PETITION NUMBER / SPONSOR	REASON FOR PETITION	ACTION DATE
1989		
89P-0191 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 Dec 06, 1989
89P-0191 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 Jul 13, 1989
89P-0446 Boehringer Ingelheim Animal Health, Inc.	Request to differ the dosage form and strength in a Type A medicated feed article.	Approved Dec 29, 1989
1990		
89P-0509 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 Jan 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 Mar 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 Apr 12, 1990
90P-0181/CP1 American Cyanamid	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 Jul 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 Aug 21, 1990
90P-0213/PRC1 Micrel Limited, Inc.	Request reconsideration of 90P-0213/CPI.	Denied Oct 16, 1990
1991		
90P-0434/CP 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 Feb 27, 1991
91P-0048/CP Sanofi Animal Health, Inc.	Request permission to change the dosage form for Sulfaquinoxaline sodium solution. The pioneer NADA is 006-677.	Denied
91P-0071/CP1 Fermenta Animal Health Co.	Request permission to change the strength for oxytetracycline injection. The pioneer is NADA 113-232.	Approved Dec 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.	See note*

PETITION NUMBER / SPONSOR	REASON FOR PETITION	ACTION / DATE
1991, con't		
91P-0277/CP1 The Upjohn Co.	Request permission to file an ANADA for a different dosage form of neomycin soluble powder. *The petition was approved but the applicant may not file an ANADA until the pioneer product has been DESI finalized and approved.	Approved* Sep 03, 1992
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* Dec 02, 1991
91P-0316/CP1 Vet-A-Mix Animal Health	Request permission to file an ANADA for a different strength of sulfamethazine oblets. The pioneer is NADA 122-271.	Approved Sep 11, 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 Jan 03, 1992
1992		
91P-0071/CP1 Fermenta Animal Health Co.	Request permission to label the product in subject ANADA as "OXYJECT 180" instead of "OXYJECT 185" as originally approved.	Acknowledged Jun 01, 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 Aug 04, 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 Jan 22, 1992

PETITION NUMBER SPONSOR	REASON FOR PETITION	ACTION DATE
	1992, con't	
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 Feb 13, 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 Apr 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 May 12, 1992
92P-0254/CP1 Hill Dermaceuticals, Inc.	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 Sep 02, 1992
92P-0363/CP1 Phoenix Pharmaceutical, 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 Oct 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 Nov 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 Nov 23, 1992
92P-0402/CP1 Arkansas Microspecialties Co.	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 Nov 23, 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 Apr 12, 1993
92P-0498/CP1 Fermenta Animal Health	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 Jan 29, 1993
92P-0511/CP1 Fermenta Animal Health	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 Jan 29, 1993
	1993	
93P-0294/CP1 Phoenix Scientific, 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 Nov 03, 1993

PETITION NUMBER / SPONSOR	REASON FOR PETITION	ACTION DATE
1994		
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 Feb 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 illigrams 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 Mar 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 Jun 29, 1994
1995		
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 Jan 12, 1995
95P-0036/CP1 Norbrook Laboratories Limited	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 Apr 24, 1995
95P-0350/CP1 Phoenix Scientific, 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 Jan 15, 1996
1996		
96P-0098/CP1 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 Jul 15, 1996

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1996, con't		
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 Apr 15, 1996
1997		
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 Jan 10, 1997
97P-0072/CP1 VetrePharm Research, 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 phenybutazone 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 Apr 11, 1997
1998		
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 Jan 30, 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 Jan 30, 1998
98P-0159/CP1 Phoenix Scientific, 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 Jun 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 Jun 22, 1998

PETITION NUMBER / SPONSOR	REASON FOR PETITION	ACTION DATE
YEAR		
1998, con't		
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 Jul 08, 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 Oct 30, 1998
98P-0862/CP1 Phoenix Scientific, 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 Dec 18, 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 Dec 18, 1998
98P-1037/CP1 Phoenix Scientific, 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 Mar 03, 1999
98P-1196/CP1 Phoenix Scientific, 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 Mar 26, 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.	Approved Mar 03, 1999
1999		
99P-0627/CP1 Phoenix Scientific, 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 May 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.	Denied Nov 05, 1999

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	1999, con't	
99P-0923/CP1 Altana, 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 Jun 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.	Denied Nov 05, 1999
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.	Denied Mar 20, 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.	Approved Dec 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.	Approved Mar 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.	Approved Mar 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.	Approved Mar 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.	Approved Mar 07, 2000

PETITION NUMBER SPONSOR	REASON FOR PETITION	ACTION DATE
	2000	
00P-0117/CP1 Phoenix Scientific, 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 Mar 09, 2000
00P-0444/CP1 Phoenix Scientific, 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 Mar 22, 2000
00P-0596/CP1 Phoenix Scientific, 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 May 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.	Denied Jun 30, 2000
00P-1342/CP1 Phoenix Scientific, 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 Aug 15, 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 Jul 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.	Approved Dec 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.	Denied Jul 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.	Denied Jul 26, 2001
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 Jan 29, 2001

PETITION NUMBER SPONSOR	REASON FOR PETITION	ACTION DATE
	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 Sep 18, 2002
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 Apr 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.	Approved Apr 09, 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 Apr 11, 2001
01P-0139/CP1 Vetoquinol 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 Dec 19, 2001
01P-0140/CP1 Vetoquinol 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 Dec 19, 2001
01P-0141/CP1 Vetoquinol 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 Dec 19, 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 Aug 10, 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 Sep 17, 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 Nov 06, 2001

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2001, con't		
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 Feb 14, 2002
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 Nov 06, 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 Nov 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.	Approved Oct 21, 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 Nov 07, 2002
02P-0189/CP1 Phoenix Scientific, 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 Nov 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.	Approved Nov 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.	Approved Dec 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.	Approved Dec 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).	Approved Dec 10, 2002

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YEAR		
2002, con't		
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 Dec 10, 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 Apr 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 Oct 31, 2002
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 Jan 31, 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 Jan 16, 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 Mar 05, 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 Jun 04, 2003
03P-0219/CP1 Vetoquinol 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 Jul 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.	Approved Jul 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 Oct 08, 2003

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	2003, con't	
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 (Zimecterin® 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 Nov 12, 2003