# Section 7.0

## Suitability Petition Actions

| Petition<br>Sponsor | Year<br>Description | Action |
|---|---|---|
| | **1989** | |
| **89P-0191/CP1**<br>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**<br>Jul 13, 1989 |
| **89P-0191/PRC1**<br>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**<br>Dec 06, 1989 |
| **89P-0446/CP1**<br>Boehringer Ingelheim Vetmedica, Inc. | Request to differ the dosage form and strength in a Type A medicated feed article. | **Approved**<br>Dec 29, 1989 |
| **89P-0509/CP1**<br>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**<br>Jan 24, 1990 |
| | **1990** | |
| **90P-0051/CP1**<br>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**<br>Mar 21, 1990 |
| **90P-0073/CP1**<br>A. L. Laboratories | Request to revoke approval of petition 89P-0446/CP approved in 1989 for Boehringer Ingelheim Animal Health, Inc. | **Denied**<br>Apr 12, 1990 |
| **90P-0181/CP1**<br>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**<br>Jul 31, 1990 |
| **90P-0213/CP1**<br>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**<br>Aug 21, 1990 |
| **90P-0213/PRC1**<br>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**<br>Oct 16, 1990 |
| **90P-0434/CP1**<br>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**<br>Feb 27, 1991 |
| | **1991** | |
| **91P-0048/CP1**<br>Sanofi Animal Health, Inc. | Request permission to change the dosage form for Sulfaquinoxaline sodium solution. The pioneer NADA is 006-677. | **Denied**<br>Mar 21, 1991 |
| **91P-0071/CP1**<br>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***<br><br>**Approved**<br>Dec 02, 1991<br><br>**Acknowledged**<br>Jun 01, 1992 |

# Section 7.0

## Suitability Petition Actions

| Petition Sponsor | Description | Year Action |
|---|---|---|
| | **1991 cont.** | |
| **91P-0255/CP1**<br>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**<br>Aug 04, 1992 |
| **91P-0277/CP1**<br>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***<br>Sep 03, 1991 |
| **91P-0285/CP1**<br>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 nonlactating 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***<br>Dec 02, 1991 |
| **91P-0316/CP1**<br>Vet-A-Mix, Inc. | Request permission to file an ANADA for a different strength of sulfamethazine oblets. The pioneer is NADA 122-271. | **Approved**<br>Sep 11, 1991 |
| **91P-0421/CP1**<br>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**<br>Jan 03, 1992 |
| **91P-0437/CP1**<br>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. Also request different strength, and route of administration compared to pioneer.The pioneer product is NADA 009-505. | **Denied**<br>Jan 22, 1992 |
| **91P-0489/CP1**<br>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. | **Approved**<br>Feb 13, 1992 |

# Section 7.0

## Suitability Petition Actions

| Petition Sponsor | Description | Year Action |
|---|---|---|
| | **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 and change in strength from 325 g/lb to 200 mg/ml. 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** Halocarbon Laboratories, Div. of 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** Sep 02, 1992 |
| **92P-0363/CP1** IVX Animal Health, Inc. | Request permission to file an ANADA for the use of a different oral dosage form (liquid) and strength for neomycin sulfate. The pioneer product is NADA 011-315. | **Approved** 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 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** 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 Co. | Request permission to change dosage form from a soluble 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 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** Jan 29, 1993 |
| | **1993** | |
| **93P-0294/CP1** IVX Animal Health, Inc. | Request permission to file an ANADA for a change in strength of gentamicin sulfate oral solution in a pump dispenser from 4.35 milligrams per milliliter to 5.0 milligrams per milliliter. The delivery volume would also change from 1.15 milliliter per pump to 1.0 milliliter per pump. The pioneer product is NADA 130-464. | **Approved** Nov 03, 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. A request was also made for use of etorphine hydrochloride alone vs. etorphine and diprenorphine hydrochloride. The pioneer product is NADA 095-017. | **Denied** Feb 16, 1994 |

# Section 7.0

## Suitability Petition Actions

| Petition Sponsor | Description | Year Action |
|---|---|---|
| | **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. Based on a different proprietary matrix, the implant would deliver the same amount of norgestomet over the 9-day implantation period. 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 |
| **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 |
| | **1995** | |
| **95P-0036/CP1** Norbrook Laboratories Ltd. | Request permission to file an ANADA (hybrid application) for a generic new animal drug with a dosage form different from the pioneer product. The pioneer product, NADA 055-089, sponsored by Beecham Laboratories, is a powder formulation containing 25 milligrams amoxicillin per vial for reconstitution with Water for Injection USP, to an oil-based suspension with a nominal concentration of 250 milligrams amoxicillin base per milliliter. The Norbrook formulation is an oil-based suspension containing 250 milligrams amoxicillin base per milliliter. The pioneer product is indicated for intramuscular or subcutaneous administration, while the generic product will be indicated only for intramuscular administration. | **Denied** Apr 24, 1995 |
| **95P-0350/CP1** IVX Animal Health, Inc. | Request permission to file an ANADA for a generic new animal drug which differs from that of the pioneer product only by the addition of 1.5% benzyl alcohol to the formula. The pioneer product is Ivomex 1% Injection, NADA 128-409, sponsored by Merck Research Laboratories. | **Not required** Jan 16, 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** Apr 15, 1996 |

## Section 7.0

## Suitability Petition Actions

| Petition Sponsor | Description | Year Action |
|---|---|---|
| | **1996, cont.** | |
| **96P-0098/PRC1** Equi Aid Products, Inc. | Filed for reconsideration: Request permission to file an ANADA for a generic new animal drug which differs from that of the pioneer product in two ways: 1) the generic product would be a palatable product to mix with cat food instead of the tablet dosage form of the pioneer product; and 2) pyrantel pamoate would be the only active ingredient instead of pyrantel pamoate and praziquantel. The pioneer product is Drontal Tablets, NADA 141-008, sponsored by Bayer Corp., Agriculture Division, Animal Health. | **Denied** Aug 2, 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** Jan 10, 1997 |
| | **1997** | |
| **97P-0072/CP1** Bioniche Animal Health USA, Inc. | Request permission to file an ANADA for a generic new animal drug, Butequine™ Paste (phenylbutazone paste) which differs from the pioneer product, Butazolidin Paste, Coopers Animal Health, NADA 116-087 by the following characteristics: Butequine™ Paste: 20 grams of phenylbutazone per 60 milliliter syringe of paste (1 gram per 3 milliliter). Butezolidin Paste (pioneer): 12 grams of phenylbutazone per 60 gram syringe of paste (1 gram per 5 grams). The dosage (1-2 grams of phenylbutazone per 500 pounds body weight) is the same in both products. However, in the generic product, the dosage would be given as 3-6 milliliters as opposed to 5-10 grams of the pioneer product. | **Approved** Apr 11, 1997 |
| **97P-0473/CP1** Macleod Pharmaceuticals, Inc. | Request permission to file an ANADA for a generic new animal drug, Unibute Paste (phenylbutazone paste) which differs from the pioneer product, Butazolidin Paste, Mallinckrodt Veterinary, Inc, NADA 116-087 by the following characteristics: Unibute Paste: 20 grams of phenylbutazone per 60 grams of paste. Butazolidin Paste (pioneer): 12 grams of phenylbutazone per 60 grams of paste. The dosage (1-2 grams of phenylbutazone per 500 pounds body weight) is the same in both products. | **Approved** 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 |
| | **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** 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 |

## Section 7.0

## Suitability Petition Actions

| Petition Sponsor | Description | Year Action |
|---|---|---|
| | **1998, cont.** | |
| **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** 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** Oct 01, 1998<br>**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. | **Filed** Oct 21, 1998<br>**Approved** Dec 18, 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** Nov 23, 1998<br>**Approved** Mar 03, 1999 |
| **98P-1196/CP1** IVX Animal Health, Inc. | Request permission to file an ANADA for a generic new animal drug propofol which differs from the pioneer product, propofol (Rapinovet®) Schering-Plough Animal Health Corp., NADA 141-070, by the following characteristics: Propofol generic differs from the pioneer product in concentration and by the addition of a preservative. | **Filed** Dec 17, 1998<br>**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. | **Filed** Dec 29, 1998<br>**Approved** Mar 03, 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** Mar 22, 1999<br>**Denied** May 27, 1999 |

## Section 7.0

## Suitability Petition Actions

| Petition Sponsor | Description | Year Action |
|---|---|---|
| | **1999, cont.** | |
| **99P-0794/CP1**<br>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**<br>Mar 31, 1999<br>**Denied**<br>Nov 05, 1999 |
| **99P-0923/CP1**<br>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. | **Filed**<br>Apr 02, 1999<br>**Approved**<br>Jun 28, 1999 |
| **99P-2733/CP1**<br>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**<br>Aug 12, 1999<br>**Denied**<br>Nov 05, 1999 |
| **99P-2733/PRC1**<br>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**<br>Dec 10, 1999<br>**Denied**<br>Mar 20, 2000 |
| **99P-4167/CP1**<br>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**<br>Sep 20, 1999<br>**Approved**<br>Dec 07, 1999 |
| **99P-5328/CP1**<br>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**<br>Dec 03, 1999<br>**Approved**<br>Mar 21, 2000 |
| **99P-5329/CP1**<br>Tyler Group, Inc. | Request permission to file an ANADA for a generic new animal drug, furosemide, which differs from the pioneer product, Lasix®, Hoechst Roussel Vet, NADA 034-621 by the following characteristics: the proposed generic product will have a dosage form as a palatable chewable tablet as opposed to the pioneer product which is a tablet. | **Filed**<br>Dec 03, 1999<br>**Approved**<br>Mar 20, 2000 |
| **99P-5330/CP1**<br>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**<br>Dec 03, 1999<br>**Approved**<br>Mar 20, 2000 |

# Section 7.0

## Suitability Petition Actions

| Petition Sponsor | Description | Year Action |
|---|---|---|
| | **1999, cont.** | |
| **99P-5331/CP1**<br>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 of a dose unit packet of palatable pellets (administered in a small amount of feed or dissolved in water and administered orally via syringe) as opposed to the pioneer product which is a tablet. | **Filed**<br>Dec 13, 1999<br><br>**Approved**<br>Mar 07, 2000 |
| | **2000** | |
| **00P-0117/CP1**<br>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**<br>Jan 01, 2000<br><br>**Approved**<br>Mar 09, 2000 |
| **00P-0444/CP1**<br>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 will contain spectinomycin dihydrochloride pentahydrate whereas the pioneer product contains spectinomycin sulfate tetrahydrate. | **Filed**<br>Feb 04, 2000<br><br>**Denied**<br>Mar 22, 2000 |
| **00P-0596/CP1**<br>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 dosage form, powder, whereas the pioneer approved product is a tablet. | **Filed**<br>Feb 14, 2000<br><br>**Not required**<br>May 05, 2000 |
| **00P-1225/CP1**<br>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**<br>Mar 31, 2000<br><br>**Denied**<br>Jun 30, 2000 |
| **00P-1342/CP1**<br>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**<br>Jun 15, 2000<br><br>**Approved**<br>Aug 15, 2000 |
| **00P-1486/CP1**<br>Equi Aid Products, Inc. | Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, ivermectin (Eqvalan®), Merial Ltd., NADA 134-314 by the following characteristics: the generic product will consist of a different dosage form ('chewable') and strength (22.7 milligrams per 'chewable') from the pioneer. | **Filed**<br>Aug 29, 2000<br><br>**Denied**<br>Jul 26, 2001 |

## Section 7.0

## Suitability Petition Actions

| Petition Sponsor | Description | Year Action |
|---|---|---|
| | **2000, cont.** | |
| **00P-1486/PRC1**<br>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**<br>Aug 16, 2001<br><br>**Approved**<br>Sep 18, 2002 |
| **00P-1519/CP1**<br>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**<br>Sep 15, 2000<br><br>**Approved**<br>Dec 07, 2000 |
| **00P-1594/CP1**<br>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**<br>Oct 31, 2000<br><br>**Denied**<br>Jul 26, 2001 |
| **00P-1600/CP1**<br>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**<br>Nov 03, 2000<br><br>**Denied**<br>Jul 26, 2001 |
| **00P-1655/CP1**<br>Highland VetPharma, LLC | Request permission to file an ANADA for a generic new animal drug phenylbutazone which differs from the pioneer product, phenylbutazone (Phenylbute®), Phoenix Scientific, Inc., NADA 091-818 by the following characteristics: the generic product will consist of a different dosage form ('chewable' tablet) from the pioneer. | **Filed**<br>Dec 06, 2000<br><br>**Approved**<br>Jan 29, 2001 |
| | **2001** | |
| **01P-0045/CP1**<br>Bimeda, Inc. | Request permission to file an ANADA for a generic new animal drug, lincomycin hydrochloride and spectinomycin dihydrochloride pentahydrate, which differs from the pioneer product, Pharmacia & Upjohn Co.'s NADA 046-109 by the following characteristics: The generic product will provide for a product containing spectinomycin dihydrochloride pentahydrate whereas the pioneer product contains spectinomycin sulfate tetrahydrate. | **Filed**<br>Jan 26, 2001<br><br>**Approved**<br>Apr 20, 2001 |
| **01P-0066/CP1**<br>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**<br>Feb 06, 2001<br><br>**Approved**<br>Apr 09, 2001 |
| **01P-0124/CP1**<br>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**<br>Mar 12, 2001<br><br>**Approved**<br>Apr 11, 2001 |

## Section 7.0

## Suitability Petition Actions

| Petition Sponsor | Description | Year Action |
|---|---|---|
| | **2001, cont.** | |
| **01P-0139/CP1**<br>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**<br>Mar 21, 2001<br>**Approved**<br>Dec 19, 2001 |
| **01P-0140/CP1**<br>Vétoquinol N.-A., Inc. | Request permission to file an ANADA for a generic new animal drug, cefadroxil, which differs from the pioneer product, Cefa-Drops®, Fort Dodge Animal Health, Division of AHP, NADA 140-684, by the following characteristics: The proposed generic product dosage form is a paste. | **Filed**<br>Mar 21, 2001<br>**Approved**<br>Dec 19, 2001 |
| **01P-0141/CP1**<br>Vétoquinol N.-A., Inc. | Request permission to file an ANADA for a generic new animal drug, amoxicillin, which differs from the pioneer product, Amoxi-Drop®, Pfizer Inc., NADA 055-085, by the following characteristics: The proposed generic product dosage form is a paste. | **Filed**<br>Mar 21, 2001<br>**Approved**<br>Dec 19, 2001 |
| **01P-0349/CP1**<br>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**<br>Aug 10, 2001<br>**Withdrawn**<br>Sep 17, 2001 |
| **01P-0349/WDL1**<br>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**<br>Sep 17, 2001<br>**Filed**<br>Sep 17, 2001 |
| **01P-0382/CP1**<br>ECO LLC | Request permission to file an ANADA for a generic new animal drug ivermectin/pyrantel which differs from the pioneer product, Heartgard® Plus, Merial Ltd., NADA 140-971 by the following characteristics: The generic product will consist of a different dosage form (compressed chewable tablet) from the pioneer. | **Filed**<br>Sep 04, 2001<br>**Approved**<br>Nov 06, 2001 |
| **01P-0385/CP1**<br>Cross Vetpharm Group Ltd. | Request permission to file an ANADA for a generic new animal drug oxytetracycline which differs from the pioneer product, Medamycin® Injectable, Boehringer Ingelheim Vetmedica, Inc., NADA 108-963, by the following characteristics: The generic product will consist of a different concentration (300 milligrams per milliliter) from the pioneer. | **Filed**<br>Sep 04, 2001<br>**Denied**<br>Feb 14, 2002 |
| **01P-0394/CP1**<br>ECO LLC | Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, Heartgard 30® Chewables, Merial Ltd., NADA 140-886 by the following characteristics: The generic product will consist of a different dosage form (compressed chewable tablet) from the pioneer. | **Filed**<br>Sep 06, 2001<br>**Approved**<br>Nov 06, 2001 |

## Section 7.0

## Suitability Petition Actions

| Petition Sponsor | Description | Year Action |
|---|---|---|
| | **2001, cont.** | |
| **01P-0425/CP1**<br>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**<br>Sep 20, 2001<br><br>**Approved**<br>Nov 15, 2001 |
| **01P-0427/CP1**<br>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), strength, and route of administration from the pioneer. | **Filed**<br>Sep 20, 2001<br><br>**Approved**<br>Oct 21, 2002 |
| | **2002** | |
| **02P-0084/CP1**<br>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 (liquid suspension), different method of administration (via stomach tube), and different strength from the pioneer. | **Filed**<br>Feb 26, 2002<br><br>**Approved**<br>Nov 07, 2002 |
| **02P-0189/CP1**<br>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**<br>Apr 30, 2002<br><br>**Approved**<br>Nov 07, 2002 |
| **02P-0198/CP1**<br>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**<br>May 03, 2002<br><br>**Approved**<br>Nov 07, 2002 |
| **02P-0396/CP1**<br>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**<br>Sep 05, 2002<br><br>**Approved**<br>Dec 10, 2002 |
| **02P-0416/CP1**<br>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**<br>Sep 18, 2002<br><br>**Approved**<br>Dec 10, 2002 |
| **02P-0423/CP1**<br>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**<br>Sep 26, 2002<br><br>**Approved**<br>Dec 10, 2002 |

## Section 7.0

## Suitability Petition Actions

| Petition Sponsor | Description | Year Action |
|---|---|---|
| | **2002, cont.** | |
| **02P-0429/CP1**<br>Highland VetPharma, LLC | Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product (Heartgard® for Cats) Merial Ltd., NADA 141-078 by the following characteristics: The generic product will consist of a different dosage form (molded chewable tablet) from the pioneer (extruded chewable tablet). | **Filed**<br>Sep 30, 2002<br>**Approved**<br>Dec 10, 2002 |
| **02P-0470/CP1**<br>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**<br>Oct 31, 2002<br>**Approved**<br>Apr 17, 2003 |
| **02P-0474/CP1**<br>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**<br>Oct 31, 2002<br>**Withdrawn** |
| **02P-0474/WDL1**<br>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**<br>Jan 31, 2003<br>**Filed**<br>Jan 31, 2003 |
| | **2003** | |
| **03P-0013/CP1**<br>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), strength and method of administration (oral drench only) from the pioneer. | **Filed**<br>Jan 16, 2004<br>**Withdrawn**<br>Jan 16, 2004 |
| **03P-0013/WDL1**<br>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**<br>Mar 05, 2003<br>**Filed**<br>Mar 05, 2003 |
| **03P-0108/CP1**<br>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 (sucrose). | **Filed**<br>Mar 20, 2003<br>**Approved**<br>Jun 04, 2003 |
| **03P-0219/CP1**<br>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**<br>May 19, 2003<br>**Approved**<br>Jul 31, 2003 |

## Section 7.0

## Suitability Petition Actions

| Petition Sponsor | Description | Year Action |
|---|---|---|
| | **2003, cont.** | |
| **03P-0223/CP1**<br>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**<br>May 23, 2003<br>**Approved**<br>Jul 31, 2003 |
| **03P-0469/CP1**<br>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, dosage form (hard palatable treat), and method of administration from the pioneer. | **Filed**<br>Oct 08, 2003<br>**Approved**<br>Dec 04, 2003 |
| **03P-0523/CP1**<br>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) and strength from the pioneer. | **Filed**<br>Nov 12, 2003<br>**Approved**<br>Dec 04, 2003 |
| **03P-0552/CP1**<br>Jurox PTY, Limited | Request permission to file an ANADA for a generic new animal drug carprofen which differs from the pioneer product, Rimadyl® Caplets, Pfizer, Inc., NADA 141-053 by the following characteristics: The generic product will have a different dosage form (liquid) and different strength concentration) from the pioneer. | **Filed**<br>Dec 10, 2003<br>**Approved**<br>Mar 19, 2004 |
| | **2004** | |
| **04P-0032/CP1**<br>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 characteristic(s): The generic product will have a different strength (concentration) from the pioneer. | **Filed**<br>Jan 20, 2004<br>**Approved**<br>Mar 24, 2004 |
| **04P-0058/CP1**<br>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 characteristic(s): The generic product will have a different dosage form, powder, whereas the pioneer approved product is a tablet. | **Filed**<br>Feb 09, 2004<br>**Withdrawn**<br>Feb 09, 2004 |
| **04P-0058/WDL1**<br>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 dosage form, powder, whereas the pioneer approved product is a tablet. | **Acknowledged**<br>Mar 04, 2004 |
| **04P-0127/CP1**<br>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**<br>Mar 16, 2004<br>**Denied**<br>May 11, 2004 |

## Section 7.0

## Suitability Petition Actions

| Petition<br>Sponsor | Year<br>Description | Action |
|---|---|---|
| | **2004, cont.** | |
| **04P-0127/PRC1**<br>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 characteristic(s): The generic product will have a different dosage form (tablet), different strength, and dosage regimen from the pioneer. | **Filed**<br>Jun 10, 2004<br><br>**Denied**<br>Oct 27, 2004 |
| **04P-0128/CP1**<br>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 characteristic(s): The generic product will have a different strength and dosage regimen from the pioneer. | **Filed**<br>Mar 16, 2004<br><br>**Denied**<br>May 13, 2004 |
| **04P-0130/CP1**<br>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 characteristic(s): The generic product will have a different strength (concentration) from the pioneer. | **Filed**<br>Jan 20, 2004<br><br>**Withdrawn**<br>Mar 16, 2004 |
| **04P-0130/WDL1**<br>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 characteristic(s): The generic product will have a different strength (concentration) from the pioneer. | **Filed**<br>Mar 16, 2004<br><br>**Acknowledged**<br>May 21, 2004 |
| **04P-0136/CP1**<br>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 from the pioneer. | **Filed**<br>Mar 18, 2004<br><br>**Approved**<br>May 19, 2004 |
| **04P-0167/CP1**<br>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 characteristic(s): 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**<br>Apr 08, 2004<br><br>**Withdrawn**<br>Apr 26, 2004 |
| **04P-0167/WDL1**<br>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 characteristic(s): The generic product will have a change in strength of oral solution in a pump dispenser from 4.35 milligrams per milliliter to 4.86 milligrams per milliliter. The delivery volume would also change from 1.15 milliliter per pump to 1.05 milliliter per pump. | **Acknowledged**<br>Apr 26, 2004<br><br>**Filed**<br>Apr 26, 2004 |
| **04P-0175/CP1**<br>Intervet, Inc. | Request permission to file an ANADA for a generic new animal drug progesterone which differs from the pioneer product, EAZI-Breed™ CIDR® Cattle Insert, Pharmacia & Upjohn Co., NADA 141-200 by the following characteristics: The generic product will have a change in strength (concentration) from the pioneer. | **Filed**<br>Apr 14, 2004<br><br>**Approved**<br>Jul 28, 2004 |

## Section 7.0

## Suitability Petition Actions

| Petition Sponsor | Description | Year Action |
|---|---|---|
| | **2004, cont.** | |
| **04P-0197/CP1**<br>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 of the generic product would also change from 1.15 milliliter per pump to 1.05 milliliter per pump. | **Filed**<br>Apr 26, 2004<br><br>**Approved**<br>Jun 24, 2004 |
| **04P-0372/CP1**<br>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 (scored chewable tablet) from the pioneer. | **Filed**<br>Aug 20, 2004<br><br>**Approved**<br>Oct 08, 2004 |
| **04P-0376/CP1**<br>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 from the pioneer. | **Filed**<br>Aug 24, 2004<br><br>**Approved**<br>Nov 03, 2004 |
| **04P-0383/CP1**<br>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**<br>Aug 31, 2004<br><br>**Approved**<br>Nov 16, 2004 |
| **04P-0384/CP1**<br>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 and dosage form from the pioneer. | **Filed**<br>Aug 31, 2004<br><br>**Approved**<br>Nov 16, 2004 |
| **04P-0489/CP1**<br>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**<br>Nov 05, 2004<br><br>**Withdrawn**<br>Nov 09, 2004 |
| **04P-0489/WDL1**<br>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 characteristic(s): The generic product will differ in packaging and presentation of the active ingredients. | **Filed**<br>Nov 05, 2004<br><br>**Acknowledged**<br>Nov 09, 2004 |
| **04P-0507/CP1**<br>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, Legend™, 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**<br>Nov 05, 2004 |

## Section 7.0

## Suitability Petition Actions

| Petition Sponsor | Description | Year Action |
|---|---|---|
| | **2004, cont.** | |
| **04P-0507/WDL1**<br>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 characteristic(s): The generic product will differ in the packaging and presentation of the pioneer product. | **Filed**<br>Nov 05, 2004<br><br>**Acknowledged**<br>Nov 09, 2004 |
| **04P-0551/CP1**<br>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) and strength from the pioneer. | **Filed**<br>Dec 21, 2004<br><br>**Approved**<br>Jan 28, 2005 |
| | **2005** | |
| **05P-0170/CP1**<br>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) and method of administration from the pioneer. | **Filed**<br>May 06, 2005<br><br>**Approved**<br>Jul 01, 2005 |
| **05P-0277/CP1**<br>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**<br>Jul 08, 2005<br><br>**Withdrawn**<br>Jul 20, 2005 |
| **05P-0277/WDL1**<br>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**<br>Apr 20, 2005<br><br>**Acknowledged**<br>Jul 20, 2005 |
| | **2006** | |
| **06P-0060/CP1**<br>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**<br>Feb 01, 2006<br><br>**Approved**<br>Apr 04, 2006 |
| **06P-0093/CP1**<br>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%). | **Filed**<br>May 05, 2006<br><br>**Denied**<br>Nov 20, 2006 |

## Section 7.0

## Suitability Petition Actions

| Petition Sponsor | Description | Year Action |
|---|---|---|
| | **2006, cont.** | |
| **06P-0093/PRC1**<br>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**<br>Jun 02, 2006<br><br>**Denied** |
| **06P-0263/CP1**<br>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**<br>Jun 21, 2006<br><br>**Approved**<br>Sep 06, 2006 |
| | **2007** | |
| **07P-0175/CP1**<br>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**<br>May 02, 2007 |
| **07P-0177/CP1**<br>Norbrook Laboratories Ltd. | Request permission to file an ANADA for a generic new animal drug meloxicam which differs from the pioneer product, Metacam® 1.5 mg/ml Oral Suspension, Boehringer Ingelheim, NADA 141-231 by the following characteristics. The generic will differ in dosage form (chewable tablets) and different strength. | **Filed**<br>May 02, 2007 |