is a compressed chewable tablet and Heartgard-30® is an ‘extruded’ chewable tablet.	Filed	09/15/2000
00P-1519/CP1	Smart Drug Systems, Inc.	Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, ivermectin (Heartgard-30®), Merial Ltd., NADA 140-886 by the following characteristics: Ivermectin generic is a compressed chewable tablet and Heartgard-30® is an ‘extruded’ chewable tablet.	Approved	12/07/2000
00P-1594/CP1	Highland VetPharma, LLC	Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, ivermectin (Eqvalan®), Merial Ltd., NADA 134-314 by the following characteristics: The generic product will consist of a different dosage form (chewable bolus) from the pioneer.	Filed	10/31/2000
00P-1594/CP1	Highland VetPharma, LLC	Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, ivermectin (Eqvalan®), Merial Ltd., NADA 134-314 by the following characteristics: The generic product will consist of a different dosage form (chewable bolus) from the pioneer.	Denied	07/26/2001
00P-1600/CP1	Buford Biomedical, Inc.	Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, ivermectin (Eqvalan® Paste), Merial Ltd., NADA 134-314 by the following characteristics: Ivermectin generic is a 6.8% powder formulation to be administered in the feed.	Filed	11/03/2000
00P-1600/CP1	Buford Biomedical, Inc.	Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, ivermectin (Eqvalan® Paste), Merial Ltd., NADA 134-314 by the following characteristics: Ivermectin generic is a 6.8% powder formulation to be administered in the feed.	Denied	07/26/2001

Number	Petitioner	Description	Action	Date
00P-1655/CP1	Highland VetPharma, LLC	Request permission to file an ANADA for a generic new animal drug phenylbutazone which differs from the pioneer product, phenylbutazone (Phenylbute®), Phoenix Scientific, Inc., NADA 091-818 by the following characteristics: the generic product will consist of a different dosage form ('chewable' tablet) from the pioneer.	Filed	12/06/2000
00P-1655/CP1	Highland VetPharma, LLC	Request permission to file an ANADA for a generic new animal drug phenylbutazone which differs from the pioneer product, phenylbutazone (Phenylbute®), Phoenix Scientific, Inc., NADA 091-818 by the following characteristics: the generic product will consist of a different dosage form ('chewable' tablet) from the pioneer.	Approved	01/29/2001
01P-0045/CP1	Bimeda, Inc.	Request permission to file an ANADA for a generic new animal drug, lincomycin hydrochloride and spectinomycin dihydrochloride pentahydrate, which differs from the pioneer product, Pharmacia & Upjohn Co.'s NADA 046-109 by the following characteristics: The generic product will provide for a product containing spectinomycin dihydrochloride pentahydrate whereas the pioneer product contains spectinomycin sulfate tetrahydrate.	Filed	01/26/2001
01P-0045/CP1	Bimeda, Inc.	Request permission to file an ANADA for a generic new animal drug, lincomycin hydrochloride and spectinomycin dihydrochloride pentahydrate, which differs from the pioneer product, Pharmacia & Upjohn Co.'s NADA 046-109 by the following characteristics: The generic product will provide for a product containing spectinomycin dihydrochloride pentahydrate whereas the pioneer product contains spectinomycin sulfate tetrahydrate.	Approved	04/20/2001
01P-0066/CP1	First Priority, Inc.	Request permission to file an ANADA for a generic new animal drug, ivermectin/pyrantel, which differs from the pioneer product, Heartgard™ Plus (ivermectin/pyrantel), Merial Limited's NADA 140-971 by the following characteristic: Ivermectin/pyrantel generic is a compressed chewable tablet and Heartgard™ Plus is an 'extruded' chewable tablet.	Filed	02/06/2001
01P-0066/CP1	First Priority, Inc.	Request permission to file an ANADA for a generic new animal drug, ivermectin/pyrantel, which differs from the pioneer product, Heartgard™ Plus (ivermectin/pyrantel), Merial Limited's NADA 140-971 by the following characteristic: Ivermectin/pyrantel generic is a compressed chewable tablet and Heartgard™ Plus is an 'extruded' chewable tablet.	Approved	04/09/2001

Number	Petitioner	Description	Action	Date
01P-0124/CP1	First Priority, Inc.	Request permission to file an ANADA for a generic new animal drug, phenylbutazone, which differs from the pioneer product, Phenylbute™, Phoenix Scientific, Inc., NADA 091-818, by the following characteristics: The proposed generic product dosage form is a chewable tablet.	Filed	03/12/2001
01P-0124/CP1	First Priority, Inc.	Request permission to file an ANADA for a generic new animal drug, phenylbutazone, which differs from the pioneer product, Phenylbute™, Phoenix Scientific, Inc., NADA 091-818, by the following characteristics: The proposed generic product dosage form is a chewable tablet.	Approved	04/11/2001
01P-0139/CP1	Vétoquinol N.-A., Inc.	Request permission to file an ANADA for a generic new animal drug, prednisolone, which differs from the pioneer product, PrednisTab®, Lloyd, Inc., NADA 140-921, by the following characteristics: The proposed generic product dosage form is a paste.	Filed	03/21/2001
01P-0139/CP1	Vétoquinol N.-A., Inc.	Request permission to file an ANADA for a generic new animal drug, prednisolone, which differs from the pioneer product, PrednisTab®, Lloyd, Inc., NADA 140-921, by the following characteristics: The proposed generic product dosage form is a paste.	Approved	12/19/2001
01P-0140/CP1	Vétoquinol N.-A., Inc.	Request permission to file an ANADA for a generic new animal drug, cefadroxil, which differs from the pioneer product, Cefa-Drops®, Fort Dodge Animal Health, Division of AHP, NADA 140-684, by the following characteristics: The proposed generic product dosage form is a paste.	Filed	03/21/2001
01P-0140/CP1	Vétoquinol N.-A., Inc.	Request permission to file an ANADA for a generic new animal drug, cefadroxil, which differs from the pioneer product, Cefa-Drops®, Fort Dodge Animal Health, Division of AHP, NADA 140-684, by the following characteristics: The proposed generic product dosage form is a paste.	Approved	12/19/2001
01P-0141/CP1	Vétoquinol N.-A., Inc.	Request permission to file an ANADA for a generic new animal drug, amoxicillin, which differs from the pioneer product, Amoxi-Drop®, Pfizer Inc., NADA 055-085, by the following characteristics: The proposed generic product dosage form is a paste.	Filed	03/21/2001
01P-0141/CP1	Vétoquinol N.-A., Inc.	Request permission to file an ANADA for a generic new animal drug, amoxicillin, which differs from the pioneer product, Amoxi-Drop®, Pfizer Inc., NADA 055-085, by the following characteristics: The proposed generic product dosage form is a paste.	Approved	12/19/2001

Number	Petitioner	Description	Action	Date
01P-0349/CP1	Smart Drug Systems, Inc.	Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, Ivomec®, Merial Ltd., NADA 128-409 by the following characteristics: The generic product will consist of a different dosage form (compressed rod) and strength (35-60%) from the pioneer.	Filed	08/10/2001
00P-1486/PRC1	Equi Aid Products, Inc.	Request permission for reconsideration to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, ivermectin (Eqvalan®), Merial Ltd., NADA 134-314 by the following characteristics: the generic product will consist of a different dosage form ('chewable') and strength (22.7 milligrams per 'chewable') from the pioneer.	Filed	08/16/2001
00P-1486/PRC1	Equi Aid Products, Inc.	Request permission for reconsideration to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, ivermectin (Eqvalan®), Merial Ltd., NADA 134-314 by the following characteristics: the generic product will consist of a different dosage form ('chewable') and strength (22.7 milligrams per 'chewable') from the pioneer.	Approved	09/18/2002
01P-0382/CP1	ECO LLC	Request permission to file an ANADA for a generic new animal drug ivermectin/pyrantel which differs from the pioneer product, Heartgard® Plus, Merial Ltd., NADA 140-971 by the following characteristics: The generic product will consist of a different dosage form (compressed chewable tablet) from the pioneer.	Filed	09/04/2001
01P-0382/CP1	ECO LLC	Request permission to file an ANADA for a generic new animal drug ivermectin/pyrantel which differs from the pioneer product, Heartgard® Plus, Merial Ltd., NADA 140-971 by the following characteristics: The generic product will consist of a different dosage form (compressed chewable tablet) from the pioneer.	Approved	11/06/2001
01P-0385/CP1	Cross Vetpharm Group Ltd.	Request permission to file an ANADA for a generic new animal drug oxytetracycline which differs from the pioneer product, Medamycin® Injectable, Boehringer Ingelheim Vetmedica, Inc., NADA 108-963, by the following characteristics: The generic product will consist of a different concentration (300 milligrams per milliliter) from the pioneer.	Filed	09/04/2001
01P-0385/CP1	Cross Vetpharm Group Ltd.	Request permission to file an ANADA for a generic new animal drug oxytetracycline which differs from the pioneer product, Medamycin® Injectable, Boehringer Ingelheim Vetmedica, Inc., NADA 108-963, by the following characteristics: The generic product will consist of a different concentration (300 milligrams per milliliter) from the pioneer.	Denied	02/14/2002

Number	Petitioner	Description	Action	Date
01P-0394/CP1	ECO LLC	Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, Heartgard 30® Chewables, Merial Ltd., NADA 140-886 by the following characteristics: The generic product will consist of a different dosage form (compressed chewable tablet) from the pioneer.	Filed	09/06/2001
01P-0394/CP1	ECO LLC	Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, Heartgard 30® Chewables, Merial Ltd., NADA 140-886 by the following characteristics: The generic product will consist of a different dosage form (compressed chewable tablet) from the pioneer.	Approved	11/06/2001
01P-0349/WDL1	Smart Drug Systems, Inc.	Request permission to withdraw petition to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, Ivomec®, Merial Ltd., NADA 128-409 by the following characteristics: The generic product will consist of a different dosage form (compressed rod) and strength (35-60%) from the pioneer.	Acknowledged	09/17/2001
01P-0349/WDL1	Smart Drug Systems, Inc.	Request permission to withdraw petition to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, Ivomec®, Merial Ltd., NADA 128-409 by the following characteristics: The generic product will consist of a different dosage form (compressed rod) and strength (35-60%) from the pioneer.	Filed	09/17/2001
01P-0425/CP1	First Priority	Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, Heartgard 30® Chewables, Merial Limited's NADA 140-886 by the following characteristic: The generic product will consist of a different dosage form (compressed chewable tablet) from the pioneer.	Filed	09/20/2001
01P-0425/CP1	First Priority	Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, Heartgard 30® Chewables, Merial Limited's NADA 140-886 by the following characteristic: The generic product will consist of a different dosage form (compressed chewable tablet) from the pioneer.	Approved	11/15/2001
01P-0427/CP1	Karen A. Sisson	Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, Eqvalan®, Merial Ltd., NADA 134-314 by the following characteristics: The generic product will consist of a different dosage form (liquid) from the pioneer.	Filed	09/20/2001
01P-0427/CP1	Karen A. Sisson	Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, Eqvalan®, Merial Ltd., NADA 134-314 by the following characteristics: The generic product will consist of a different dosage form (liquid) from the pioneer.	Approved	10/21/2002

Number	Petitioner	Description	Action	Date
02P-0084/CP1	Pharmaceutical Solutions, Inc.	Request permission to file an ANADA for a generic new animal drug trimethoprim and sulfadiazine which differs from the pioneer product, Tribrissen® 400 Oral Paste, Schering-Plough Animal Health Corp., NADA 131-918, by the following characteristics: The generic product will consist of a different dosage form (solution), different method of administration (via stomach tube), and different strength from the pioneer.	Filed	02/26/2002
02P-0084/CP1	Pharmaceutical Solutions, Inc.	Request permission to file an ANADA for a generic new animal drug trimethoprim and sulfadiazine which differs from the pioneer product, Tribrissen® 400 Oral Paste, Schering-Plough Animal Health Corp., NADA 131-918, by the following characteristics: The generic product will consist of a different dosage form (solution), different method of administration (via stomach tube), and different strength from the pioneer.	Approved	11/07/2002
02P-0189/CP1	IVX Animal Health, Inc.	Request permission to file an ANADA for a generic new animal drug praziquantel which differs from the pioneer product, Droncit®, Bayer Corp., NADA 111-798, by the following characteristics: The generic product will consist of a different dosage form (solution) from the pioneer.	Filed	04/30/2002
02P-0189/CP1	IVX Animal Health, Inc.	Request permission to file an ANADA for a generic new animal drug praziquantel which differs from the pioneer product, Droncit®, Bayer Corp., NADA 111-798, by the following characteristics: The generic product will consist of a different dosage form (solution) from the pioneer.	Approved	11/07/2002
02P-0198/CP1	Richdel, Inc.	Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, Eqvalan® Paste, Merial Ltd., NADA 134-314, by the following characteristics: The generic product will consist of a different dosage form (gel) from the pioneer.	Filed	05/03/2002
02P-0198/CP1	Richdel, Inc.	Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, Eqvalan® Paste, Merial Ltd., NADA 134-314, by the following characteristics: The generic product will consist of a different dosage form (gel) from the pioneer.	Approved	11/07/2002
02P-0396/CP1	Intervet, Inc.	Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, Eqvalan® Paste 1.87%, Merial Ltd., NADA 134 -314 by the following characteristics: The generic product will consist of a different dosage form ('soft-chew') and strength (0.45%) from the pioneer.	Filed	09/05/2002

Number	Petitioner	Description	Action	Date
02P-0396/CP1	Intervet, Inc.	Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, Eqvalan® Paste 1.87%, Merial Ltd., NADA 134 -314 by the following characteristics: The generic product will consist of a different dosage form (‘soft-chew’) and strength (0.45%) from the pioneer.	Approved	12/10/2002
02P-0416/CP1	Highland VetPharma, LLC	Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, (Eqvalan®), Merial Ltd., NADA 134-314, by the following characteristics: the generic product will consist of a different dosage form (palatable chewable bolus) and strength (22.75 milligrams per 'chewable') from the pioneer.	Filed	09/18/2002
02P-0416/CP1	Highland VetPharma, LLC	Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, (Eqvalan®), Merial Ltd., NADA 134-314, by the following characteristics: the generic product will consist of a different dosage form (palatable chewable bolus) and strength (22.75 milligrams per 'chewable') from the pioneer.	Approved	12/10/2002
02P-0423/CP1	Highland VetPharma, LLC	Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product (Heartgard® Plus), Merial Ltd., NADA 141-971, by the following characteristics: The generic product will consist of a different dosage form (molded chewable tablet) from the pioneer (extruded chewable tablet).	Filed	09/26/2002
02P-0423/CP1	Highland VetPharma, LLC	Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product (Heartgard® Plus), Merial Ltd., NADA 141-971, by the following characteristics: The generic product will consist of a different dosage form (molded chewable tablet) from the pioneer (extruded chewable tablet).	Approved	12/10/2002
02P-0429/CP1	Highland VetPharma, LLC	Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product (Heartgard® for Cats) Merial Ltd., NADA 141-078 by the following characteristics: The generic product will consist of a different dosage form (molded chewable tablet) from the pioneer (extruded chewable tablet).	Filed	09/30/2002
02P-0429/CP1	Highland VetPharma, LLC	Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product (Heartgard® for Cats) Merial Ltd., NADA 141-078 by the following characteristics: The generic product will consist of a different dosage form (molded chewable tablet) from the pioneer (extruded chewable tablet).	Approved	12/10/2002

Number	Petitioner	Description	Action	Date
02P-0470/CP1	Karen A. Sisson	Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, Eqvalan®, Merial Ltd., NADA 134-314, by the following characteristics: The generic product will consist of a different dosage form (granule/crumble) from the pioneer.	Filed	10/31/2002
02P-0470/CP1	Karen A. Sisson	Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, Eqvalan®, Merial Ltd., NADA 134-314, by the following characteristics: The generic product will consist of a different dosage form (granule/crumble) from the pioneer.	Approved	04/17/2003
02P-0474/CP1	Phoenix Scientific, Inc.	Request permission to file an ANADA for a generic new animal drug tiamulin hydrogen fumarate which differs from the pioneer product, Denagard™ (tiamulin) Soluble Antibiotic, Boehringer Ingelheim Vetmedica, Inc., NADA 134-644, by the following characteristics: The generic product will contain 45% tiamulin, as tiamulin hydrogen fumarate, whereas the pioneer contains 45% tiamulin hydrogen fumarate.	Filed	10/31/2002
02P-0474/WDL1	Phoenix Scientific, Inc.	Request permission to withdraw petition to file an ANADA for a generic new animal drug tiamulin hydrogen fumarate which differs from the pioneer product, Denagard™ (tiamulin) Soluble Antibiotic, Boehringer Ingelheim Vetmedica, Inc., NADA 134-644, by the following characteristics: The generic product will contain 45% tiamulin, as tiamulin hydrogen fumarate, whereas the pioneer contains 45% tiamulin hydrogen fumarate.	Filed	01/31/2003
02P-0474/WDL1	Phoenix Scientific, Inc.	Request permission to withdraw petition to file an ANADA for a generic new animal drug tiamulin hydrogen fumarate which differs from the pioneer product, Denagard™ (tiamulin) Soluble Antibiotic, Boehringer Ingelheim Vetmedica, Inc., NADA 134-644, by the following characteristics: The generic product will contain 45% tiamulin, as tiamulin hydrogen fumarate, whereas the pioneer contains 45% tiamulin hydrogen fumarate.	Acknowledged	01/31/2003
03P-0013/WDL1	First Priority, Inc.	Request permission to withdraw petition to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, Eqvalan® (ivermectin) Paste for Horses, Merial Ltd., NADA 134-314, by the following characteristics: The generic product will have a different dosage form (solution) and strength from the pioneer.	Filed	03/05/2003
03P-0013/WDL1	First Priority, Inc.	Request permission to withdraw petition to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, Eqvalan® (ivermectin) Paste for Horses, Merial Ltd., NADA 134-314, by the following characteristics: The generic product will have a different dosage form (solution) and strength from the pioneer.	Acknowledged	03/05/2003

Number	Petitioner	Description	Action	Date
03P-0108/CP1	Cross Vetpharm Group, Ltd.	Request permission to file an ANADA for a generic new animal drug apramycin which differs from the pioneer product, Apralan® (apramycin sulfate), Elanco Animal Health, NADA 106-964, by the following characteristic: The generic product will have a different excipient.	Filed	03/20/2003
03P-0108/CP1	Cross Vetpharm Group, Ltd.	Request permission to file an ANADA for a generic new animal drug apramycin which differs from the pioneer product, Apralan® (apramycin sulfate), Elanco Animal Health, NADA 106-964, by the following characteristic: The generic product will have a different excipient.	Approved	06/04/2003
03P-0219/CP1	Vétoquinol N.-A., Inc.	Request permission to file an ANADA for a generic new animal drug, amoxicillin, which differs from the pioneer product, Robamox®-V (amoxicillin trihydrate), Teva Pharmaceuticals USA, NADA 065-495, by the following characteristics: The generic product will have a different dosage form (paste) and strength from the pioneer.	Filed	05/19/2003
03P-0219/CP1	Vétoquinol N.-A., Inc.	Request permission to file an ANADA for a generic new animal drug, amoxicillin, which differs from the pioneer product, Robamox®-V (amoxicillin trihydrate), Teva Pharmaceuticals USA, NADA 065-495, by the following characteristics: The generic product will have a different dosage form (paste) and strength from the pioneer.	Approved	07/31/2003
03P-0223/CP1	Richdel, Inc.	Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, Eqvalan® (ivermectin) Liquid for Horses, Merial Ltd., NADA 140-439 by the following characteristic: The generic product will have a different dosage form (solubilized gel) from the pioneer.	Filed	05/23/2003
03P-0223/CP1	Richdel, Inc.	Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, Eqvalan® (ivermectin) Liquid for Horses, Merial Ltd., NADA 140-439 by the following characteristic: The generic product will have a different dosage form (solubilized gel) from the pioneer.	Approved	07/31/2003
03P-0469/CP1	Eugene G. Keller	Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, Eqvalan® Paste, Merial Ltd., NADA 134-314 by the following characteristics: The generic product will have a different strength and dosage form from the pioneer.	Filed	10/08/2003
03P-0469/CP1	Eugene G. Keller	Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, Eqvalan® Paste, Merial Ltd., NADA 134-314 by the following characteristics: The generic product will have a different strength and dosage form from the pioneer.	Approved	12/04/2003

Number	Petitioner	Description	Action	Date
03P-0523/CP1	Karen A. Sisson	Request permission to file an ANADA for a generic new animal drug ivermectin/ praziquantel which differs from the pioneer product, ivermectin/praziquantel (Zimectrin® Gold Paste), Merial Ltd., NADA 141-214 by the following characteristics: The generic product will consist of a different dosage form (granule/ crumble) from the pioneer.	Filed	11/12/2003
03P-0523/CP1	Karen A. Sisson	Request permission to file an ANADA for a generic new animal drug ivermectin/ praziquantel which differs from the pioneer product, ivermectin/praziquantel (Zimectrin® Gold Paste), Merial Ltd., NADA 141-214 by the following characteristics: The generic product will consist of a different dosage form (granule/ crumble) from the pioneer.	Approved	12/04/2003
03P-0552/CP1	Jurox PTY, Limited	Request permission to file an ANADA for a generic new animal drug carprofen which differs from the pioneer product, Rimadyl® Caplets, Pfizer, Inc., NADA 141-053 by the following characteristics: The generic product will have a different dosage form (liquid) and different strength concentration) from the pioneer.	Filed	12/10/2003
03P-0552/CP1	Jurox PTY, Limited	Request permission to file an ANADA for a generic new animal drug carprofen which differs from the pioneer product, Rimadyl® Caplets, Pfizer, Inc., NADA 141-053 by the following characteristics: The generic product will have a different dosage form (liquid) and different strength concentration) from the pioneer.	Approved	03/19/2004
03P-0013/CP1	First Priority, Inc.	Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, Eqvalan® (ivermectin) Paste for Horses, Merial Ltd., NADA 134-314, by the following characteristics: The generic product will have a different dosage form (solution) and strength from the pioneer.	Filed	01/16/2004
04P-0032/CP1	Pennfield Oil Co.	Request permission to file an ANADA for a generic new animal drug chlortetracycline/ sulfamethazine which differs from the pioneer product, Aureo S 700®, Alpharma, Inc., NADA 035-805 by the following characteristics): The generic product will have a different strength (concentration) from the pioneer.	Filed	01/20/2004
04P-0032/CP1	Pennfield Oil Co.	Request permission to file an ANADA for a generic new animal drug chlortetracycline/ sulfamethazine which differs from the pioneer product, Aureo S 700®, Alpharma, Inc., NADA 035-805 by the following characteristics): The generic product will have a different strength (concentration) from the pioneer.	Approved	03/24/2004
04P-0130/CP1	Smart Drug Systems, Inc.	Request permission to file an ANADA for a generic new animal drug amoxicillin which differs from the pioneer product, Amox-Tabs®, Pfizer Inc., NADA 055-078 and NADA 055-081 by the following characteristics): The generic product will have a different strength (concentration) from the pioneer.	Filed	01/20/2004

Number	Petitioner	Description	Action	Date
04P-0058/CP1	Cross Vetpharm Group, Ltd.	Request permission to file an ANADA for a generic new animal drug phenylbutazone which differs from the pioneer product, Butatron®, Cross Vetpharm Group, Inc., NADA 044-756 by the following characteristics): The generic product will have a different physical form, powder, whereas the pioneer approved product is a tablet.	Filed	02/09/2004
04P-0058/WDL1	Cross Vetpharm Group Ltd.	Request permission to withdraw request to file an ANADA for a generic new animal drug phenylbutazone which differs from the pioneer product, Butatron® , Cross Vetpharm Group, Inc., NADA 044-756 by the following characteristic(s): The generic product will have a different physical form, powder, whereas the pioneer approved product is a tablet.	Acknowledged	03/04/2004
04P-0127/CP1	Smart Drug Systems, Inc.	Request permission to file an ANADA for a generic new animal drug clindamycin hydrochloride which differs from the pioneer product, Antirobe®, Pharmacia & Upjohn Co., NADA 120-161 by the following characteristics: The generic product will have a different dosage form (tablet) and different strength (concentration) from the pioneer.	Filed	03/16/2004
04P-0127/CP1	Smart Drug Systems, Inc.	Request permission to file an ANADA for a generic new animal drug clindamycin hydrochloride which differs from the pioneer product, Antirobe®, Pharmacia & Upjohn Co., NADA 120-161 by the following characteristics: The generic product will have a different dosage form (tablet) and different strength (concentration) from the pioneer.	Denied	05/11/2004
04P-0128/CP1	Smart Drug Systems, Inc.	Request permission to file an ANADA for a generic new animal drug amoxicillin trihydrate/clavulanate potassium which differs from the pioneer product, Clavamox® Tablets, Pfizer Inc., NADA 055-099 by the following characteristics): The generic product will have a different strength (concentration) from the pioneer.	Filed	03/16/2004
04P-0128/CP1	Smart Drug Systems, Inc.	Request permission to file an ANADA for a generic new animal drug amoxicillin trihydrate/clavulanate potassium which differs from the pioneer product, Clavamox® Tablets, Pfizer Inc., NADA 055-099 by the following characteristics): The generic product will have a different strength (concentration) from the pioneer.	Denied	05/13/2004
04P-0130/WDL1	Smart Drug Systems, Inc.	Request permission to withdraw request to file an ANADA for a generic new animal drug amoxicillin which differs from the pioneer product, Amox-Tabs®, Pfizer Inc., NADA 055-078 and NADA 055-081 by the following characteristics): The generic product will have a different strength (concentration) from the pioneer.	Filed	03/16/2004

Number	Petitioner	Description	Action	Date
04P-0130/WDL1	Smart Drug Systems, Inc.	Request permission to withdraw request to file an ANADA for a generic new animal drug amoxicillin which differs from the pioneer product, Amox-Tabs®, Pfizer Inc., NADA 055-078 and NADA 055-081 by the following characteristics): The generic product will have a different strength (concentration) from the pioneer.	Acknowledged	05/21/2004
04P-0136/CP1	Intervet, Inc.	Request permission to file an ANADA for a generic new animal drug florfenicol which differs from the pioneer product, Nuflor®, Schering-Plough Animal Health Corp., NADA 141-063 by the following characteristics: The generic product will have a different strength (concentration) from the pioneer.	Filed	03/18/2004
04P-0136/CP1	Intervet, Inc.	Request permission to file an ANADA for a generic new animal drug florfenicol which differs from the pioneer product, Nuflor®, Schering-Plough Animal Health Corp., NADA 141-063 by the following characteristics: The generic product will have a different strength (concentration) from the pioneer.	Approved	05/19/2004
04P-0167/CP1	First Priority, Inc.	Request permission to file an ANADA for a generic new animal drug gentamicin sulfate which differs from the pioneer product, Garacin®, Schering-Plough Animal Health, NADA 130-464 by the following characteristics): The generic product will have a change in strength of oral solution in a pump dispenser from 4.35 milligrams per milliliter to 4.86 milligrams per milliliter. The delivery volume would also change from 1.15 milliliter per pump to 1.05 milliliter per pump.	Filed	04/08/2004
04P-0175/CP1	Intervet, Inc.	Request permission to file an ANADA for a generic new animal drug progesterone which differs from the pioneer product, EAZI-Breed™ CIDR® Cattle Insert, Pharmacia & Upjohn Co., NADA 141-200 by the following characteristics: The generic product will have a change in strength (concentration) from the pioneer.	Filed	04/14/2004
04P-0175/CP1	Intervet, Inc.	Request permission to file an ANADA for a generic new animal drug progesterone which differs from the pioneer product, EAZI-Breed™ CIDR® Cattle Insert, Pharmacia & Upjohn Co., NADA 141-200 by the following characteristics: The generic product will have a change in strength (concentration) from the pioneer.	Approved	07/28/2004
04P-0167/WDL1	First Priority, Inc.	Request permission to withdraw petition to file an ANADA for a generic new animal drug gentamicin sulfate which differs from the pioneer product, Garacin®, Schering-Plough Animal Health, NADA 130-464 by the following characteristics): The generic product will have a change in strength of oral solution in a pump dispenser from 4.35 milligrams per milliliter to 4.86 milligrams per milliliter. The delivery volume would also change from 1.15 milliliter per pump to 1.05 milliliter per pump.	Acknowledged	04/26/2004

Number	Petitioner	Description	Action	Date
04P-0167/WDL1	First Priority, Inc.	Request permission to withdraw petition to file an ANADA for a generic new animal drug gentamicin sulfate which differs from the pioneer product, Garacin®, Schering-Plough Animal Health, NADA 130-464 by the following characteristics): The generic product will have a change in strength of oral solution in a pump dispenser from 4.35 milligrams per milliliter to 4.86 milligrams per milliliter. The delivery volume would also change from 1.15 milliliter per pump to 1.05 milliliter per pump.	Filed	04/26/2004
04P-0197/CP1	First Priority, Inc.	Request permission to file an ANADA for a generic new animal drug gentamicin sulfate which differs from the pioneer product, Garacin®, Schering-Plough Animal Health, NADA 130-464 by the following characteristics: The generic product will have a change in strength of oral solution in a pump dispenser from 4.35 milligrams per milliliter to 4.77 milligrams per milliliter. The delivery volume would also change from 1.15 milliliter per pump to 1.05 milliliter per pump.	Filed	04/26/2004
04P-0197/CP1	First Priority, Inc.	Request permission to file an ANADA for a generic new animal drug gentamicin sulfate which differs from the pioneer product, Garacin®, Schering-Plough Animal Health, NADA 130-464 by the following characteristics: The generic product will have a change in strength of oral solution in a pump dispenser from 4.35 milligrams per milliliter to 4.77 milligrams per milliliter. The delivery volume would also change from 1.15 milliliter per pump to 1.05 milliliter per pump.	Approved	06/24/2004
04P-0127/PRC1	Smart Drug Systems, Inc.	Request permission for reconsideration to file an ANADA for a generic new animal drug clindamycin hydrochloride which differs from the pioneer product, Antirobe®, Pharmacia & Upjohn Co., NADA 120-161 by the following characteristics): The generic product will have a different dosage form (tablet) and different strength (concentration) from the pioneer.	Filed	06/10/2004
04P-0127/PRC1	Smart Drug Systems, Inc.	Request permission for reconsideration to file an ANADA for a generic new animal drug clindamycin hydrochloride which differs from the pioneer product, Antirobe®, Pharmacia & Upjohn Co., NADA 120-161 by the following characteristics): The generic product will have a different dosage form (tablet) and different strength (concentration) from the pioneer.	Denied	10/27/2004
04P-0372/CP1	Intervet, Inc.	Request permission to file an ANADA for a generic new animal drug carprofen which differs from the pioneer product, Rimadyl® Caplets, Pfizer, Inc., NADA 141-053 by the following characteristics: The generic product will have a different dosage form (chewable tablet) from the pioneer.	Filed	08/20/2004

Number	Petitioner	Description	Action	Date
04P-0372/CP1	Intervet, Inc.	Request permission to file an ANADA for a generic new animal drug carprofen which differs from the pioneer product, Rimadyl® Caplets, Pfizer, Inc., NADA 141-053 by the following characteristics: The generic product will have a different dosage form (chewable tablet) from the pioneer.	Approved	10/08/2004
04P-0376/CP1	Bioniche Animal Health USA, Inc.	Request permission to file an ANADA for a generic new animal drug progesterone which differs from the pioneer product, EAZI-Breed™ CIDR® Cattle Insert, Pharmacia & Upjohn Co., NADA 141-200 by the following characteristics: The generic product will have a change in strength (concentration) from the pioneer.	Filed	08/24/2004
04P-0376/CP1	Bioniche Animal Health USA, Inc.	Request permission to file an ANADA for a generic new animal drug progesterone which differs from the pioneer product, EAZI-Breed™ CIDR® Cattle Insert, Pharmacia & Upjohn Co., NADA 141-200 by the following characteristics: The generic product will have a change in strength (concentration) from the pioneer.	Approved	11/03/2004
04P-0383/CP1	Ancare New Zealand, Ltd.	Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, Ivomec® Pour-On for Cattle, Merial Ltd., NADA 140-841 by the following characteristics: The generic product will have a change in strength (concentration) from the pioneer.	Filed	08/31/2004
04P-0383/CP1	Ancare New Zealand, Ltd.	Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, Ivomec® Pour-On for Cattle, Merial Ltd., NADA 140-841 by the following characteristics: The generic product will have a change in strength (concentration) from the pioneer.	Approved	11/16/2004
04P-0384/CP1	Ancare New Zealand, Ltd.	Request permission to file an ANADA for a generic new animal drug levamisole hydrochloride which differs from the pioneer product, Levasole® Soluble Drench Powder, Schering-Plough Animal Health Corp., NADA 112-051 by the following characteristics: The generic product will have a change in strength (concentration) and dosage form from the pioneer.	Filed	08/31/2004
04P-0384/CP1	Ancare New Zealand, Ltd.	Request permission to file an ANADA for a generic new animal drug levamisole hydrochloride which differs from the pioneer product, Levasole® Soluble Drench Powder, Schering-Plough Animal Health Corp., NADA 112-051 by the following characteristics: The generic product will have a change in strength (concentration) and dosage form from the pioneer.	Approved	11/16/2004

Number	Petitioner	Description	Action	Date
04P-0489/CP1	Bioniche Animal Health USA, Inc.	Request permission to file an ANADA for a generic new animal drug serum gonadotropin and chorionic gonadotropin which differs from the pioneer product, P.G. 600®, Intervet, Inc., NADA 140-856 by the following characteristics: The generic product will differ in packaging and presentation of the active ingredients.	Filed	11/05/2004
04P-0489/WDL1	Bioniche Animal Health USA, Inc.	Request permission to withdraw request to file an ANADA for a generic new animal drug serum gonadotropin and chorionic gonadotropin which differs from the pioneer product, P.G. 600®, Intervet, Inc., NADA 140-856 by the following characteristics): The generic product will differ in packaging and presentation of the active ingredients.	Filed	11/05/2004
04P-0489/WDL1	Bioniche Animal Health USA, Inc.	Request permission to withdraw request to file an ANADA for a generic new animal drug serum gonadotropin and chorionic gonadotropin which differs from the pioneer product, P.G. 600®, Intervet, Inc., NADA 140-856 by the following characteristics): The generic product will differ in packaging and presentation of the active ingredients.	Acknowledged	11/09/2004
04P-0507/CP1	Bioniche Animal Health USA, Inc.	Request permission to file an ANADA for a generic new animal drug hyaluronate sodium which differs from the pioneer product, LegendTM, Bayer Healthcare LLC, Animal Health Division, NADA 140-883 by the following characteristics: The generic product will differ in the packaging and presentation of the pioneer product.	Filed	11/05/2004
04P-0507/WDL1	Bioniche Animal Health USA, Inc.	Request permission to withdrawal request to file an ANADA for a generic new animal drug hyaluronate sodium which differs from the pioneer product, LegendTM, Bayer Healthcare LLC, Animal Health Division, NADA 140-883 by the following characteristics)): The generic product will differ in the packaging and presentation of the pioneer product.	Filed	11/05/2004
04P-0507/WDL1	Bioniche Animal Health USA, Inc.	Request permission to withdrawal request to file an ANADA for a generic new animal drug hyaluronate sodium which differs from the pioneer product, LegendTM, Bayer Healthcare LLC, Animal Health Division, NADA 140-883 by the following characteristics)): The generic product will differ in the packaging and presentation of the pioneer product.	Acknowledged	11/09/2004
04P-0551/CP1	Intervet, Inc.	Request permission to file an ANADA for a generic new animal drug omeprazole which differs from the pioneer product, UlcerGard™, Merial Ltd., NADA 141-227 by the following characteristics: The generic product will have a different dosage form (tablet) from the pioneer.	Filed	12/21/2004

Number	Petitioner	Description	Action	Date
04P-0551/CP1	Intervet, Inc.	Request permission to file an ANADA for a generic new animal drug omeprazole which differs from the pioneer product, UlcerGard™, Merial Ltd., NADA 141-227 by the following characteristics: The generic product will have a different dosage form (tablet) from the pioneer.	Approved	01/28/2005
05P-0277/WDL1	Pharmacia & Upjohn Co.	Request permission to withdraw request to file an ANADA for a generic new animal drug ceftiofur hydrochloride which differs from the pioneer product, Excenel® RTU, Pharmacia & Upjohn Co., NADA 140-890, by the following characteristics: The generic product will have a limited route of administration (subcutaneous) in cattle from the pioneer.	Filed	04/20/2005
05P-0277/WDL1	Pharmacia & Upjohn Co.	Request permission to withdraw request to file an ANADA for a generic new animal drug ceftiofur hydrochloride which differs from the pioneer product, Excenel® RTU, Pharmacia & Upjohn Co., NADA 140-890, by the following characteristics: The generic product will have a limited route of administration (subcutaneous) in cattle from the pioneer.	Acknowledged	07/20/2005
05P-0170/CP1	Intervet, Inc.	Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, Eqvalan® Oral Liquid, Merial Ltd., NADA 140-439, by the following characteristics: The generic product will have a different strength (concentration per unit) and a different dosage form (soft chew) from the pioneer.	Filed	05/06/2005
05P-0170/CP1	Intervet, Inc.	Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, Eqvalan® Oral Liquid, Merial Ltd., NADA 140-439, by the following characteristics: The generic product will have a different strength (concentration per unit) and a different dosage form (soft chew) from the pioneer.	Approved	07/01/2005
05P-0277/CP1	Pharmacia & Upjohn Co.	Request permission to file an ANADA for a generic new animal drug ceftiofur hydrochloride which differs from the pioneer product, Excenel® RTU, Pharmacia & Upjohn Co., NADA 140-890, by the following characteristics: The generic product will have a limited route of administration (subcutaneous) in cattle from the pioneer.	Filed	07/08/2005
06P-0060/CP1	Macleod Pharmaceuticals, Inc.	Request permission to file an ANADA for a generic new animal drug phenylbutazone which differs from the pioneer product, Phenylzone® Paste, Schering-Plough Animal Health Corp., NADA 116-087 by the following characteristics: The generic product will have a different dosage form, granules, whereas the pioneer product is a paste.	Filed	02/01/2006

Number	Petitioner	Description	Action	Date
06P-0060/CP1	Macleod Pharmaceuticals, Inc.	Request permission to file an ANADA for a generic new animal drug phenylbutazone which differs from the pioneer product, Phenylzone® Paste, Schering-Plough Animal Health Corp., NADA 116-087 by the following characteristics: The generic product will have a different dosage form, granules, whereas the pioneer product is a paste.	Approved	04/04/2006
06P-0093/CP1	ECO LLC	Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, Ivomec® 1%, Merial Ltd., NADA 128-409, by the following characteristic(s): The generic will differ in strength (2%) from the pioneer product (1%).	Denied	05/05/2006
06P-0093/PRC1	ECO LLC	Request permission for reconsideration to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, Ivomec® 1%, Merial Ltd., NADA 128-409, by the following characteristic(s): The generic will differ in strength (2%) from the pioneer product (1%).	Filed	06/02/2006
06P-0263/CP1	Sparhawk Laboratories, Inc.	Request permission to file an ANADA for a generic new animal drug neomycin which differs from the pioneer product, Neomycin Soluble Powder, Pharmacia & Upjohn Co., NADA 011-315 by the following characteristics: The generic will differ in dosage form.	Filed	06/21/2006
06P-0263/CP1	Sparhawk Laboratories, Inc.	Request permission to file an ANADA for a generic new animal drug neomycin which differs from the pioneer product, Neomycin Soluble Powder, Pharmacia & Upjohn Co., NADA 011-315 by the following characteristics: The generic will differ in dosage form.	Approved	09/06/2006
07P-0175/CP1	Norbrook Laboratories Ltd.	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	05/02/2007
07P-0175/CP1	Norbrook Laboratories Ltd.	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.	Approved	11/26/2007
07P-0177/CP1	Norbrook Laboratories Ltd.	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 141-231 by the following characteristics. The generic will differ in dosage form (chewable tablets) and different strength.	Filed	05/02/2007

Number	Petitioner	Description	Action	Date
07P-0177/CP1	Norbrook Laboratories Ltd.	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 141-231 by the following characteristics. The generic will differ in dosage form (chewable tablets) and different strength.	Denied	01/14/2008
08P-0186/CP1	Norbrook Laboratories Ltd.	Request permission to file an ANADA for a generic new animal drug meloxicam chewable tablet which differs from the pioneer product, Metacam® Oral Suspension sponsored by Boehringer Ingelheim Vetmedica, Inc., under NADA 141-213 by the following characteristics: differ in dosage form and strength. The generic product will be a chewable tablet whereas the pioneer's product is an oral suspension and strength. The generic product will be in 1 mg and 2.5 mg tablets where the reference product is 1.5 mg/mL.	Filed	03/12/2008
08P-0186/CP1	Norbrook Laboratories Ltd.	Request permission to file an ANADA for a generic new animal drug meloxicam chewable tablet which differs from the pioneer product, Metacam® Oral Suspension sponsored by Boehringer Ingelheim Vetmedica, Inc., under NADA 141-213 by the following characteristics: differ in dosage form and strength. The generic product will be a chewable tablet whereas the pioneer's product is an oral suspension and strength. The generic product will be in 1 mg and 2.5 mg tablets where the reference product is 1.5 mg/mL.	Denied	08/21/2008
09P-0110/CP1	Pet Medicus Laboratories, Inc.	Request permission to file an ANADA for a generic new animal drug marbofloxacin which differs from the pioneer product, Zeniquin® tablets sponsored by Pfizer Inc., under NADA 141-151 by the following characteristics: The proposed generic new animal drug is a bi-layered, quadrisected tablet available in 25 mg and 200 mg strengths. The reference listed new animal drug is a coated, single scored tablet available in 25 mg, 50 mg, 100 mg, and 200 mg strengths. The proposed generic new animal drug is intended to deliver the same amount of active ingredient per pound of body weight as the reference listed new animal drug	Filed	02/24/2009
09P-0110/CP1	Pet Medicus Laboratories, Inc.	Request permission to file an ANADA for a generic new animal drug marbofloxacin which differs from the pioneer product, Zeniquin® tablets sponsored by Pfizer Inc., under NADA 141-151 by the following characteristics: The proposed generic new animal drug is a bi-layered, quadrisected tablet available in 25 mg and 200 mg strengths. The reference listed new animal drug is a coated, single scored tablet available in 25 mg, 50 mg, 100 mg, and 200 mg strengths. The proposed generic new animal drug is intended to deliver the same amount of active ingredient per pound of body weight as the reference listed new animal drug	Approved	05/27/2009

Number	Petitioner	Description	Action	Date
09-P-0162-1	PetMedicus Laboratories Ltd.	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.	Filed	03/26/2009
09-P-0162-1	PetMedicus Laboratories Ltd.	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.	Approved	06/19/2009
09P-0245/CP1	Lachman Consultant Service, Inc.	The petitioner requests to file an ANADA for enrofloxacin palatable tablet that differs from the pioneer product BAYTRIL (enrofloxacin) TASTE TABS, sponsored by Bayer Healthcare LLC, under NADA 140-441. The generic will differ in strength, 272 mg, the largest pioneer product strength is 136 mg.	Filed	05/22/2009
09P-0245/CP1	Lachman Consultant Service, Inc.	The petitioner requests to file an ANADA for enrofloxacin palatable tablet that differs from the pioneer product BAYTRIL (enrofloxacin) TASTE TABS, sponsored by Bayer Healthcare LLC, under NADA 140-441. The generic will differ in strength, 272 mg, the largest pioneer product strength is 136 mg.	Approved	11/23/2009
09P-0306/CP1	Lachman Consultant Service, Inc.	The petitioner requests to file an ANADA for pimobendan chewable tablet that differs from the pioneer product VETMEDIN (pimobendan) Chewable Tablets sponsored by Boehringer Ingelheim Vetmedica, Inc., under NADA 140-273. The generic will add a 10 mg tablet size.	Filed	06/26/2009
09P-0306/CP1	Lachman Consultant Service, Inc.	The petitioner requests to file an ANADA for pimobendan chewable tablet that differs from the pioneer product VETMEDIN (pimobendan) Chewable Tablets sponsored by Boehringer Ingelheim Vetmedica, Inc., under NADA 140-273. The generic will add a 10 mg tablet size.	Approved	02/22/2010
09P-0337/CP1	Lachman Consultant Service, Inc.	The petitioner requests to file an ANADA for enrofloxacin an injectable solution for dogs that differs from the pioneer product, BAYTRIL Antibacterial Injectable Solution 2.27% NADA 140-913 by Bayer Heathcare LLC. The generic will differ in strength (2.5%).	Filed	07/20/2009

Number	Petitioner	Description	Action	Date
09P-0337/CP1	Lachman Consultant Service, Inc.	The petitioner requests to file an ANADA for enrofloxacin an injectable solution for dogs that differs from the pioneer product, BAYTRIL Antibacterial Injectable Solution 2.27% NADA 140-913 by Bayer Heathcare LLC. The generic will differ in strength (2.5%).	Approved	11/09/2009
09P-0341/CP1	Lachman Consultant Service, Inc.	The petitioner requests to file an ANADA for florfenicol a concentrated solution that differs from the pioneer product, Nuflor® sponsored by Schering-Plough Animal Health Corp. The generic will differ in strength (10%) whereas the reference product is 2.3%.	Filed	07/20/2009
09P-0341/CP1	Lachman Consultant Service, Inc.	The petitioner requests to file an ANADA for florfenicol a concentrated solution that differs from the pioneer product, Nuflor® sponsored by Schering-Plough Animal Health Corp. The generic will differ in strength (10%) whereas the reference product is 2.3%.	Approved	11/23/2009
09-P-0450-1	Precision Consultants, Inc.	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).	Filed	09/21/2009
09-P-0450-1	Precision Consultants, Inc.	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).	Denied	05/18/2010
09P-0453/CP	Piedmont Animal Health	The petitioner is requesting to file an ANADA for a milbemycin oxime soft chewable tablet that differs from the pioneer product, INTERCEPTOR FLAVOR Tabs, sponsored by Novartis Animal Health US, Inc. under NADA 140-915. The generic product will differ by texture, hardness and size from the pioneer product which is a hard chewable tablet.	Filed	09/21/2009
09P-0453/CP	Piedmont Animal Health	The petitioner is requesting to file an ANADA for a milbemycin oxime soft chewable tablet that differs from the pioneer product, INTERCEPTOR FLAVOR Tabs, sponsored by Novartis Animal Health US, Inc. under NADA 140-915. The generic product will differ by texture, hardness and size from the pioneer product which is a hard chewable tablet.	Approved	11/25/2009

Number	Petitioner	Description	Action	Date
09P-0462/CP	Piedmont Animal Health	The petitioner is requesting to file an ANADA for a carprofen soft chewable tablet that differs from the pioneer product, RIMADYL, sponsored by Pfizer, Inc. under NADA 141-111. The generic product will differ by texture, hardness and size from the pioneer product which is a hard chewable tablet.	Filed	09/21/2009
09P-0462/CP	Piedmont Animal Health	The petitioner is requesting to file an ANADA for a carprofen soft chewable tablet that differs from the pioneer product, RIMADYL, sponsored by Pfizer, Inc. under NADA 141-111. The generic product will differ by texture, hardness and size from the pioneer product which is a hard chewable tablet.	Approved	12/18/2009
09P-0499/CP1	Parnell Technologies Pty Ltd.	The petitioner requests to file an ANADA for gonadorelin injection for use in dairy cattle that differs from the pioneer product, Cystorelin® sponsored by Merial Ltd. under NADA 098-379. The pioneer product contains 43 µg gonadorelin per mL. The proposed generic product will differ in strength from 86 µg /mL.	Filed	10/08/2009
10P-0028/CP1	Parnell Technologies Pty Ltd.	The petitioner requests to file an ANADA for gonadorelin injection for use in dairy cattle that differs from the pioneer product, Cystorelin® sponsored by Merial Ltd. under NADA 098-379. The pioneer product contains 43 µg gonadorelin per mL. The proposed generic product is for a change in strength to 100 µg gonadorelin per mL.	Filed	10/08/2009
10-P-0170/CP	Lannett Company, Inc.	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.	Filed	03/23/2010
10-P-0170/CP	Lannett Company, Inc.	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.	Denied	06/15/2010
10P-0552/CP	Huvepharma AD	Request to increase the strength of Salinomycin sodium Type A medicated feed article from 60 g/lb to 90 g/lb	Filed	10/10/2010

Number	Petitioner	Description	Action	Date
10P-0552/CP	Huvepharma AD	Request to increase the strength of Salinomycin sodium Type A medicated feed article from 60 g/lb to 90 g/lb	Approved	01/04/2011
11P-0078-0001/ CP	Ceva Sante Animale	Request permission for change in strength	Denied	02/02/2011
10P-0639-1	Dinsmore & Shohl, LLP	Request to change the strength and dosage form of an omeprazole paste (37% w/w) to a 570 mg omeprazole tablet (19% w/w).	Approved	03/22/2011
11-P-0335-1	Norbrook, Inc.	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.	Filed	05/06/2011
11-P-0335-1	Norbrook, Inc.	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.	Approved	06/22/2011
11-P-0397-1	NewMarket Pharmaceuticals, LLC	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.	Filed	05/20/2011
11-P-0397-1	NewMarket Pharmaceuticals, LLC	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.	Denied	08/11/2011

Number	Petitioner	Description	Action	Date
12-P-0072-1	Cook Animal Health	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.	Filed	01/27/2012
12-P-0072-1	Cook Animal Health	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.	Denied	03/22/2012
12-P-0313-1	Con Vet GmbH & Co.	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.	Filed	03/29/2012
12-P-0313-1	Con Vet GmbH & Co.	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.	Denied	08/15/2012
12-P-0462	Douglass Oeller Consulting, Inc.	The petitioner requests to file an ANADA for a generic hyaluronate sodium injectable solution that differs from the pioneer product, LEGEND Injectable Solution, sponsored by Bayer Healthcare LLC, Animal Health Division, under NADA 140-883. The generic product will differ in strength and packaging. The RLNAD is 10 mg/mL solution supplied as a 2 mL, single-dose vial for intra-articular (IA) or intravenous (IV) use; or, as a 4 mL single-dose vial for IV use only. The generic product proposes an injectable solution, supplied as a 1.18 mL (20 mg; 16.9 mg/mL) pre-filled, single-dose, glass syringe for IV or IA injection; or, as a 2.35 mL (40 mg; 17.0 mg/mL) pre-filled, single-dose, glass syringe for IV use only.	Filed	05/09/2012

Number	Petitioner	Description	Action	Date
12-P-0462	Douglass Oeller Consulting, Inc.	The petitioner requests to file an ANADA for a generic hyaluronate sodium injectable solution that differs from the pioneer product, LEGEND Injectable Solution, sponsored by Bayer Healthcare LLC, Animal Health Division, under NADA 140-883. The generic product will differ in strength and packaging. The RLNAD is 10 mg/mL solution supplied as a 2 mL, single-dose vial for intra-articular (IA) or intravenous (IV) use; or, as a 4 mL single-dose vial for IV use only. The generic product proposes an injectable solution, supplied as a 1.18 mL (20 mg; 16.9 mg/mL) pre-filled, single-dose, glass syringe for IV or IA injection; or, as a 2.35 mL (40 mg; 17.0 mg/mL) pre-filled, single-dose, glass syringe for IV use only.	Approved	11/29/2012
12-P-0492-1	Med-Pharmex, Inc.	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.	Filed	05/16/2012
12-P-0492-1	Med-Pharmex, Inc.	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.	Approved	08/02/2012
12-P-0497-1	Piedmont Animal Health	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.	Filed	05/18/2012
12-P-0497-1	Piedmont Animal Health	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.	Approved	08/31/2012

Number	Petitioner	Description	Action	Date
12-P-0794-1	Piedmont Animal Health	The petitioner requests to file an ANADA for a generic combination praziquantel, pyrantel pamoate, and febantel soft chewable tablet that differs from the pioneer product, DRONTAL PLUS TASTE TABS, sponsored by Bayer HealthCare LLC, Animal Health Division, under NADA 141-007. The generic product will differ in dosage form. The RLNAD is a compressed hard tablet while the proposed generic product will be a soft chewable tablet.	Filed	07/20/2012
12-P-0794-1	Piedmont Animal Health	The petitioner requests to file an ANADA for a generic combination praziquantel, pyrantel pamoate, and febantel soft chewable tablet that differs from the pioneer product, DRONTAL PLUS TASTE TABS, sponsored by Bayer HealthCare LLC, Animal Health Division, under NADA 141-007. The generic product will differ in dosage form. The RLNAD is a compressed hard tablet while the proposed generic product will be a soft chewable tablet.	Approved	10/11/2012
12-P-0940-1	Alpharma LLC, a Subsidiary of Pfizer, Inc.	he petitioner requests to file an ANADA for a generic florfenicol in drinking water that differs from the pioneer product, NUFLOR 2.3% Concentrate Solution, sponsored by Intervet, Inc., under NADA 141-206. The generic product with differ in the dosage form and strength. The RLNAD is a 2.3 % (23 mg/mL) concentrate solution while the proposed generic product will be soluble granules containing 20% florfenicol.	Filed	08/28/2012
12-P-0940-1	Alpharma LLC, a Subsidiary of Pfizer, Inc.	he petitioner requests to file an ANADA for a generic florfenicol in drinking water that differs from the pioneer product, NUFLOR 2.3% Concentrate Solution, sponsored by Intervet, Inc., under NADA 141-206. The generic product with differ in the dosage form and strength. The RLNAD is a 2.3 % (23 mg/mL) concentrate solution while the proposed generic product will be soluble granules containing 20% florfenicol.	Approved	10/22/2012
12-P-0945-0001	Center for Regulatory Services, Inc.	The petitioner requests to file an ANADA for a generic pimobedan chewable tablet that differs from the pioneer product, VETMEDIN Chewable Tablets, sponsored by Boehringer Ingelheim Vetmedica, Inc., under NADA 141-273. The generic product will differ in concentration. The RLNAD is approved in tablet strengths of 1.25, 2.5, and 5 mg, wherease the generic product proposes to add an additional 10 mg tablet.	Filed	08/30/2012
12-P-0945-0001	Center for Regulatory Services, Inc.	The petitioner requests to file an ANADA for a generic pimobedan chewable tablet that differs from the pioneer product, VETMEDIN Chewable Tablets, sponsored by Boehringer Ingelheim Vetmedica, Inc., under NADA 141-273. The generic product will differ in concentration. The RLNAD is approved in tablet strengths of 1.25, 2.5, and 5 mg, wherease the generic product proposes to add an additional 10 mg tablet.	Approved	11/08/2012

Number	Petitioner	Description	Action	Date
12-P-1128-0001	Dechra, Ltd.	The petitioner requests to file an ANADA for a generic pimobedan chewable tablet that differs from the pioneer product, VETMEDIN Chewable Tablets, sponsored by Boehringer Ingelheim Vetmedica, Inc., under NADA 141-273. The generic product will differ in concentration. The RLNAD is approved in tablet strengths of 1.25, 2.5, and 5 mg, whereas the generic product proposes to add an additional 10 mg tablet.	Filed	10/24/2012
12-P-1128-0001	Dechra, Ltd.	The petitioner requests to file an ANADA for a generic pimobedan chewable tablet that differs from the pioneer product, VETMEDIN Chewable Tablets, sponsored by Boehringer Ingelheim Vetmedica, Inc., under NADA 141-273. The generic product will differ in concentration. The RLNAD is approved in tablet strengths of 1.25, 2.5, and 5 mg, whereas the generic product proposes to add an additional 10 mg tablet.	Approved	02/05/2013
12-P-1170-0002	Cephazone Pharma LLC	The petitioner requests to file an ANADA for a generic ceftiofur hydrochloride sterile suspension that differs from the pioneer products, EXCENEL RTU and EXCENEL RTU EZ, sponsored by Pharmacia & Upjohn Co., a Division of Pfizer, Inc., under NADA 140-890 AND 141-288, respectively. The generic product will differ in the active pharmaceutical ingredient (API). The API of the RLNADs is ceftiofur hydrochloride and the proposed API of the generic product is ceftiofur sodium.	Filed	11/27/2012
12-P-1170-0002	Cephazone Pharma LLC	The petitioner requests to file an ANADA for a generic ceftiofur hydrochloride sterile suspension that differs from the pioneer products, EXCENEL RTU and EXCENEL RTU EZ, sponsored by Pharmacia & Upjohn Co., a Division of Pfizer, Inc., under NADA 140-890 AND 141-288, respectively. The generic product will differ in the active pharmaceutical ingredient (API). The API of the RLNADs is ceftiofur hydrochloride and the proposed API of the generic product is ceftiofur sodium.	Denied	02/11/2013
13-P-0426-0001	Shotwell & Carr, Inc.	The petitioner requests to file an ANADA for a generic cyclosporine oral solution that differs from the pioneer product, ATOPICA gelatin capsule, sponsored by Novartis Animal Health US under NADA 141-218. The generic product will differ in dosage form. The RLNAD is approved as gelatin capsules (10% w/w) and the proposed generic product is an oral solution (10% w/w).	Filed	04/22/2013
13-P-0426-0001	Shotwell & Carr, Inc.	The petitioner requests to file an ANADA for a generic cyclosporine oral solution that differs from the pioneer product, ATOPICA gelatin capsule, sponsored by Novartis Animal Health US under NADA 141-218. The generic product will differ in dosage form. The RLNAD is approved as gelatin capsules (10% w/w) and the proposed generic product is an oral solution (10% w/w).	Approved	08/01/2013

Number	Petitioner	Description	Action	Date
13-P-1101-0001	Piedmont Animal Health	The petitioner requests to file an ANADA for a generic clindamycin hydrochloride tablet that differs from the pioneer product, ANTIROBE Capsules, sponsored by Zoetis Inc. under NADA 120-161. The generic product will differ in dosage form. The RLNAD is approved as a capsule available in 25 mg, 75 mg, 150 mg, and 300 mg capsule strengths. The proposed generic product is a soft chewable tablet that will be available in the same strengths as the pioneer.	Filed	05/22/2013
13-P-1101-0001	Piedmont Animal Health	The petitioner requests to file an ANADA for a generic clindamycin hydrochloride tablet that differs from the pioneer product, ANTIROBE Capsules, sponsored by Zoetis Inc. under NADA 120-161. The generic product will differ in dosage form. The RLNAD is approved as a capsule available in 25 mg, 75 mg, 150 mg, and 300 mg capsule strengths. The proposed generic product is a soft chewable tablet that will be available in the same strengths as the pioneer.	Approved	11/18/2013
13-P-0632-0001	Piedmont Animal Health	The petitioner requests to file an ANADA for a generic deracoxib formed soft chewable tablet that differs from the pioneer product, DERAMAXX Chewable Tablets, sponsored by Novartis Animal Health US, Inc. under NADA 141-203. The generic product will differ in dosage form. The RLNAD is approved as a compressed tablet and the proposed generic product is a formed soft chewable tablet.	Filed	05/24/2013
13-P-0632-0001	Piedmont Animal Health	The petitioner requests to file an ANADA for a generic deracoxib formed soft chewable tablet that differs from the pioneer product, DERAMAXX Chewable Tablets, sponsored by Novartis Animal Health US, Inc. under NADA 141-203. The generic product will differ in dosage form. The RLNAD is approved as a compressed tablet and the proposed generic product is a formed soft chewable tablet.	Approved	07/19/2013
13-P-0996-0001	Piedmont Animal Health	The petitioner requests to file an ANADA for a generic cefpodoxime proxetil tablet that differs from the pioneer product, SIMPLICEF tablets, sponsored by Zoetis Inc. under NADA 141-232. The generic product will differ in dosage form. The RLNAD is approved as a film-coated tablet and the proposed generic product is a formed soft chewable tablet.	Filed	08/13/2013
13-P-0996-0001	Piedmont Animal Health	The petitioner requests to file an ANADA for a generic cefpodoxime proxetil tablet that differs from the pioneer product, SIMPLICEF tablets, sponsored by Zoetis Inc. under NADA 141-232. The generic product will differ in dosage form. The RLNAD is approved as a film-coated tablet and the proposed generic product is a formed soft chewable tablet.	Approved	12/09/2013

Number	Petitioner	Description	Action	Date
13-P-1078-0001	Parnell Technologies Pty Ltd.	The petitioner requests to remove the intravenous route of administration from their approved ANADA 200-541, GONABREED (gonadorelin acetate) injectable solution. The approved generic product and the pioneer product, CYSTORELIN Injectable Solution, sponsored by Merial Ltd. Under NADA 098-379, are currently both approved for intravenous and intramuscular administration.	Filed	09/03/2013
13-P-1078-0001	Parnell Technologies Pty Ltd.	The petitioner requests to remove the intravenous route of administration from their approved ANADA 200-541, GONABREED (gonadorelin acetate) injectable solution. The approved generic product and the pioneer product, CYSTORELIN Injectable Solution, sponsored by Merial Ltd. Under NADA 098-379, are currently both approved for intravenous and intramuscular administration.	Denied	12/11/2013
13-P-1511-001	PetaStrip, LLC	The petitioner requests to file an ANADA for a generic ivermectin that differs from the pioneer product, HEARTGUARD for Cats, sponsored by Merial Ltd. under NADA 141-078. The generic product will differ in dosage form. The RLNAD is approved as a soft chewable tablet. The proposed dosage form is an ivermectin impregnated soluble oral thin film.	Filed	11/07/2013
13-P-1511-001	PetaStrip, LLC	The petitioner requests to file an ANADA for a generic ivermectin that differs from the pioneer product, HEARTGUARD for Cats, sponsored by Merial Ltd. under NADA 141-078. The generic product will differ in dosage form. The RLNAD is approved as a soft chewable tablet. The proposed dosage form is an ivermectin impregnated soluble oral thin film.	Denied	01/31/2014
13-P-1512-001	PetaStrip, LLC	The petitioner requests to file an ANADA for a generic ivermectin that differs from the pioneer product, HEARTGUARD Chewables for Dogs, sponsored by Merial Ltd. under NADA 140-886. The generic product will differ in dosage form. The RLNAD is approved as a soft chewable tablet. The proposed dosage form is an ivermectin impregnated soluble oral thin film.	Filed	11/07/2013
13-P-1512-001	PetaStrip, LLC	The petitioner requests to file an ANADA for a generic ivermectin that differs from the pioneer product, HEARTGUARD Chewables for Dogs, sponsored by Merial Ltd. under NADA 140-886. The generic product will differ in dosage form. The RLNAD is approved as a soft chewable tablet. The proposed dosage form is an ivermectin impregnated soluble oral thin film.	Denied	01/31/2014
14-P-0748-0001	Piedmont Animal Health	The petitioner requested to file an ANADA for a generic milbemycin oxime that differs from the pioneer product, INTERCEPTOR FLAVOR TABS, sponsored by Novartis Animal Health US, Inc under NADA 140-915. The generic product will differ in dosage form. The RLNAD is approved as a hard compressed tablet. The proposed dosage form is a soft chewable tablet.	Filed	06/02/2014

Number	Petitioner	Description	Action	Date
14-P-0748-0001	Piedmont Animal Health	The petitioner requested to file an ANADA for a generic milbemycin oxime that differs from the pioneer product, INTERCEPTOR FLAVOR TABS, sponsored by Novartis Animal Health US, Inc under NADA 140-915. The generic product will differ in dosage form. The RLNAD is approved as a hard compressed tablet. The proposed dosage form is a soft chewable tablet.	Approved	08/26/2014
14-P-0772-0001	Piedmont Animal Health	The petitioner requested to file an ANADA for a generic pimobendan that differs from the pioneer product, VETMEDIN Chewable Tablets, sponsored by Boehringer Ingelheim Vetmedica, Inc. under NADA 141-273. The generic product will differ in dosage form. The RLNAD is approved as a compressed, hard, chewable tablet. The proposed dosage form is a soft chewable tablet.	Filed	06/06/2014
14-P-0772-0001	Piedmont Animal Health	The petitioner requested to file an ANADA for a generic pimobendan that differs from the pioneer product, VETMEDIN Chewable Tablets, sponsored by Boehringer Ingelheim Vetmedica, Inc. under NADA 141-273. The generic product will differ in dosage form. The RLNAD is approved as a compressed, hard, chewable tablet. The proposed dosage form is a soft chewable tablet.	Approved	08/26/2014
14-P-0794-0001	e5 Pharma, LLC.	The petitioner requested to file an ANADA for a generic methimazole that differs from the pioneer product, FELIMAZOLE, sponsored by Dechra, Ltd under NADA 141-292. The generic product will differ in dosage form. The RLNAD is approved as a film-coated tablet. The proposed dosage form is a soft chewable tablet.	Filed	06/12/2014
14-P-0794-0001	e5 Pharma, LLC.	The petitioner requested to file an ANADA for a generic methimazole that differs from the pioneer product, FELIMAZOLE, sponsored by Dechra, Ltd under NADA 141-292. The generic product will differ in dosage form. The RLNAD is approved as a film-coated tablet. The proposed dosage form is a soft chewable tablet.	Approved	08/26/2014
14-P-1694	Parnell Corporate Services US, Inc.	The petitioner requested to file an ANADA for a generic carprofen injectable solution that differs from the pioneer product, RIMADYL Injectable, sponsored by Zoetis Inc., under NADA 141-199. The generic product will differ in formulation with change in concentration of multiple inactive ingredients (Benzyl Alcohol, L-Arginine), removal of multiple inactive ingredients (Glycholic Acid, Lecithin, and Sodium Hydroxide), and addition of an inactive ingredient (Macrogol PEG USP).	Filed	10/23/2014

Number	Petitioner	Description	Action	Date
14-P-1694	Parnell Corporate Services US, Inc.	The petitioner requested to file an ANADA for a generic carprofen injectable solution that differs from the pioneer product, RIMADYL Injectable, sponsored by Zoetis Inc., under NADA 141-199. The generic product will differ in formulation with change in concentration of multiple inactive ingredients (Benzyl Alcohol, L-Arginine), removal of multiple inactive ingredients (Glycholic Acid, Lecithin, and Sodium Hydroxide), and addition of an inactive ingredient (Macrogol PEG USP).	Denied	01/07/2015
14-P-1802	e5 Pharma, LLC.	The petitioner requested to file an ANADA for a generic methimazole that differs from the pioneer product, FELIMAZOLE, sponsored by Dechra, Ltd. under NADA 141-292. The generic product will differ in dosage form. The RLNAD is approved as a film-coated tablet. The proposed dosage form is an oral solution.	Filed	10/28/2014
14-P-1802	e5 Pharma, LLC.	The petitioner requested to file an ANADA for a generic methimazole that differs from the pioneer product, FELIMAZOLE, sponsored by Dechra, Ltd. under NADA 141-292. The generic product will differ in dosage form. The RLNAD is approved as a film-coated tablet. The proposed dosage form is an oral solution.	Approved	01/13/2015
14-P-1975	e5 Pharma, LLC.	The petitioner requested to file an ANADA for a generic clomipramine hydrochloride chewable tablet that differs from the pioneer product, CLOMICALM, sponsored by Novartis Animal Health US, Inc. under NADA 141-120. The generic product will differ in dosage form. The RLNAD is approved as a scored tablet. The proposed change is for a scored, chewable tablet.	Filed	11/19/2014
14-P-1975	e5 Pharma, LLC.	The petitioner requested to file an ANADA for a generic clomipramine hydrochloride chewable tablet that differs from the pioneer product, CLOMICALM, sponsored by Novartis Animal Health US, Inc. under NADA 141-120. The generic product will differ in dosage form. The RLNAD is approved as a scored tablet. The proposed change is for a scored, chewable tablet.	Approved	01/07/2015
15-P-2231-0001	Cross Vetpharm Group Ltd.	The petitioner requested to file an ANADA for a generic enrofloxacin tablet that differs from the pioneer product, BAYTRIL (enrofloxacin) Taste Tabs, sponsored by Novartis Animal Health US,Inc. under NADA 140-441. The proposed change is to add an additional strength of 272 mg.	Filed	06/17/2015
15-P-2231-0001	Cross Vetpharm Group Ltd.	The petitioner requested to file an ANADA for a generic enrofloxacin tablet that differs from the pioneer product, BAYTRIL (enrofloxacin) Taste Tabs, sponsored by Novartis Animal Health US,Inc. under NADA 140-441. The proposed change is to add an additional strength of 272 mg.	Approved	08/05/2015

Number	Petitioner	Description	Action	Date
16-P-0134	Summit Pharmaceuticals Inc.	The petitioner requested to file an ANADA for a generic phenylbutazone paste for use in horses that differs from the pioneer product, EQUIZONE Powder, sponsored by A & G Pharmaceuticals, Inc. under ANADA 200-334. The proposed change is in dosage form, the method of dispensing and flavoring. The RLNAD is approved as a powder in a jar, and is citrus flavored. The proposed change is to a paste, in a 60 mL dial-a-dose syringe and apple flavoring.	Filed	01/20/2016
16-P-0134	Summit Pharmaceuticals Inc.	The petitioner requested to file an ANADA for a generic phenylbutazone paste for use in horses that differs from the pioneer product, EQUIZONE Powder, sponsored by A & G Pharmaceuticals, Inc. under ANADA 200-334. The proposed change is in dosage form, the method of dispensing and flavoring. The RLNAD is approved as a powder in a jar, and is citrus flavored. The proposed change is to a paste, in a 60 mL dial-a-dose syringe and apple flavoring.	Denied	04/08/2016
16-P-1169	e5 Pharma, LLC.	The petitioner requests to file an ANADA for a generic methimazole tablet that differs from the pioneer product, FELIMAZOLE, sponsored by Dechra, Ltd under NADA 141-292. The proposed change is in dosage form. The RLNAD is approved as a coated tablet. The proposed change is for a rapidly disintigrating tablet.	Filed	04/13/2016
16-P-1169	e5 Pharma, LLC.	The petitioner requests to file an ANADA for a generic methimazole tablet that differs from the pioneer product, FELIMAZOLE, sponsored by Dechra, Ltd under NADA 141-292. The proposed change is in dosage form. The RLNAD is approved as a coated tablet. The proposed change is for a rapidly disintigrating tablet.	Denied	06/08/2016
16-P-1991	Felix Pharmaceuticals Pvt. Ltd.	The petitioner requested to file an ANADA for a generic carprofen tablet for use in dogs that differs from the pioneer product, Rimadyl® (carprofen) chewable tablet, sponsored by Zoetis Inc. under 141-111. The proposed change is in doage form. The RLNAD is approved as a compressed tablet. The proposed change is for a soft chewable tablet.	Filed	07/12/2016
16-P-1991	Felix Pharmaceuticals Pvt. Ltd.	The petitioner requested to file an ANADA for a generic carprofen tablet for use in dogs that differs from the pioneer product, Rimadyl® (carprofen) chewable tablet, sponsored by Zoetis Inc. under 141-111. The proposed change is in doage form. The RLNAD is approved as a compressed tablet. The proposed change is for a soft chewable tablet.	Approved	09/21/2016

Number	Petitioner	Description	Action	Date
16-P-3015	Felix Pharmaceuticals Pvt. Ltd.	The petitioner requests to file an ANADA for a generic enrofloxacin tablet for use in dogs and cats that differs from the pioneer product, Baytril® Taste Tabs (enrofloxacin) antibacterial tablets, sponsored by Bayer HealthCare, LLC, Animal Health Division, under 140-441. The proposed change is in dosage form. The RLNAD is approved as a compressed tablet. The proposed change is for a soft chewable tablet.	Filed	09/28/2016
16-P-3015	Felix Pharmaceuticals Pvt. Ltd.	The petitioner requests to file an ANADA for a generic enrofloxacin tablet for use in dogs and cats that differs from the pioneer product, Baytril® Taste Tabs (enrofloxacin) antibacterial tablets, sponsored by Bayer HealthCare, LLC, Animal Health Division, under 140-441. The proposed change is in dosage form. The RLNAD is approved as a compressed tablet. The proposed change is for a soft chewable tablet.	Approved	01/12/2017
16-P-3427	Felix Pharmaceuticals Pvt. Ltd.	The petitioner requests to file an ANADA for a generic deracoxib tablet for use in dogs that differs from the pioneer product, Derramaxx® (deracoxib) chewable tablet, sponsored by Elanco US, Inc. under 141-203. The proposed change is in dosage form. The RLNAD is approved as a compressed tablet. The proposed change is for a soft chewable tablet.	Filed	10/16/2016
16-P-3427	Felix Pharmaceuticals Pvt. Ltd.	The petitioner requests to file an ANADA for a generic deracoxib tablet for use in dogs that differs from the pioneer product, Derramaxx® (deracoxib) chewable tablet, sponsored by Elanco US, Inc. under 141-203. The proposed change is in dosage form. The RLNAD is approved as a compressed tablet. The proposed change is for a soft chewable tablet.	Approved	01/12/2017
16-P-3428	Felix Pharmaceuticals Pvt. Ltd.	The petitioner requests to file an ANADA for a generic cefpodoxime tablet for use in dogs that differs from the pioneer product, Simplicef® (cefpodoxime) tablet, sponsored by Zoetis Inc. under 141-232. The proposed change is in dosage form. The RLNAD is approved as a compressed, film-coated tablet. The proposed change is for a soft chewable tablet.	Filed	10/17/2016
16-P-3428	Felix Pharmaceuticals Pvt. Ltd.	The petitioner requests to file an ANADA for a generic cefpodoxime tablet for use in dogs that differs from the pioneer product, Simplicef® (cefpodoxime) tablet, sponsored by Zoetis Inc. under 141-232. The proposed change is in dosage form. The RLNAD is approved as a compressed, film-coated tablet. The proposed change is for a soft chewable tablet.	Approved	01/10/2017

Number	Petitioner	Description	Action	Date
17-P-1221	Aurora Pharmaceutical, LLC	The petitioner requests to file an ANADA for a generic firocoxib solution 0.45% w/v (weight per volume) for use in horses that differs from the pioneer product, Equioxx® (firocoxib) Oral Paste, sponsored by Merial Ltd, under 141-253. The proposed change is in dosage form and strength. The RLNAD is approved as an oral paste at 8.2 mg/g. The administration dosage will remain the same at 0.045 mg/lb. The proposed change in strength and dosage form is for a solution at 0.45% w/v.	Filed	02/27/2017
17-P-1221	Aurora Pharmaceutical, LLC	The petitioner requests to file an ANADA for a generic firocoxib solution 0.45% w/v (weight per volume) for use in horses that differs from the pioneer product, Equioxx® (firocoxib) Oral Paste, sponsored by Merial Ltd, under 141-253. The proposed change is in dosage form and strength. The RLNAD is approved as an oral paste at 8.2 mg/g. The administration dosage will remain the same at 0.045 mg/lb. The proposed change in strength and dosage form is for a solution at 0.45% w/v.	Approved	05/19/2017
17-P-1225	Aurora Pharmaceutical, LLC	The petitioner requests to file an ANADA for a generic omeprazole suspension 4.5% w/v (weight per volume) for use in horses that differs from the pioneer product, GastroGard® (omeprazole) Oral Paste, sponsored by Merial Ltd, under 141-123. The proposed change is in dosage form and strength. The RLNAD is approved as an oral paste at a concentration of 37% w/w in an adjusted dose syringe. The administration dosage will remain the same at 1.8 mg/lb (4 mg/kg) of body weight for active gastric ulcers and 0.9 mg/lb (2 mg/kg) of body weight for prevention of ulcers. The proposed change in strength and dosage form is for a multi-dose oral suspension with a lower strength of 4.5% w/v.	Filed	02/27/2017
17-P-1225	Aurora Pharmaceutical, LLC	The petitioner requests to file an ANADA for a generic omeprazole suspension 4.5% w/v (weight per volume) for use in horses that differs from the pioneer product, GastroGard® (omeprazole) Oral Paste, sponsored by Merial Ltd, under 141-123. The proposed change is in dosage form and strength. The RLNAD is approved as an oral paste at a concentration of 37% w/w in an adjusted dose syringe. The administration dosage will remain the same at 1.8 mg/lb (4 mg/kg) of body weight for active gastric ulcers and 0.9 mg/lb (2 mg/kg) of body weight for prevention of ulcers. The proposed change in strength and dosage form is for a multi-dose oral suspension with a lower strength of 4.5% w/v.	Denied	05/18/2017

Number	Petitioner	Description	Action	Date
17-P-4255	Kindred Biosciences	The petitioner requests to file an ANADA for a generic pergolide mesylate pellet for use in horses that differs from the pioneer product, Prascend® (pergolide mesylate) tablets, sponsored by Boehringer Ingelheim Vetmedica, Inc., under 141-331. The proposed change is in dosage form. The RLNAD is approved as a compressed tablet. The proposed change is for an extruded pellet to be used as a top-dress on the horse's daily ration.	Filed	07/17/2017
17-P-4255	Kindred Biosciences	The petitioner requests to file an ANADA for a generic pergolide mesylate pellet for use in horses that differs from the pioneer product, Prascend® (pergolide mesylate) tablets, sponsored by Boehringer Ingelheim Vetmedica, Inc., under 141-331. The proposed change is in dosage form. The RLNAD is approved as a compressed tablet. The proposed change is for an extruded pellet to be used as a top-dress on the horse's daily ration.	Approved	09/29/2017
17-P-6968	Ceva Animal Health, LLC	The petitioner requests to file an ANADA for a generic cyclosporine oral solution (10% w/w cyslosporine non-aqueous solution) that differs from the pioneer product, Atopica® gelatin capsule, sponsored by Elanco US, Inc. under NADA 141-218. The generic product will differ in dosage form.	Filed	12/21/2017
17-P-6968	Ceva Animal Health, LLC	The petitioner requests to file an ANADA for a generic cyclosporine oral solution (10% w/w cyslosporine non-aqueous solution) that differs from the pioneer product, Atopica® gelatin capsule, sponsored by Elanco US, Inc. under NADA 141-218. The generic product will differ in dosage form.	Approved	03/15/2018
18-P-1185	Provetica Animal Health LLC	The petitioner requets to file an ANADA for a generic ivermectin/pyrantel pamoate flavored soft tab that differs from the pioneer product, Heartgard® Plus Chewables, sponsored by Merial Ltd., under NADA 140-971. The generic product will differ in dosage form (flavored soft tab versus chewable tablet).	Filed	03/19/2018
18-P-1185	Provetica Animal Health LLC	The petitioner requests to file an ANADA for a generic ivermectin/pyrantel pamoate flavored soft tab that differs from the pioneer product, Heartgard® PlusChewables, sponsored by Merial Ltd., under NADA 140-971. The generic product will differ in dosage form (flavored soft tab versus chewable tablet).	Filed	03/19/2018
18-P-1185	Provetica Animal Health LLC	The petitioner requests to file an ANADA for a generic ivermectin/pyrantel pamoate flavored soft tab that differs from the pioneer product, Heartgard® PlusChewables, sponsored by Merial Ltd., under NADA 140-971. The generic product will differ in dosage form (flavored soft tab versus chewable tablet).	Approved	06/13/2018

Number	Petitioner	Description	Action	Date
18-P-1349	Felix Pharmaceuticals Pvt. Ltd.	The petitioner requests to file an ANADA for a generic pimobendan that differs from the pioneer product, Vetmedin® (pimobendan) Tablets, sponsored by Boehringer Ingelheim Vetmedica, Inc. under NADA 141-273. The generic product will differ in dosage form. The proposed change is from a compressed tablet (pioneer product) to a soft chewable tablet.	Filed	04/02/2018
18-P-1349	Felix Pharmaceuticals Pvt. Ltd.	The petitioner requests to file an ANADA for a generic pimobendan that differs from the pioneer product, Vetmedin® (pimobendan) Tablets, sponsored by Boehringer Ingelheim Vetmedica, Inc. under NADA 141-273. The generic product will differ in dosage form. The proposed change is from a compressed tablet (pioneer product) to a soft chewable tablet.	Approved	06/13/2018
18-P-1351	Felix Pharmaceuticals Pvt. Ltd.	The petitioner requests to file an ANADA for a generic marbofloxacin that differs from the pioneer product, Zeniquin® (marbofloxacin) Tablets, sponsored by Zoetis Inc. under NADA 141-151. The generic product will differ in dosage form. The proposed change is from a compressed tablet (pioneer product) to a compressed chewable tablet.	Filed	04/02/2018
18-P-1351	Felix Pharmaceuticals Pvt. Ltd.	The petitioner requests to file an ANADA for a generic marbofloxacin that differs from the pioneer product, Zeniquin® (marbofloxacin) Tablets, sponsored by Zoetis Inc. under NADA 141-151. The generic product will differ in dosage form. The proposed change is from a compressed tablet (pioneer product) to a compressed chewable tablet.	Approved	06/07/2018
18-P-1352	Felix Pharmaceuticals Pvt. Ltd.	The petitioner requests to file an ANADA for a generic marbofloxacin that differs from the pioneer product, Zeniquin® (marbofloxacin) Tablets, sponsored by Zoetis Inc. under NADA 141-151. The generic product will differ in dosage form. The proposed change is from a compressed tablet (pioneer product) to a soft chewable tablet.	Filed	04/02/2018
18-P-1352	Felix Pharmaceuticals Pvt. Ltd.	The petitioner requests to file an ANADA for a generic marbofloxacin that differs from the pioneer product, Zeniquin® (marbofloxacin) Tablets, sponsored by Zoetis Inc. under NADA 141-151. The generic product will differ in dosage form. The proposed change is from a compressed tablet (pioneer product) to a soft chewable tablet.	Approved	06/07/2018
18-P-1740	Provetica Animal Health LLC	The petitioner requests to file an ANADA for a generic deracoxib tablet for use in dogs that differs from the pioneer product, Derramaxx® (deracoxib) chewable tablet, sponsored by Elanco US, Inc. under 141-203. The proposed change is for a scored tablet presentation on the 12 mg and 100 mg sizes.	Filed	05/03/2018

Number	Petitioner	Description	Action	Date
18-P-1740	Provetica Animal Health LLC	The petitioner requests to file an ANADA for a generic deracoxib tablet for use in dogs that differs from the pioneer product, Derramaxx® (deracoxib) chewable tablet, sponsored by Elanco US, Inc. under 141-203. The proposed change is for a scored tablet presentation on the 12 mg and 100 mg sizes.	Denied	08/08/2018
18-P-2344	Noble Pharma, LLC	The petitioner requests to file an ANADA for a generic praziquantel tablet for use in dogs that differs from the pioneer product, Tapeworm Dewormer for Dogs (praziquantel) 34 mg tablet, sponsored by Bayer HealthCare, LLC, Animal Health Division under 111-798. The proposed change is for a soft, chewable scored tablet - light brown in color.	Filed	06/15/2018
2018-P-2407	Ray Law Firm, PLLC	The petitioner requests to file an ANADA for a generic carprofen chewable tablet for use in dogs that differs from the reference listed new animal drug (RLNAD), RIMADYL® (carprofen) chewable tablets, sponsored by Zoetis Inc. under NADA 141-111. The proposed change is for the addition of two tablet strengths: 37.5 mg (unscored) and 50 mg (scored). The RLNAD is approved in 25 mg, 75 mg, and 100 mg tablet strengths; all tablet strengths approved for the RLNAD are scored.	Filed	06/20/2018
2018-P-2407	Ray Law Firm, PLLC	The petitioner requests to file an ANADA for a generic carprofen chewable tablet for use in dogs that differs from the reference listed new animal drug (RLNAD), RIMADYL® (carprofen) chewable tablets, sponsored by Zoetis Inc. under NADA 141-111. The proposed change is for the addition of two tablet strengths: 37.5 mg (unscored) and 50 mg (scored). The RLNAD is approved in 25 mg, 75 mg, and 100 mg tablet strengths; all tablet strengths approved for the RLNAD are scored.	Approved	11/09/2018
2018-P-2985	Norbrook Laboratories, Ltd.	The petitioner requests to file an ANADA for a generic methimazole oral solution for use in cats that differs from the reference listed new animal drug (RLNAD), FELIMAZOLE® Coated Tablets (methimazole), sponsored by Dechra, Ltd. under NADA 141-292. The proposed change is for an oral solution (5 mg/mL strength); the RLNAD is approved as coated tablets in 2.5 mg and 5 mg tablet strengths.	Filed	07/30/2018
2018-P-2985	Norbrook Laboratories, Ltd.	The petitioner requests to file an ANADA for a generic methimazole oral solution for use in cats that differs from the reference listed new animal drug (RLNAD), FELIMAZOLE® Coated Tablets (methimazole), sponsored by Dechra, Ltd. under NADA 141-292. The proposed change is for an oral solution (5 mg/mL strength); the RLNAD is approved as coated tablets in 2.5 mg and 5 mg tablet strengths.	Approved	10/12/2018

Number	Petitioner	Description	Action	Date
2018-P-3211	Aurora Pharmaceutical LLC	The petitioner requests to file an ANADA for a generic firocoxib oral solution for use in horses that differs from the reference listed new animal drug (RLNAD), Equioxx® (firocoxib) Oral Paste, sponsored by Merial, Inc. under NADA 141-253. The proposed change is in dosage form and strength. The petitioner proposes a generic product that is an oral solution with a strength of 1.14% w/v (weight per volume). The RLNAD is approved as an oral paste; the strength of the RLNAD is 8.2 mg/g.	Filed	08/17/2018
2018-P-3211	Aurora Pharmaceutical LLC	The petitioner requests to file an ANADA for a generic firocoxib oral solution for use in horses that differs from the reference listed new animal drug (RLNAD), Equioxx® (firocoxib) Oral Paste, sponsored by Merial, Inc. under NADA 141-253. The proposed change is in dosage form and strength. The petitioner proposes a generic product that is an oral solution with a strength of 1.14% w/v (weight per volume). The RLNAD is approved as an oral paste; the strength of the RLNAD is 8.2 mg/g.	Denied	11/15/2018
2018-P-3535	Norbrook Laboratories Limited	The petitioner requests to file an ANADA for a generic pimobendan oral solution for use in dogs that differs from the reference listed new animal drug (RLNAD), Vetmedin® (pimobendan) Chewable Tablets, sponsored by Boehringer Ingelheim Vetmedica, Inc. under NADA 141-273. The proposed change is for an oral solution (4 mg/mL strength); the RLNAD is approved as chewable tablets in 1.25 mg, 2.5 mg, 5 mg, and 10 mg tablet strengths.	Filed	09/18/2018
2018-P-3535	Norbrook Laboratories Limited	The petitioner requests to file an ANADA for a generic pimobendan oral solution for use in dogs that differs from the reference listed new animal drug (RLNAD), Vetmedin® (pimobendan) Chewable Tablets, sponsored by Boehringer Ingelheim Vetmedica, Inc. under NADA 141-273. The proposed change is for an oral solution (4 mg/mL strength); the RLNAD is approved as chewable tablets in 1.25 mg, 2.5 mg, 5 mg, and 10 mg tablet strengths.	Approved	12/14/2018
2016-P-1169	e5 Pharma, LLC	The petitioner requests a decision on the petition for reconsideration for suitability petition FDA-2016-P-1169. In suitability petition FDA-2016-P-1169, the petitioner requested to file an ANADA for a generic methimazole tablet for use in cats that differed from the reference listed new animal drug (RLNAD), FELIMAZOLE® Coated Tablets (methimazole), sponsored by Dechra, Ltd. under NADA 141-292. The proposed change was in dosage form. The petitioner proposed a rapidly-disintegrating tablet; the RLNAD is approved as coated tablets. The petitioner was issued a denial letter dated June 10, 2016.	Filed	09/27/2018

Number	Petitioner	Description	Action	Date
2016-P-1169	e5 Pharma, LLC	The petitioner requests a decision on the petition for reconsideration for suitability petition FDA-2016-P-1169. In suitability petition FDA-2016-P-1169, the petitioner requested to file an ANADA for a generic methimazole tablet for use in cats that differed from the reference listed new animal drug (RLNAD), FELIMAZOLE® Coated Tablets (methimazole), sponsored by Dechra, Ltd. under NADA 141-292. The proposed change was in dosage form. The petitioner proposed a rapidly-disintegrating tablet; the RLNAD is approved as coated tablets. The petitioner was issued a denial letter dated June 10, 2016.	Denied	11/02/2018
2018-P-3672	Zoetis Inc.	The petitioner requests to file an ANADA for a generic nicarbazin Type A medicated article for use in chickens (except laying hens) that differs from the reference listed new animal drug (RLNAD), Nicarb® 25% (nicarbazin) Type A medicated article, sponsored by Phibro Animal Health Corp. under NADA 009-476. The proposed change is in dosage form from a powder formulation (RLNAD) to a granular formulation (proposed generic product).	Filed	09/27/2018
2018-P-3672	Zoetis Inc.	The petitioner requests to file an ANADA for a generic nicarbazin Type A medicated article for use in chickens (except laying hens) that differs from the reference listed new animal drug (RLNAD), Nicarb® 25% (nicarbazin) Type A medicated article, sponsored by Phibro Animal Health Corp. under NADA 009-476. The proposed change is in dosage form from a powder formulation (RLNAD) to a granular formulation (proposed generic product).	Approved	12/21/2018
2018-P-4642	Provetica Animal Health LLC	The petitioner requests to file an ANADA for a generic cyclosporine oral solution for use in dogs that differs from the reference listed new animal drug (RLNAD), Atopica™ (cyclosporine capsules) USP MODIFIED, sponsored by Elanco US Inc. under NADA 141-218. The proposed change is for an unencapsulated oral solution (10% w/w cyclosporine non-aqueous solution); the RLNAD is approved as gelatin capsules in 10 mg, 25 mg, 50 mg, and 100 mg capsule strengths.	Filed	12/03/2018
2018-P-4642	Provetica Animal Health LLC	The petitioner requests to file an ANADA for a generic cyclosporine oral solution for use in dogs that differs from the reference listed new animal drug (RLNAD), Atopica™ (cyclosporine capsules) USP MODIFIED, sponsored by Elanco US Inc. under NADA 141-218. The proposed change is for an unencapsulated oral solution (10% w/w cyclosporine non-aqueous solution); the RLNAD is approved as gelatin capsules in 10 mg, 25 mg, 50 mg, and 100 mg capsule strengths.	Approved	02/21/2019

Number	Petitioner	Description	Action	Date
2019-P-0412	Summit Pharmaceuticals Inc.	The petitioner requests to file an ANADA for a generic phenylpropanolamine hydrochloride tablet for use in dogs that differs from the reference listed new animal drug (RLNAD), PROIN®(phenylpropanolamine hydrochloride) Chewable Tablets, sponsored by Pegasus Laboratories, Inc. under NADA 141-324. The proposed change is in dosage form and strength. The petitioner proposes a generic product that is an unscored, film-coated tablet in all tablet strengths approved for the RLNAD (25 mg, 50 mg, and 75 mg), as well as two additional tablet strengths (12.5 mg and 37.5 mg). The RLNAD is approved as scored, chewable tablets in 25 mg, 50 mg, and 75 mg tablet strengths.	Filed	12/21/2018
2019-P-0412	Summit Pharmaceuticals Inc.	The petitioner requests to file an ANADA for a generic phenylpropanolamine hydrochloride tablet for use in dogs that differs from the reference listed new animal drug (RLNAD), PROIN®(phenylpropanolamine hydrochloride) Chewable Tablets, sponsored by Pegasus Laboratories, Inc. under NADA 141-324. The proposed change is in dosage form and strength. The petitioner proposes a generic product that is an unscored, film-coated tablet in all tablet strengths approved for the RLNAD (25 mg, 50 mg, and 75 mg), as well as two additional tablet strengths (12.5 mg and 37.5 mg). The RLNAD is approved as scored, chewable tablets in 25 mg, 50 mg, and 75 mg tablet strengths.	Approved	03/21/2019
2019-P-0916	Dr. James H. Schafer, US Agent for Felix Pharmaceuticals Private Limited	The petitioner requests to file an ANADA for a generic praziquantel tablet for use in dogs and cats that differs from the reference listed new animal drug (RLNAD), Droncit® (praziquantel tablets), sponsored by Bayer HealthCare LLC, Animal Health Division under NADA 111-798. The proposed change is in dosage form from a compressed tablet (RLNAD) to a compressed, chewable tablet (proposed generic product).	Filed	02/25/2019
2019-P-0916	Dr. James H. Schafer, US Agent for Felix Pharmaceuticals Private Limited	The petitioner requests to file an ANADA for a generic praziquantel tablet for use in dogs and cats that differs from the reference listed new animal drug (RLNAD), Droncit® (praziquantel tablets), sponsored by Bayer HealthCare LLC, Animal Health Division under NADA 111-798. The proposed change is in dosage form from a compressed tablet (RLNAD) to a compressed, chewable tablet (proposed generic product).	Approved	05/15/2019
2019-P-0941	Dr. James H. Schafer, US Agent for Felix Pharmaceuticals Private Limited	The petitioner requests to file an ANADA for a generic praziquantel/pyrantel pamoate tablet for use in cats that differs from the reference listed new animal drug (RLNAD), Drontal® (praziquantel/pyrantel pamoate) Tablets, sponsored by Bayer HealthCare LLC, Animal Health Division under NADA 141-008. The proposed change is in dosage form from a compressed tablet (RLNAD) to a compressed, chewable tablet (proposed generic product).	Filed	02/25/2019

Number	Petitioner	Description	Action	Date
2019-P-0941	Dr. James H. Schafer, US Agent for Felix Pharmaceuticals Private Limited	The petitioner requests to file an ANADA for a generic praziquantel/pyrantel pamoate tablet for use in cats that differs from the reference listed new animal drug (RLNAD), Drontal® (praziquantel/pyrantel pamoate) Tablets, sponsored by Bayer HealthCare LLC, Animal Health Division under NADA 141-008. The proposed change is in dosage form from a compressed tablet (RLNAD) to a compressed, chewable tablet (proposed generic product).	Approved	05/15/2019
2019-P-1566	Noble Pharma, LLC	The petitioner requests to file an ANADA for a generic ivermectin and pyrantel (aspamoate salt) chewable for use in dogs that differs from the reference listed new animal drug (RLNAD), Heartgard® Plus (ivermectin/ pyrantel) Chewables,sponsored by Boehringer Ingelheim Animal Health USA Inc. under NADA 140-971. The proposed change is in dosage form from an extruded, unscored, and meat-based chewable tablet (RLNAD) to an extruded, scored, and flavored soft chewable (proposed generic product).	Filed	04/02/2019
2019-P-3109	Noble Pharma, LLC	The petitioner requests to file an ANADA for a generic pyrantel pamoate/praziquantel soft chew for use in dogs that differs from the reference listed new animal drug (RLNAD), Virbantel® (pyrantel pamoate/ praziquantel) Flavored Chewables, sponsored by Virbac AH, Inc. under NADA 141-261. The proposed change is in dosage form from a pork liver-flavored chewable tablet (RLNAD) to an extruded, chicken liver-flavored soft chew (proposed generic product).	Filed	06/26/2019
2019-P-3109	Noble Pharma, LLC	The petitioner requests to file an ANADA for a generic pyrantel pamoate/praziquantel soft chew for use in dogs that differs from the reference listed new animal drug (RLNAD), Virbantel® (pyrantel pamoate/ praziquantel) Flavored Chewables, sponsored by Virbac AH, Inc. under NADA 141-261. The proposed change is in dosage form from a pork liver-flavored chewable tablet (RLNAD) to an extruded, chicken liver-flavored soft chew (proposed generic product).	Approved	09/04/2019
2020-P-0963	Aurora Pharmaceutical, Inc.	The petitioner requests to file an ANADA for a generic deracoxib oral solution for use in dogs that differs from the reference listed new animal drug (RLNAD), Deramaxx™ (deracoxib) Chewable Tablets, sponsored by Elanco US Inc. under NADA 141-203. The proposed change is in dosage form and strength. The petitioner proposes a generic product that is an oral solution with a strength of 1.80% w/v (weight per volume). The RLNAD is approved as half-scored, chewable tablets in 12 mg, 25 mg, 75 mg, and 100 mg tablet strengths.	Filed	02/27/2020

Number	Petitioner	Description	Action	Date
2020-P-0963	Aurora Pharmaceutical, Inc.	The petitioner requests to file an ANADA for a generic deracoxib oral solution for use in dogs that differs from the reference listed new animal drug (RLNAD), Deramaxx™ (deracoxib) Chewable Tablets, sponsored by Elanco US Inc. under NADA 141-203. The proposed change is in dosage form and strength. The petitioner proposes a generic product that is an oral solution with a strength of 1.80% w/v (weight per volume). The RLNAD is approved as half-scored, chewable tablets in 12 mg, 25 mg, 75 mg, and 100 mg tablet strengths.	Approved	05/14/2020
2020-P-1074	Akorn Animal Health Inc.	The petitioner requests to file an ANADA for a generic polymyxin B, bacitracin, neomycin, and hydrocortisone ophthalmic ointment for use in dogs and cats that differs from the reference listed new animal drug (RLNAD), CORTISPORIN® OPHTHALMIC OINTMENT Veterinary (polymyxin B, bacitracin, neomycin, hydrocortisone), sponsored by Intervet, Inc. under NADA 065-476. The proposed change is in the strength of one of the active pharmaceutical ingredients (polymyxin B). The petitioner proposes a generic product that is an ophthalmic ointment containing 10,000 units polymyxin B sulfate/gram, 400 units bacitracin zinc/gram, 5 mg neomycin sulfate/gram, and 10 mg (1%) hydrocortisone/gram. The RLNAD is approved as an ophthalmic ointment containing 5,000 units polymyxin B sulfate/gram, 400 units bacitracin zinc/gram, 5 mg neomycin sulfate/ gram, and 10 mg (1%) hydrocortisone/gram.	Filed	03/10/2020
2020-P-1074	Akorn Animal Health Inc.	The petitioner requests to file an ANADA for a generic polymyxin B, bacitracin, neomycin, and hydrocortisone ophthalmic ointment for use in dogs and cats that differs from the reference listed new animal drug (RLNAD), CORTISPORIN® OPHTHALMIC OINTMENT Veterinary (polymyxin B, bacitracin, neomycin, hydrocortisone), sponsored by Intervet, Inc. under NADA 065-476. The proposed change is in the strength of one of the active pharmaceutical ingredients (polymyxin B). The petitioner proposes a generic product that is an ophthalmic ointment containing 10,000 units polymyxin B sulfate/gram, 400 units bacitracin zinc/gram, 5 mg neomycin sulfate/gram, and 10 mg (1%) hydrocortisone/gram. The RLNAD is approved as an ophthalmic ointment containing 5,000 units polymyxin B sulfate/gram, 400 units bacitracin zinc/gram, 5 mg neomycin sulfate/ gram, and 10 mg (1%) hydrocortisone/gram.	Approved	06/03/2020

Number	Petitioner	Description	Action	Date
2020-P-2102	Aurora Pharmaceutical, Inc.	The petitioner requests to file an ANADA for a generic firocoxib oral solution for use in horses that differs from the reference listed new animal drug (RLNAD), Equioxx® (firocoxib) Oral Paste, sponsored by Boehringer Ingelheim Animal Health USA Inc. under NADA 141-253. The proposed generic product would differ from the RLNAD in dosage form and strength. The petitioner proposes a generic product that is an oral solution with a strength of 0.9% w/v (weight per volume). The RLNAD is approved as an oral paste; the strength of the RLNAD is 8.2 mg/g.	Filed	10/20/2020
2020-P-2234	Ray Law Firm, PLLC	The petitioner requests to file an ANADA for generic cefpodoxime proxetil tablets for the treatment of skin infections (wounds and abscesses) in dogs caused by susceptible strains of Staphylococcus pseudintermedius, Staphylococcus aureus, Streptococcus canis (group G, ß hemoltyic), Escherichia coli, Pasteurella multocida, and Proteus mirabilis that differ from the reference listed new animal drug (RLNAD), SIMPLICEF® (cefpodoxime proxetil tablets), sponsored by Zoetis Inc. under NADA 141-232. The proposed changes are the addition of a 50 mg tablet strength and the removal of scoring from the 100 and 200 mg tablet strengths. The RLNAD is approved as scored tablets in 100 mg and 200 mg tablet strengths.	Filed	11/24/2020
2020-P-2234	Ray Law Firm, PLLC	The petitioner requests to file an ANADA for generic cefpodoxime proxetil tablets for the treatment of skin infections (wounds and abscesses) in dogs caused by susceptible strains of Staphylococcus pseudintermedius, Staphylococcus aureus, Streptococcus canis (group G, ß hemoltyic), Escherichia coli, Pasteurella multocida, and Proteus mirabilis that differ from the reference listed new animal drug (RLNAD), SIMPLICEF® (cefpodoxime proxetil tablets), sponsored by Zoetis Inc. under NADA 141-232. The proposed changes are the addition of a 50 mg tablet strength and the removal of scoring from the 100 and 200 mg tablet strengths. The RLNAD is approved as scored tablets in 100 mg and 200 mg tablet strengths.	Approved	02/16/2021
2021-P-0086	Felix Pharmaceuticals Pvt. Ltd.	The petitioner requests to file an ANADA for a generic clindamycin tablet for use in dogs that differs from the reference listed new animal drug (RLNAD), Antirobe® (clindamycin hydrochloride capsules, USP), sponsored by Zoetis Inc. under NADA 120-161. The proposed change is in dosage form from a capsule (RLNAD) to a tablet (proposed generic product).	Filed	01/15/2021

Number	Petitioner	Description	Action	Date
2021-P-0086	Felix Pharmaceuticals Pvt. Ltd.	The petitioner requests to file an ANADA for a generic clindamycin tablet for use in dogs that differs from the reference listed new animal drug (RLNAD), Antirobe® (clindamycin hydrochloride capsules, USP), sponsored by Zoetis Inc. under NADA 120-161. The proposed change is in dosage form from a capsule (RLNAD) to a tablet (proposed generic product).	Approved	04/07/2021
2021-P-1085	Ray Law Firm, PLLC	The petitioner requests to file an ANADA for a generic robenacoxib tablet for use in dogs that differs from the reference listed new animal drug (RLNAD). Onsior™ (robenacoxib) tablets, sponsored by Elanco US Inc. under NADA 141-463, is the RLNAD. The proposed change is the addition of an unscored 5 mg tablet strength. The RLNAD is approved as unscored tablets in 10 mg, 20 mg, and 40 mg tablet strengths.	Filed	10/19/2021
2021-P-1085	Ray Law Firm, PLLC	The petitioner requests to file an ANADA for a generic robenacoxib tablet for use in dogs that differs from the reference listed new animal drug (RLNAD). Onsior™ (robenacoxib) tablets, sponsored by Elanco US Inc. under NADA 141-463, is the RLNAD. The proposed change is the addition of an unscored 5 mg tablet strength. The RLNAD is approved as unscored tablets in 10 mg, 20 mg, and 40 mg tablet strengths.	Approved	12/29/2021
2021-P-1173	Felix Pharmaceuticals Pvt. Ltd.	The petitioner requests to file an ANADA for a generic pimobendan oral suspension for use in dogs that differs from the reference listed new animal drug (RLNAD), Vetmedin® (pimobendan) Chewable Tablets, sponsored by Boehringer Ingelheim Animal Health USA, Inc. under NADA 141-273. The proposed change is for an oral suspension (2.5 mg/mL strength); the RLNAD is approved as scored, chewable tablets in 1.25 mg, 2.5 mg, 5 mg, and 10 mg tablet strengths.	Filed	10/27/2021
2021-P-1173	Felix Pharmaceuticals Pvt. Ltd.	The petitioner requests to file an ANADA for a generic pimobendan oral suspension for use in dogs that differs from the reference listed new animal drug (RLNAD), Vetmedin® (pimobendan) Chewable Tablets, sponsored by Boehringer Ingelheim Animal Health USA, Inc. under NADA 141-273. The proposed change is for an oral suspension (2.5 mg/mL strength); the RLNAD is approved as scored, chewable tablets in 1.25 mg, 2.5 mg, 5 mg, and 10 mg tablet strengths.	Approved	11/22/2021
2021-P-1174	Felix Pharmaceuticals Pvt. Ltd.	The petitioner requests to file an ANADA for a generic methimazole oral solution for use in cats that differs from the reference listed new animal drug (RLNAD), FELIMAZOLE® COATED TABLETS (methimazole), sponsored by Dechra, Ltd. under NADA 141-292. The proposed change is for an oral solution (5 mg/mL strength); the RLNAD is approved as unscored, coated tablets in 2.5 mg and 5 mg tablet strengths.	Filed	10/27/2021

Number	Petitioner	Description	Action	Date
2021-P-1174	Felix Pharmaceuticals Pvt. Ltd.	The petitioner requests to file an ANADA for a generic methimazole oral solution for use in cats that differs from the reference listed new animal drug (RLNAD), FELIMAZOLE® COATED TABLETS (methimazole), sponsored by Dechra, Ltd. under NADA 141-292. The proposed change is for an oral solution (5 mg/mL strength); the RLNAD is approved as unscored, coated tablets in 2.5 mg and 5 mg tablet strengths.	Approved	01/20/2022
2021-P-1175	Felix Pharmaceuticals Pvt. Ltd.	The petitioner requests to file an ANADA for a generic levothyroxine sodium oral solution for use in dogs that differs from the reference listed new animal drug (RLNAD), Thyro-Tabs® Canine (levothyroxine sodium tablets), USP, sponsored by Lloyd, Inc. under NADA 141-448. The proposed change is for an oral solution (200 µg/mL and 400 µg/mL strengths); the RLNAD is approved as scored, color-coded tablets in 0.1 mg, 0.2 mg, 0.3 mg, 0.4 mg, 0.5 mg, 0.6 mg, 0.7 mg, 0.8 mg, and 1.0 mg tablet strengths.	Filed	10/27/2021
2021-P-1175	Felix Pharmaceuticals Pvt. Ltd.	The petitioner requests to file an ANADA for a generic levothyroxine sodium oral solution for use in dogs that differs from the reference listed new animal drug (RLNAD), Thyro-Tabs® Canine (levothyroxine sodium tablets), USP, sponsored by Lloyd, Inc. under NADA 141-448. The proposed change is for an oral solution (200 µg/mL and 400 µg/mL strengths); the RLNAD is approved as scored, color-coded tablets in 0.1 mg, 0.2 mg, 0.3 mg, 0.4 mg, 0.5 mg, 0.6 mg, 0.7 mg, 0.8 mg, and 1.0 mg tablet strengths.	Approved	12/30/2021
2021-P-1245	Schafer Veterinary Consultants, LLC	The petitioner requests to file an ANADA for generic chewable amoxicillin and clavulanate potassium tablets for use in dogs and cats that differ from the reference listed new animal drug (RLNAD), CLAVAMOX® CHEWABLE (amoxicillin and clavulanate potassium tablets), sponsored by Zoetis Inc. under NADA 055-099. The proposed change is the addition of a 500 mg tablet strength for use in dogs only. The RLNAD is approved as chewable tablets in a 62.5 mg tablet strength for use in dogs and cats and in 125 mg, 250 mg, and 375 mg tablet strengths for use in dogs only.	Filed	11/19/2021
2021-P-1245	Schafer Veterinary Consultants, LLC	The petitioner requests to file an ANADA for generic chewable amoxicillin and clavulanate potassium tablets for use in dogs and cats that differ from the reference listed new animal drug (RLNAD), CLAVAMOX® CHEWABLE (amoxicillin and clavulanate potassium tablets), sponsored by Zoetis Inc. under NADA 055-099. The proposed change is the addition of a 500 mg tablet strength for use in dogs only. The RLNAD is approved as chewable tablets in a 62.5 mg tablet strength for use in dogs and cats and in 125 mg, 250 mg, and 375 mg tablet strengths for use in dogs only.	Approved	01/19/2022

Number	Petitioner	Description	Action	Date
2022-P-1049	Noble Pharma, LLC	The petitioner requests to file an ANADA for a generic firocoxib tablet for use in dogs that differs from the reference listed new animal drug (RLNAD), Previcox® (firocoxib) Chewable Tablets, sponsored by Boehringer Ingelheim Animal Health USA, Inc. under NADA 141-230. The proposed change is in dosage form from a compressed, barbecue-flavored, and half-scored chewable tablet (RLNAD) to an extruded, chicken liver-flavored, and half-scored soft chewable tablet (proposed generic product).	Filed	06/07/2022
2022-P-1049	Noble Pharma, LLC	The petitioner requests to file an ANADA for a generic firocoxib tablet for use in dogs that differs from the reference listed new animal drug (RLNAD), Previcox® (firocoxib) Chewable Tablets, sponsored by Boehringer Ingelheim Animal Health USA, Inc. under NADA 141-230. The proposed change is in dosage form from a compressed, barbecue-flavored, and half-scored chewable tablet (RLNAD) to an extruded, chicken liver-flavored, and half-scored soft chewable tablet (proposed generic product).	Approved	09/08/2022
2022-P-1642	Noble Pharma, LLC	The petitioner requests to file an ANADA for a generic carprofen chewable tablet for use in dogs that differs from the reference listed new animal drug (RLNAD), RIMADYL® (carprofen) Chewable Tablets, sponsored by Zoetis Inc. under NADA 141-111. The proposed change is in dosage form from a compressed, liver-flavored, and half-scored hard chewable tablet (RLNAD) to an extruded, chicken liver-flavored, and half-scored soft chewable tablet (proposed generic product).	Filed	07/21/2022
2022-P-1642	Noble Pharma, LLC	The petitioner requests to file an ANADA for a generic carprofen chewable tablet for use in dogs that differs from the reference listed new animal drug (RLNAD), RIMADYL® (carprofen) Chewable Tablets, sponsored by Zoetis Inc. under NADA 141-111. The proposed change is in dosage form from a compressed, liver-flavored, and half-scored hard chewable tablet (RLNAD) to an extruded, chicken liver-flavored, and half-scored soft chewable tablet (proposed generic product).	Approved	10/25/2022
2022-P-2076	Noble Pharma, LLC	The petitioner requests to file an ANADA for a generic maropitant citrate tablet for use in dogs that differs from the reference listed new animal drug (RLNAD), Cerenia® (maropitant citrate) Tablets, sponsored by Zoetis Inc. under NADA 141-262. The proposed change is in dosage form from a compressed, scored tablet (RLNAD) to an extruded, chicken liver-flavored, and scored soft chewable tablet (proposed generic product).	Filed	08/31/2022

Number	Petitioner	Description	Action	Date
2022-P-2795	Aurora Pharmaceutical, Inc.	The petitioner requests to file an ANADA for a generic meloxicam oral solution for use in dogs that differs from the reference listed new animal drug (RLNAD), Metacam® (meloxicam oral suspension), sponsored by Boehringer Ingelheim Animal Health USA, Inc. under NADA 141-213. The proposed change is for an oral solution (0.5 mg/mL and 1.5 mg/mL strengths); the RLNAD is approved as an oral suspension (0.5 mg/mL and 1.5 mg/mL strengths).	Filed	11/04/2022
2022-P-2795	Aurora Pharmaceutical, Inc.	The petitioner requests to file an ANADA for a generic meloxicam oral solution for use in dogs that differs from the reference listed new animal drug (RLNAD), Metacam® (meloxicam oral suspension), sponsored by Boehringer Ingelheim Animal Health USA, Inc. under NADA 141-213. The proposed change is for an oral solution (0.5 mg/mL and 1.5 mg/mL strengths); the RLNAD is approved as an oral suspension (0.5 mg/mL and 1.5 mg/mL strengths).	Approved	01/27/2023
2022-P-3260	Noble Pharma, LLC	The petitioner requests to file an ANADA for a generic pimobendan tablet for use in dogs that differs from the reference listed new animal drug (RLNAD), Vetmedin® (pimobendan) Chewable Tablets, sponsored by Boehringer Ingelheim Animal Health USA, Inc. under NADA 141-273. The proposed change is in dosage form from a compressed, flavored, and half-scored hard chewable tablet (RLNAD) to an extruded, chicken liver-flavored, and half-scored soft chewable tablet (proposed generic product).	Filed	12/19/2022
2022-P-3260	Noble Pharma, LLC	The petitioner requests to file an ANADA for a generic pimobendan tablet for use in dogs that differs from the reference listed new animal drug (RLNAD), Vetmedin® (pimobendan) Chewable Tablets, sponsored by Boehringer Ingelheim Animal Health USA, Inc. under NADA 141-273. The proposed change is in dosage form from a compressed, flavored, and half-scored hard chewable tablet (RLNAD) to an extruded, chicken liver-flavored, and half-scored soft chewable tablet (proposed generic product).	Approved	03/14/2023
2023-P-0075	Mizner Bioscience, LLC	The petitioner requests to file an ANADA for a generic methimazole oral solution for use in cats that differs from the reference listed new animal drug (RLNAD), Felimazole® Coated Tablets (methimazole tablets), sponsored by Dechra, Ltd. under NADA 141-292. The proposed change is for an oral solution (2.5 mg/mL and 5 mg/mL strengths); the RLNAD is approved as unscored, coated tablets in 2.5 mg and 5 mg tablet strengths.	Filed	01/05/2023

Number	Petitioner	Description	Action	Date
2023-P-0075	Mizner Bioscience, LLC	The petitioner requests to file an ANADA for a generic methimazole oral solution for use in cats that differs from the reference listed new animal drug (RLNAD), Felimazole® Coated Tablets (methimazole tablets), sponsored by Dechra, Ltd. under NADA 141-292. The proposed change is for an oral solution (2.5 mg/mL and 5 mg/mL strengths); the RLNAD is approved as unscored, coated tablets in 2.5 mg and 5 mg tablet strengths.	Approved	03/30/2023
2023-P-0092	Felix Pharmaceuticals Pvt. Ltd.	The petitioner requests to file an ANADA for a generic pimobendan oral solution for use in dogs that differs from the reference listed new animal drug (RLNAD), Vetmedin® (pimobendan) Chewable Tablets, sponsored by Boehringer Ingelheim Animal Health USA, Inc. under NADA 141-273. The proposed change is for an oral solution (2.5 mg/mL strength); the RLNAD is approved as scored, chewable tablets in 1.25 mg, 2.5 mg, 5 mg, and 10 mg tablet strengths.	Filed	01/09/2023
2023-P-0092	Felix Pharmaceuticals Pvt. Ltd.	The petitioner requests to file an ANADA for a generic pimobendan oral solution for use in dogs that differs from the reference listed new animal drug (RLNAD), Vetmedin® (pimobendan) Chewable Tablets, sponsored by Boehringer Ingelheim Animal Health USA, Inc. under NADA 141-273. The proposed change is for an oral solution (2.5 mg/mL strength); the RLNAD is approved as scored, chewable tablets in 1.25 mg, 2.5 mg, 5 mg, and 10 mg tablet strengths.	Approved	03/29/2023
2023-P-0101	Mizner Bioscience, LLC	The petitioner requests to file an ANADA for a generic cyclosporine oral solution for use in dogs that differs from the reference listed new animal drug (RLNAD), Atopica™ (cyclosporine capsules) USP MODIFIED, sponsored by Elanco US Inc. under NADA 141-218. The proposed change is for an unencapsulated oral solution (100 mg/mL; 10% w/w cyclosporine); the RLNAD is approved as gelatin capsules in 10 mg, 25 mg, 50 mg, and 100 mg capsule strengths.	Filed	01/09/2023
2023-P-0101	Mizner Bioscience, LLC	The petitioner requests to file an ANADA for a generic cyclosporine oral solution for use in dogs that differs from the reference listed new animal drug (RLNAD), Atopica™ (cyclosporine capsules) USP MODIFIED, sponsored by Elanco US Inc. under NADA 141-218. The proposed change is for an unencapsulated oral solution (100 mg/mL; 10% w/w cyclosporine); the RLNAD is approved as gelatin capsules in 10 mg, 25 mg, 50 mg, and 100 mg capsule strengths.	Approved	03/29/2023

Number	Petitioner	Description	Action	Date
2023-P-0851	Norbrook Laboratories Limited	The petitioner requests to file an ANADA for a generic trilostane oral suspension for use in dogs that differs from the reference listed new animal drug (RLNAD), VETORYL® CAPSULES (trilostane), sponsored by Dechra, Ltd. under NADA 141-291. The proposed change is for an oral suspension (20 mg/mL strength); the RLNAD is approved as capsules in 5 mg, 10 mg, 30 mg, 60 mg, and 120 mg capsule strengths.	Filed	03/07/2023
2023-P-0851	Norbrook Laboratories Limited	The petitioner requests to file an ANADA for a generic trilostane oral suspension for use in dogs that differs from the reference listed new animal drug (RLNAD), VETORYL® CAPSULES (trilostane), sponsored by Dechra, Ltd. under NADA 141-291. The proposed change is for an oral suspension (20 mg/mL strength); the RLNAD is approved as capsules in 5 mg, 10 mg, 30 mg, 60 mg, and 120 mg capsule strengths.	Approved	05/18/2023
2023-P-2155	Felix Pharmaceuticals Pvt. Ltd.	The petitioner requests to file an ANADA for a generic maropitant citrate tablet for use in dogs that differs from the reference listed new animal drug (RLNAD), Cerenia® (maropitant citrate) Tablets, sponsored by Zoetis Inc. under NADA 141-262. The proposed change is in dosage form from a compressed tablet (RLNAD) to a compressed, chewable tablet (proposed generic product).	Filed	05/26/2023
2023-P-2155	Felix Pharmaceuticals Pvt. Ltd.	The petitioner requests to file an ANADA for a generic maropitant citrate tablet for use in dogs that differs from the reference listed new animal drug (RLNAD), Cerenia® (maropitant citrate) Tablets, sponsored by Zoetis Inc. under NADA 141-262. The proposed change is in dosage form from a compressed tablet (RLNAD) to a compressed, chewable tablet (proposed generic product).	Approved	08/28/2023
2023-P-2347	Aurora Pharmaceutical, Inc.	The petitioner requests to file an ANADA for a generic grapiprant oral solution for use in dogs that differs from the reference listed new animal drug (RLNAD), Galliprant® (grapiprant tablets), sponsored by Elanco US Inc. under NADA 141-455. The proposed change is for an oral solution (15 mg/mL strength); the RLNAD is approved as tablets in 20 mg, 60 mg, and 100 mg tablet strengths. The RLNAD's 20 mg and 60 mg tablets are scored, whereas the RLNAD's 100 mg tablet is unscored.	Filed	06/08/2023
2023-P-2347	Aurora Pharmaceutical, Inc.	The petitioner requests to file an ANADA for a generic grapiprant oral solution for use in dogs that differs from the reference listed new animal drug (RLNAD), Galliprant® (grapiprant tablets), sponsored by Elanco US Inc. under NADA 141-455. The proposed change is for an oral solution (15 mg/mL strength); the RLNAD is approved as tablets in 20 mg, 60 mg, and 100 mg tablet strengths. The RLNAD's 20 mg and 60 mg tablets are scored, whereas the RLNAD's 100 mg tablet is unscored.	Approved	08/31/2023

Number	Petitioner	Description	Action	Date
2023-P-2583	Norbrook Laboratories Limited	The petitioner requests to file an ANADA for a generic pimobendan oral suspension for use in dogs that differs from the reference listed new animal drug (RLNAD), Vetmedin® (pimobendan) Chewable Tablets, sponsored by Boehringer Ingelheim Animal Health USA, Inc. under NADA 141-273. The proposed change is for an oral suspension (5 mg/mL strength); the RLNAD is approved as scored, chewable tablets in 1.25 mg, 2.5 mg, 5 mg, and 10 mg tablet strengths.	Filed	06/22/2023
2023-P-2583	Norbrook Laboratories Limited	The petitioner requests to file an ANADA for a generic pimobendan oral suspension for use in dogs that differs from the reference listed new animal drug (RLNAD), Vetmedin® (pimobendan) Chewable Tablets, sponsored by Boehringer Ingelheim Animal Health USA, Inc. under NADA 141-273. The proposed change is for an oral suspension (5 mg/mL strength); the RLNAD is approved as scored, chewable tablets in 1.25 mg, 2.5 mg, 5 mg, and 10 mg tablet strengths.	Approved	09/18/2023
2023-P-2728	Felix Pharmaceuticals Pvt. Ltd.	The petitioner requests to file an ANADA for generic cefpodoxime proxetil tablets for use in dogs that differ from the reference listed new animal drug (RLNAD), SIMPLICEF® (cefpodoxime proxetil tablets), sponsored by Zoetis Inc. under NADA 141-232. The proposed change is in dosage form from a compressed, film-coated tablet (RLNAD) to a compressed, chewable tablet (proposed generic product).	Filed	07/03/2023
2023-P-2728	Felix Pharmaceuticals Pvt. Ltd.	The petitioner requests to file an ANADA for generic cefpodoxime proxetil tablets for use in dogs that differ from the reference listed new animal drug (RLNAD), SIMPLICEF® (cefpodoxime proxetil tablets), sponsored by Zoetis Inc. under NADA 141-232. The proposed change is in dosage form from a compressed, film-coated tablet (RLNAD) to a compressed, chewable tablet (proposed generic product).	Approved	10/12/2023
2023-P-5171	Ceva Santé Animale	The petitioner requests to file an ANADA for a generic methimazole oral solution for use in cats that differs from the reference listed new animal drug (RLNAD), Felimazole® Coated Tablets (methimazole tablets), sponsored by Dechra, Ltd. under NADA 141-292. The proposed change is for an oral solution (10 mg/mL strength); the RLNAD is approved as unscored, coated tablets in 2.5 mg and 5 mg tablet strengths.	Filed	11/17/2023
2023-P-5171	Ceva Santé Animale	The petitioner requests to file an ANADA for a generic methimazole oral solution for use in cats that differs from the reference listed new animal drug (RLNAD), Felimazole® Coated Tablets (methimazole tablets), sponsored by Dechra, Ltd. under NADA 141-292. The proposed change is for an oral solution (10 mg/mL strength); the RLNAD is approved as unscored, coated tablets in 2.5 mg and 5 mg tablet strengths.	Approved	02/02/2024

Number	Petitioner	Description	Action	Date
2024-P-0889	Aurora Pharmaceutical, Inc.	The petitioner requests to file an ANADA for a generic afoxolaner oral solution for use in dogs that differs from the reference listed new animal drug (RLNAD), NexGard® (afoxolaner) chewables, sponsored by Boehringer Ingelheim Animal Health USA, Inc. under NADA 141-406. The proposed change is for an oral solution (4.56% w/v); the RLNAD is approved as soft chewables in 11.3 mg, 28.3 mg, 68 mg, and 136 mg strengths.	Filed	02/20/2024
2024-P-0889	Aurora Pharmaceutical, Inc.	The petitioner requests to file an ANADA for a generic afoxolaner oral solution for use in dogs that differs from the reference listed new animal drug (RLNAD), NexGard® (afoxolaner) chewables, sponsored by Boehringer Ingelheim Animal Health USA, Inc. under NADA 141-406. The proposed change is for an oral solution (4.56% w/v); the RLNAD is approved as soft chewables in 11.3 mg, 28.3 mg, 68 mg, and 136 mg strengths.	Approved	05/02/2024
2024-P-1716	Aurora Pharmaceutical, Inc.	The petitioner requests to file an ANADA for a generic meloxicam oral solution for use in dogs that differs from the reference listed new animal drug (RLNAD), Metacam® (meloxicam oral suspension), sponsored by Boehringer Ingelheim Animal Health USA, Inc. under NADA 141-213. The proposed change is for an oral solution (5 mg/mL strength); the RLNAD is approved as an oral suspension (0.5 mg/mL and 1.5 mg/mL strengths).	Filed	04/03/2024
2024-P-3292	Felix Pharmaceuticals Pvt. Ltd.	The petitioner requests to file an ANADA for a generic maropitant citrate oral solution for use in dogs that differs from the reference listed new animal drug (RLNAD), Cerenia® (maropitant citrate) Tablets, sponsored by Zoetis Inc. under NADA 141-262. The proposed change is for an oral solution (40 mg/mL strength); the RLNAD is approved as compressed tablets in 16 mg, 24 mg, 60 mg, and 160 mg strengths.	Filed	07/15/2024
2024-P-3292	Felix Pharmaceuticals Pvt. Ltd.	The petitioner requests to file an ANADA for a generic maropitant citrate oral solution for use in dogs that differs from the reference listed new animal drug (RLNAD), Cerenia® (maropitant citrate) Tablets, sponsored by Zoetis Inc. under NADA 141-262. The proposed change is for an oral solution (40 mg/mL strength); the RLNAD is approved as compressed tablets in 16 mg, 24 mg, 60 mg, and 160 mg strengths.	Approved	10/08/2024
2024-P-3821	Aurora Pharmaceutical, Inc.	The petitioner requests to file an ANADA for a generic afoxolaner oral solution for use in dogs that differs from the reference listed new animal drug (RLNAD), NexGard® (afoxolaner) chewables, sponsored by Boehringer Ingelheim Animal Health USA, Inc. under NADA 141-406. The proposed change is for an oral solution (1.84% w/v); the RLNAD is approved as soft chewables in 11.3 mg, 28.3 mg, 68 mg, and 136 mg strengths.	Filed	08/12/2024

Number	Petitioner	Description	Action	Date
2024-P-3821	Aurora Pharmaceutical, Inc.	The petitioner requests to file an ANADA for a generic afoxolaner oral solution for use in dogs that differs from the reference listed new animal drug (RLNAD), NexGard® (afoxolaner) chewables, sponsored by Boehringer Ingelheim Animal Health USA, Inc. under NADA 141-406. The proposed change is for an oral solution (1.84% w/v); the RLNAD is approved as soft chewables in 11.3 mg, 28.3 mg, 68 mg, and 136 mg strengths.	Approved	10/28/2024
2024-P-4126	Aurora Pharmaceutical, Inc.	The petitioner requests to file an ANADA for a generic meloxicam oral solution for use in dogs that differs from the reference listed new animal drug (RLNAD), Metacam® (meloxicam oral suspension), sponsored by Boehringer Ingelheim Animal Health USA, Inc. under NADA 141-213. The proposed change is for an oral solution (3 mg/mL strength); the RLNAD is approved as an oral suspension (0.5 mg/mL and 1.5 mg/mL strengths).	Filed	08/28/2024
2024-P-4126	Aurora Pharmaceutical, Inc.	The petitioner requests to file an ANADA for a generic meloxicam oral solution for use in dogs that differs from the reference listed new animal drug (RLNAD), Metacam® (meloxicam oral suspension), sponsored by Boehringer Ingelheim Animal Health USA, Inc. under NADA 141-213. The proposed change is for an oral solution (3 mg/mL strength); the RLNAD is approved as an oral suspension (0.5 mg/mL and 1.5 mg/mL strengths).	Approved	10/10/2024
2024-P-4290	Gelteq Ltd	The petitioner requests to file an ANADA for a generic praziquantel oral, edible gel that differs from the reference listed new animal drug (RLNAD), Tapeworm Dewormer (praziquantel tablets) for dogs, sponsored by Elanco US Inc. under NADA 111-798. The proposed change is for an oral, edible gel; the RLNAD is approved as a tablet (34 mg strength).	Filed	09/06/2024
2024-P-4290	Gelteq Ltd	The petitioner requests to file an ANADA for a generic praziquantel oral, edible gel that differs from the reference listed new animal drug (RLNAD), Tapeworm Dewormer (praziquantel tablets) for dogs, sponsored by Elanco US Inc. under NADA 111-798. The proposed change is for an oral, edible gel; the RLNAD is approved as a tablet (34 mg strength).	Approved	12/10/2024
2024-P-4728	Aurora Pharmaceutical, Inc.	The petitioner requests to file an ANADA for a generic carprofen oral solution for use in dogs that differs from the reference listed new animal drug (RLNAD), RIMADYL® (carprofen tablets) caplets, sponsored by Zoetis, Inc. under NADA 141-053. The proposed change is for an oral solution (50 mg/mL strength); the RLNAD is approved as scored caplets available in 25, 75, and 100 mg strengths.	Filed	10/08/2024

Number	Petitioner	Description	Action	Date
2024-P-4728	Aurora Pharmaceutical, Inc.	The petitioner requests to file an ANADA for a generic carprofen oral solution for use in dogs that differs from the reference listed new animal drug (RLNAD), RIMADYL® (carprofen tablets) caplets, sponsored by Zoetis, Inc. under NADA 141-053. The proposed change is for an oral solution (50 mg/mL strength); the RLNAD is approved as scored caplets available in 25, 75, and 100 mg strengths.	Approved	12/10/2024
2025-P-0506	Covenant Animal Health Partners, LLC	The petitioner requests to file an ANADA for a generic maropitant base flexible buccal strip that differs from the reference listed new animal drug (RLNAD), Cerenia® (maropitant citrate) Tablets, sponsored by Zoetis Inc. under NADA 141-262. The proposed change is for a flexible buccal strip (16 mg, 24 mg, 60 mg, and 160 mg strengths) using maropitant base as the drug substance. The RLNAD is approved as compressed tablets in 16 mg, 24 mg, 60 mg, and 160 mg strengths and uses maropitant citrate as the drug substance.	Filed	02/27/2025
2025-P-0506	Covenant Animal Health Partners, LLC	The petitioner requests to file an ANADA for a generic maropitant base flexible buccal strip that differs from the reference listed new animal drug (RLNAD), Cerenia® (maropitant citrate) Tablets, sponsored by Zoetis Inc. under NADA 141-262. The proposed change is for a flexible buccal strip (16 mg, 24 mg, 60 mg, and 160 mg strengths) using maropitant base as the drug substance. The RLNAD is approved as compressed tablets in 16 mg, 24 mg, 60 mg, and 160 mg strengths and uses maropitant citrate as the drug substance.	Denied	06/05/2025
2025-P-0983	Felix Pharmaceuticals Pvt. Ltd.	The petitioner requests to file an ANADA for generic cefpodoxime proxetil powder for oral suspension for use in dogs that differs from the reference listed new animal drug (RLNAD), SIMPLICEF® (cefpodoxime proxetil tablets), sponsored by Zoetis Inc. under NADA 141-232. The proposed change is for a powder for oral suspension (100 mg cefpodoxime per 5 mL of reconstituted suspension). The RLNAD ia approved as scored, film-coated tablets in 100 mg and 200 mg tablet strengths.	Filed	03/27/2025
2025-P-0983	Felix Pharmaceuticals Pvt. Ltd.	The petitioner requests to file an ANADA for generic cefpodoxime proxetil powder for oral suspension for use in dogs that differs from the reference listed new animal drug (RLNAD), SIMPLICEF® (cefpodoxime proxetil tablets), sponsored by Zoetis Inc. under NADA 141-232. The proposed change is for a powder for oral suspension (100 mg cefpodoxime per 5 mL of reconstituted suspension). The RLNAD ia approved as scored, film-coated tablets in 100 mg and 200 mg tablet strengths.	Denied	06/25/2025

Number	Petitioner	Description	Action	Date
2025-P-1096	Clinaxel, Inc.	The petitioner requests to file an ANADA for a generic trimethoprim and sulfadiazine oral powder for use in horses that differs from the cited reference listed new animal drug (RLNAD), EQUISUL-SDT® (sulfadiazine/ trimethoprim) oral suspension, sponsored by Aurora Pharmaceutical, Inc. under NADA 141-360. The proposed change is for an oral powder (67 mg/g trimethoprim and 333 mg/g sulfadiazine). The RLNAD is approved as an oral suspension (67 mg/mL trimethoprim and 333 mg/mL sulfadiazine).	Filed	04/17/2025
2025-P-1133	Shiloh Scientific, Inc.	The petitioner requests to file an ANADA for a generic neomycin sulfate, isoflupredone acetate, and tetracaine HCl aerosol powder for use in dogs, cats, and horses that differs from the reference listed new animal drug (RLNAD), Neo-Predef® with Tetracaine (neomycin sulfate, isoflupredone acetate, and tetracaine HCl topical powder), sponsored by Zoetis Inc. under NADA 015-433. The proposed change is for a topical, aerosol powder. The RLNAD is approved as a topical, non-aerosol powder.	Filed	04/30/2025
2025-P-1133	Shiloh Scientific, Inc.	The petitioner requests to file an ANADA for a generic neomycin sulfate, isoflupredone acetate, and tetracaine HCl aerosol powder for use in dogs, cats, and horses that differs from the reference listed new animal drug (RLNAD), Neo-Predef® with Tetracaine (neomycin sulfate, isoflupredone acetate, and tetracaine HCl topical powder), sponsored by Zoetis Inc. under NADA 015-433. The proposed change is for a topical, aerosol powder. The RLNAD is approved as a topical, non-aerosol powder.	Denied	07/01/2025
2025-P-5433	Felix Pharmaceuticals Pvt. Ltd.	The petitioner requests to file an ANADA for generic cefpodoxime proxetil powder for oral suspension for use in dogs that differs from the reference listed new animal drug (RLNAD), SIMPLICEF® (cefpodoxime proxetil tablets), sponsored by Zoetis Inc. under NADA 141-232. The proposed change is for a powder for oral suspension (100 mg cefpodoxime per 5 mL of reconstituted suspension). The proposed generic product will be reconstituted to 30 mL and 100 mL volumes. The RLNAD is approved as scored, film-coated tablets in 100 mg and 200 mg tablet strengths.	Filed	10/14/2025
2025-P-5433	Felix Pharmaceuticals Pvt. Ltd.	The petitioner requests to file an ANADA for generic cefpodoxime proxetil powder for oral suspension for use in dogs that differs from the reference listed new animal drug (RLNAD), SIMPLICEF® (cefpodoxime proxetil tablets), sponsored by Zoetis Inc. under NADA 141-232. The proposed change is for a powder for oral suspension (100 mg cefpodoxime per 5 mL of reconstituted suspension). The proposed generic product will be reconstituted to 30 mL and 100 mL volumes. The RLNAD is approved as scored, film-coated tablets in 100 mg and 200 mg tablet strengths.	Denied	01/13/2026

Number	Petitioner	Description	Action	Date
2025-P-6404	Felix Pharmaceuticals Pvt. Ltd.	The petitioner requests to file an ANADA for generic trilostane tablets for use in dogs that differ from the reference listed new animal drug (RLNAD), VETORYL® CAPSULES (trilostane), sponsored by Dechra, Ltd. under NADA 141-291. The proposed change is in dosage form from capsules in 5 mg, 10 mg, 20 mg, 30 mg, 60 mg, and 120 mg capsule strengths (RLNAD) to compressed, soft, and chewable tablets in 5 mg, 10 mg, 20 mg, 30 mg, 60 mg, and 120 mg tablet strengths (proposed generic product).	Filed	11/21/2025
2025-P-7371	Argenta	The petitioner requests to file an ANADA for a generic ivermectin oral liquid for use in horses that differs from the reference listed new animal drug (RLNAD), EQVALAN® (ivermectin paste), sponsored by Boehringer Ingelheim Animal Health USA, Inc. under NADA 134-314. The proposed changes are in dosage form and strength from a 1.87% strength oral paste (RLNAD) to a 1.0% strength oral liquid (proposed generic product).	Filed	12/23/2025
2025-P-7378	Felix Pharmaceuticals Pvt. Ltd.	The petitioner requests to file an ANADA for generic trimeprazine with prednisolone tablets for use in dogs that differ from the reference listed new animal drug (RLNAD), Temaril-P® (trimeprazine with prednisolone) tablets, sponsored by Zoetis Inc. under NADA 012-437. The proposed change is in dosage form from tablets (RLNAD) to compressed, chewable tablets (proposed generic product).	Filed	12/29/2025
2026-P-0056	Flea Assassin, LLC	The petitioner requests to file an ANADA for a generic nitenpyram capsule for use in dogs and cats that differs from the reference listed new animal drug (RLNAD), CAPSTAR® (nitenpyram) tablets, sponsored by Sergeant's Pet Care Products LLC (doing business as PetIQ), under NADA 141-175. The proposed change is in dosage form from a compressed tablet (RLNAD) to a soft-gel capsule (proposed generic product).	Filed	12/29/2025
2026-P-0056	Flea Assassin, LLC	The petitioner requests to file an ANADA for a generic nitenpyram capsule for use in dogs and cats that differs from the reference listed new animal drug (RLNAD), CAPSTAR® (nitenpyram) tablets, sponsored by Sergeant's Pet Care Products LLC (doing business as PetIQ), under NADA 141-175. The proposed change is in dosage form from a compressed tablet (RLNAD) to a soft-gel capsule (proposed generic product).	Approved	03/11/2026
2026-P-0529	Felix Pharmaceuticals Pvt. Ltd.	The petitioner requests to file an ANADA for a generic trilostane oral solution for use in dogs that differs from the reference listed new animal drug (RLNAD), VETORYL® CAPSULES (trilostane), sponsored by Dechra, Ltd. under NADA 141-291. The proposed change is for an oral solution (20 mg/mL strength); the RLNAD is approved as capsules in 5 mg, 10 mg, 20 mg, 30 mg, 60 mg, and 120 mg capsule strengths.	Filed	01/16/2026

Number	Petitioner	Description	Action	Date
2026-P-0529	Felix Pharmaceuticals Pvt. Ltd.	The petitioner requests to file an ANADA for a generic trilostane oral solution for use in dogs that differs from the reference listed new animal drug (RLNAD), VETORYL® CAPSULES (trilostane), sponsored by Dechra, Ltd. under NADA 141-291. The proposed change is for an oral solution (20 mg/mL strength); the RLNAD is approved as capsules in 5 mg, 10 mg, 20 mg, 30 mg, 60 mg, and 120 mg capsule strengths.	Approved	03/20/2026
2026-P-3367	Cronus Pharma Specialities India Pvt. Ltd.	The petitioner requests to file an ANADA for generic pergolide tablets for use in horses. The proposed generic tablets differ from the reference listed new animal drug (RLNAD), Prascend® (pergolide tablets), sponsored by Boehringer Ingelheim Animal Health USA, Inc. under NADA 141-331. The proposed change is in strength. The petitioner proposes a generic product that is half-scored tablets in the tablet strength approved for the RLNAD (1 mg), as well as unscored tablets in an additional tablet strength (0.5 mg). The RLNAD is approved as half-scored tablets in a 1 mg tablet strength.	Filed	03/21/2026
2026-P-5875	Felix Pharmaceuticals Pvt. Ltd.	The petitioner requests to file an ANADA for generic grapiprant soft chewable tablets for use in dogs that differ from the reference listed new animal drug (RLNAD), Galliprant® (grapiprant tablets), sponsored by Elanco US Inc. under NADA 141-455. The proposed change is in dosage form from a chewable tablet (RLNAD) to a soft chewable tablet (proposed generic product). The RLNAD is approved in 20 mg, 60 mg, and 100 mg tablet strengths. The RLNAD's 20 mg and 60 mg tablets are scored, whereas the RLNAD's 100 mg tablet is unscored.	Filed	05/21/2026