Section 7.0 - Suitability Petition Action

Number	Petitioner	Description	Action	Date
		1989		
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	July 1989
89P-0191/PRC	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	December 1989
89P-0446/CP1	Boehringer Ingelheim Vetmedica, Inc.	Request to differ the dosage form and strength in a Type A medicated feed article.	Approved	December 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	January 1990
		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	March 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	April 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	July 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	August 1990
90P-0213/PRC	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	October 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	February 1991
		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.	Acknowled	March 1991

Number	Petitioner	Description	Action	Date
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	March 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.	Acknowled	June 1992
	Fermenta Animal Health Co.		Approved	December 1991
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	August 1992
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*	September 199
	The Upjohn Co.		Approved*	September 199

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*	December 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.	Filed	September 199
	Vet-A-Mix, Inc.		Approved	September 199
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	January 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	January 1992

Number	Petitioner	Description	Action	Date
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	February 1992
		1992		
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	April 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	May 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	September 199
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	October 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	November 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	November 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	November 1992
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	April 1993
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	January 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	January 1993
		1993		

Number	Petitioner	Description	Action	Date
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	November 1993
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	February 1994
		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	March 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	June 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	January 1995
		1995		

Number	Petitioner	Description	Action	Date
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	April 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 require	January 1996
		1996		
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	April 1996
96P-0098/PRC	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	July 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	January 1997
		1997		

Number	Petitioner	Description	Action	Date
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	April 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	January 1998
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	January 1998
		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	June 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	June 1998

Number	Petitioner	Description	Action	Date
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	July 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	October 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	October 1998
	IVX Animal Health, Inc.		Approved	December 1998
98P-0927/CP1	Heska Corporation		Filed	October 1998
	Heska Corporation		Approved	December 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	November 1998
	IVX Animal Health, Inc.		Approved	March 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	December 1998
	IVX Animal Health, Inc.		Denied	March 1999
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	December 1998

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.	Approved	March 1999
		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	March 1999
	IVX Animal Health, Inc.		Denied	May 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	March 1999
	Veterinary Research Associates, Inc.		Denied	November 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.	Approved	June 1999
	Nycomed US, Inc.		Filed	April 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	August 1999
	Wildlife Laboratories, Inc.		Denied	November 1999

Number	Petitioner	Description	Action	Date
99P-2733/PRC	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	December 1999
	Wildlife Laboratories, Inc.		Denied	March 2000
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	September 199
	A & G Pharmaceuticals, Inc.		Approved	December 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	December 1999
	Tyler Group, Inc		Approved	March 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.	Approved	March 2000
	Tyler Group, Inc.		Filed	December 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.	Filed	December 1999
	Tyler Group, Inc.		Approved	March 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	December 1999

Number	Petitioner	Description	Action	Date
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	March 2000
		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	January 2000
	IVX Animal Health, Inc.		Approved	March 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	February 2000
	IVX Animal Health, Inc.		Denied	March 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	February 2000
	IVX Animal Health, Inc.		Not require	May 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	March 2000
	Equi Aid Products, Inc.		Denied	June 2000

Number	Petitioner	Description	Action	Date
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	June 2000
	IVX Animal Health, Inc.		Approved	August 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	July 2001
	Equi Aid Products, Inc.		Filed	August 2000
00P-1486/PRC	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	August 2001
	Equi Aid Products, Inc.		Approved	September 200
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	September 200
	Smart Drug Systems, Inc.		Approved	December 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	October 2000
	Highland VetPharma, LLC		Denied	July 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	November 2000
	Buford Biomedical, Inc.		Denied	July 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.	Approved	January 2001
	Highland VetPharma, LLC		Filed	December 2000
		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	April 2001
	Bimeda, Inc.		Filed	January 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	February 2001
	First Priority, Inc.		Approved	April 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.	Filed	March 2001
	First Priority, Inc.		Approved	April 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	March 2001
	Vétoquinol N.-A., Inc.		Approved	December 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	December 2001
	Vétoquinol N.-A., Inc.		Filed	March 2001

Number	Petitioner	Description	Action	Date
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	December 2001
	Vétoquinol N.-A., Inc.		Filed	March 2001
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	August 2001
01P-0349/WDL	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	September 200
	Smart Drug Systems, Inc.		Acknowled	September 200
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	November 2001
	ECO LLC		Filed	September 200
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	February 2002
	Cross Vetpharm Group Ltd.		Filed	September 200
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	November 2001
	ECO LLC		Filed	September 200

Number	Petitioner	Description	Action	Date
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	September 200
	First Priority		Approved	November 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	September 200
	Karen A. Sisson		Approved	October 2002
		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	November 2002
	Pharmaceutical Solutions, Inc.		Filed	February 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	April 2002
	IVX Animal Health, Inc.		Approved	November 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	May 2002
	Richdel, Inc.		Approved	November 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	September 200
	Intervet, Inc.		Approved	December 2002

Number	Petitioner	Description	Action	Date
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	September 200
	Highland VetPharma, LLC		Approved	December 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	September 200
	Highland VetPharma, LLC		Approved	December 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	December 2002
	Highland VetPharma, LLC		Filed	September 200
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	October 2002
	Karen A. Sisson		Approved	April 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	October 2002
02P-0474/WDL	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.	Acknowled	January 2003
	Phoenix Scientific, Inc.		Filed	January 2003

Number	Petitioner	Description	Action	Date
		2003		
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	January 2004
03P-0013/WDL	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.	Acknowled	March 2003
	First Priority, Inc.		Filed	March 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	June 2003
	Cross Vetpharm Group, Ltd.		Filed	March 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	May 2003
	Vétoquinol N.-A., Inc.		Approved	July 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	May 2003
	Richdel, Inc.		Approved	July 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	October 2003
	Eugene G. Keller		Approved	December 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	November 2003
	Karen A. Sisson		Approved	December 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	March 2004
	Jurox PTY, Limited		Filed	December 2003
		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	January 2004
	Pennfield Oil Co.		Approved	March 2004
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	February 2004
04P-0058/WDL	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.	Acknowled	March 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	March 2004
	Smart Drug Systems, Inc.		Denied	May 2004

Number	Petitioner	Description	Action	Date
04P-0127/PRC	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	June 2004
	Smart Drug Systems, Inc.		Denied	October 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	May 2004
	Smart Drug Systems, Inc.		Filed	March 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	January 2004
04P-0130/WDL	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.	Acknowled	May 2004
	Smart Drug Systems, Inc.		Filed	March 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	March 2004
	Intervet, Inc.		Approved	May 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	April 2004

Number	Petitioner	Description	Action	Date
04P-0167/WDL	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.	Acknowled	April 2004
	First Priority, Inc.		Filed	April 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	July 2004
	Intervet, Inc.		Filed	April 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	April 2004
	First Priority, Inc.		Approved	June 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	August 2004
	Intervet, Inc.		Approved	October 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	August 2004
	Bioniche Animal Health USA, Inc.		Approved	November 2004

Number	Petitioner	Description	Action	Date
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	August 2004
	Ancare New Zealand, Ltd.		Approved	November 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	November 2004
	Ancare New Zealand, Ltd.		Filed	August 2004
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	November 2004
04P-0489/WDL	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.	Acknowled	November 2004
	Bioniche Animal Health USA, Inc.		Filed	November 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	November 2004
04P-0507/WDL	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	November 2004
	Bioniche Animal Health USA, Inc.		Acknowled	November 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.	Filed	December 2004
	Intervet, Inc.		Approved	January 2005
		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	July 2005
	Intervet, Inc.		Filed	May 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	July 2005
05P-0277/WDL	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	April 2005
	Pharmacia & Upjohn Co.		Acknowled	July 2005
		2006		
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	February 2006
	Macleod Pharmaceuticals, Inc.		Approved	April 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	May 2006

Number	Petitioner	Description	Action	Date
06P-0093/PRC	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	June 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	June 2006
	Sparhawk Laboratories, Inc.		Approved	September 200
		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.	Filed	May 2007
	Norbrook Laboratories Ltd.		Approved	November 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.	Denied	January 2008
	Norbrook Laboratories Ltd.		Filed	May 2007
		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	March 2008
	Norbrook Laboratories Ltd.		Denied	August 2008
		2009		

Number	Petitioner	Description	Action	Date
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	February 2009
	Pet Medicus Laboratories, Inc.		Approved	May 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.	Filed	March 2009
	PetMedicus Laboratories Ltd.		Approved	June 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	May 2009
	Lachman Consultant Service, Inc.		Approved	November 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	June 2009
	Lachman Consultant Service, Inc.		Approved	February 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%).	Approved	November 2009
	Lachman Consultant Service, Inc.		Filed	July 2009

Number	Petitioner	Description	Action	Date
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	July 2009
	Lachman Consultant Service, Inc.		Approved	November 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	September 200
	Precision Consultants, Inc.		Denied	May 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.	Approved	November 2009
	Piedmont Animal Health		Filed	September 200
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	December 2009
	Piedmont Animal Health		Filed	September 200
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	October 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	October 2009

2010

Number	Petitioner	Description	Action	Date
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	March 2010
	Lannett Company, Inc.		Denied	June 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	Approved	January 2011
	Huvepharma AD		Filed	October 2010
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	March 2011
		2011		
11P-0078-0001	Ceva Sante Animale	Request permission for change in strength	Denied	February 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	June 2011
	Norbrook, Inc.		Filed	May 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	May 2011
	NewMarket Pharmaceuticals, LLC		Denied	August 2011
		2012		

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.	Denied	March 2012
	Cook Animal Health		Filed	January 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	August 2012
	Con Vet GmbH & Co.		Filed	March 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	May 2012
	Douglass Oeller Consulting, Inc.		Approved	November 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	August 2012
	Med-Pharmex, Inc.		Filed	May 2012

Number	Petitioner	Description	Action	Date
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	Approved	August 2012
	Piedmont Animal Health		Filed	May 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	October 2012
	Piedmont Animal Health		Filed	July 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	August 2012
	Alpharma LLC, a Subsidiary of Pfizer, Inc.		Approved	October 2012
12-P-0945-000	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	August 2012
	Center for Regulatory Services, Inc.		Approved	November 2012