The following corrections or additions to the January 15, 1997 list were made in December 1996. These data are present in the January 15, 1997 list but are also included here for those who need more complete information on FDA's new animal drug approvals and other actions.

New Approvals

ANADA Number: 200-007

Pioneer Product:	100-237
Trade Name :	Liqui-Vet 2XTM
Ingredients:	Pyrantel pamoate
Sponsor:	Happy Jack, Inc.
Approval Date:	10/30/96
Status:	Over-the-counter
Route:	Oral
Species:	Canine
Drug Form:	Liquid (suspension)
Concentration:	4.54 mg/mL
Indications:	To prevent reinfection of Toxocara canis in puppies and adult dogs and in lactating bitches after whelping. For removal of large roundworms (Toxocara canis and Toxascaris leonina) and hookworms (Ancylostoma caninum and Uncinaria stenocephala) in dogs and puppies.

21CFR 520.2043

NADA Number: 141-053

Trade Name :	RIMADYLâ
Ingredients:	Carprofen
Sponsor:	Pfizer, Inc.
Approval Date:	10/25/96
Status:	Prescription Only
Route:	Oral
Species:	Canine
Drug Form:	Caplets
Concentration:	25, 75, and 100 mg/caplet
Indications:	For the relief of pain and inflammation in dogs. Rimadylâ was shown to be clinically effective for the relief of signs associated with osteoarthritis in dogs.
Exclusivity:	5 years

21CFR 520.309

NADA Number: 141-070

Trade Name : RapinovetTM
Ingredients: Propofol
Sponsor: Mallinckrodt Veterinary, Inc.
Approval Date: 11/07/96
Status: Prescription Only
Route: Intravenous
Species: Canine
Drug Form: Liquid (oil in water emulsion)
Concentration: 10 mg/mL
Indications: Anesthetic injection for use in dogs as follows: 1) As a single injection to provide general anesthesia for procedures lasting up to five minutes. 2) For induction and maintenance of general anesthesia using incremental doses to effect. 3) For induction of general anesthesia where maintenance is provided by inhalant anesthetics.
Exclusivity: 5 years

21CFR 522.2005

NADA Number: 141-065

Trade Name : AVIAX™, BMDâ
Ingredients: Semduramicin, Bacitracin methylene disalicylate
Sponsor: Pfizer, Inc.
Approval Date: 10/18/96
Status: Over-the-counter
Route: Oral
Species: Avian (broiler chickens)
Drug Form: Type A medicated articles
Concentration: Semduramicin: 22.7 g of semduramicin activity/lb, BMD: 30, 50, and 60 g of BMD activity/lb.
Indications: For the prevention of coccidiosis caused by *Eimeria acervulina*, *E.brunetti*, *E.maxima*, *E.mivati/mitis*, *E.necatrix*, and *E.tenella*; and for improved feed efficiency in broiler chickens.
Tolerance: BMD: *21CFR 556.70*: 0.5 ppm in uncooked tissues of chickens. Semduramicin: the safe concentration of semduramicin in chicken muscle tissue is established at 360 ppb.
Withdrawal: None
Patent Number: The following patents are in effect for semduramicin:

Patent Number	Exp. date
4804680	7/21/2007
4912130	7/21/2007
4992466	2/12/2008
5385735	1/31/2012

Exclusivity: 3 years

21CFR 558.76 and *558.555*

NADA Number: 140-988

Trade Name :	IVOMEC™ Sustained-Release Bolus for Cattle
Ingredients:	Ivermectin
Sponsor:	Merck Research Laboratories
Approval Date:	11/18/96
Status:	Over-the-counter
Route:	Oral
Species:	Bovine
Drug Form:	Bolus
Concentration:	1.72 g/bolus
Indications:	Nematodes: For the treatment of established infections and, throughout its approximately 135-day ivermectin delivery period, controls the establishment of infection by newly ingested larvae of the following nematode species: Gastrointestinal roundworms: *Haemonchus placei, Ostertagia ostertagi, Trichostrongylus axei, Trichostrongylus colubriformis, Cooperia* spp., *Nematodirus helvetianus, Bunostomum phlebotomum, Oesophagostomum radiatum*. The drug controls established infections with hypobiotic (inhibited) fourth-stage larvae of *Ostertagia ostertagi*. Lungworms: *Dictyocaulus viviparus.* Mange Mites: For the control of established infestations of the following mange mites and prevention of reinfestation for 135 days: *Psoroptes ovis* and *Sarcoptes scabiei.* Sucking Lice: For the control of established infestations of the following sucking lice and prevention of reinfestation for 135 days: *Linognathus vituli* and *Solenopotes capillatus*. Cattle Grubs: For the control of migrating *Hypoderma* spp. larvae (grubs) acquired prior to administration of the IVOMEC bolus; thereafter, prophylaxis is provided for approximately 135 days against newly acquired larvae. Ticks: Control of the following tick will be provided by interfering with engorgement with blood and completion of the reproductive portion of the life cycle by newly acquired young adult females during the period of ivermectin delivery. However, larvae, nymphs and adult males, as well as young adult females already on the host at the time of treatment and actively in the engorgement process, may not be visibly affected: *Amblyomma americanum*.
Tolerance:	*21CFR 556.344*: 100 ppb for marker residue (ivermectin B1a) in cattle liver.
Withdrawal:	180 days
Exclusivity:	3 years

21CFR 520.1197

NADA Number: 141-075

Trade Name :	Antizol-Vet ™
Ingredients:	Fomepizole
Sponsor:	Orphan Medical, Inc.
Approval Date:	11/25/96
Status:	Prescription Only
Route:	Intravenous
Species:	Canine
Drug Form:	Liquid (solution)
Concentration:	1.5 mL vial: 1.5 g/mL; 30 mL vial: 50 mg/mL
Indications:	As an antidote for ethylene glycol (antifreeze) poisoning in dogs who have ingested or are suspected of having ingested ethylene glycol.
Exclusivity:	5 years

21CFR 522.1004 and *510.600*

NADA Number: 141-064

Trade Name :	PULMOTIL® Type A Medicated Article
Ingredients:	Tilmicosin phosphate
Sponsor:	Elanco Animal Health
Approval Date:	12/27/96
Status:	Federal (USA) law limits this drug to use under the professional supervision of a licensed veterinarian. Animal feed bearing or containing this Veterinary Feed Additive drug shall be fed to animals only by or upon a lawful veterinary feed directive issued by a licensed veterinarian in the course of the veterinarian's professional practice.
Route:	Oral
Species:	Porcine
Drug Form:	Type A medicated article
Concentration:	90.7 g/lb (200 g/kg)
Indications:	For the control of swine respiratory disease associated with *Actinobacillus pleuropneumonia* and *Pasteurella multocida*.
Tolerance:	*21CFR 556.735*: a tolerance is established for residues of parent tilmicosin (marker residue) in liver (target tissue) of cattle at 1.2 ppm and of swine at 7.5 ppm.
Withdrawal:	7 days
Patent Number:	4,820,695 Exp. date: 04/11/2006
Exclusivity:	3 years

21CFR 558.4, 558.618 and *556.735*

Supplemental Approvals

NADA Number: 006-891

Trade Name :	SUL-Q-NOX
Ingredients:	Sulfaquinoxaline
Sponsor:	I.D. Russell Co. Laboratories
Approval Date:	10/22/96
Status:	Over-the-counter
Route:	Oral
Species:	Bovine (cattle and calves), avian (chickens and turkeys)
Drug Form:	Liquid
Concentration:	31.92% as sodium and potassium salts
Indications:	For the treatment and control of coccidiosis in cattle, calves, and control of coccidiosis in chickens and turkeys. For the control of acute fowl cholera and fowl typhoid in chickens and turkeys.
Tolerance:	*21CFR 556.685*: 0.1 ppm for negligible residues of sulfaquinoxaline in the uncooked edible tissues of chickens, turkeys, calves and cattle.
Withdrawal:	Cattle, calves, chickens, and turkeys: 10 days.

This supplemental application provides for a modified formulation to include the addition of potassium hydroxide and a decrease in the amount of sodium hydroxide used.

21CFR 520.2325a

NADA Number: 140-338

Trade Name :	NAXCEL$^{\hat{a}}$ Sterile Powder
Ingredients:	Ceftiofur sodium
Sponsor:	Pharmacia & Upjohn Co.
Approval Date:	10/25/96
Status:	Prescription Only
Route:	Intramuscular
Species:	Ovine
Drug Form:	Powder: 1 and 4 g/vial
Concentration:	50 mcg/mL (reconstituted)
Indications:	For the treatment of sheep respiratory disease (sheep pneumonia) associated with *Pasteurella haemolytica* and *Pasteurella multocida*.
Tolerance:	*21CFR 556.113*: a tolerance for residues of ceftiofur in edible tissues is not required. The safe concentrations for total residues of ceftiofur in edible tissues of sheep are 4.33 ppm in muscle (non-injection), 13.0 ppm in liver, 26.0 ppm in kidney, and 26.0 ppm in fat.
Withdrawal:	Not required.

This supplemental application provides for the use of ceftiofur sodium for the treatment of bacterial pneumonia in sheep. The product was previously approved for use in cattle, swine, day-old chicks, horses, and dogs.

Patent Number: 4,464,367 Exp. date: 08/07/2001

21CFR 522.313, 556.113

NADA Number: 113-232

Trade Name :	LIQUAMYCIN[â] LA-200
Ingredients:	Oxytetracycline amphoteric
Sponsor:	Pfizer, Inc.
Approval Date:	05/31/96
Status:	Over-the-counter
Route:	Intravenous, Intramuscular
Species:	Bovine and porcine
Drug Form:	Liquid (suspension)
Concentration:	200 mg/mL
Indications:	Beef cattle and non-lactating dairy cattle: for the treatment of pneumonia and shipping fever complex associated with *Pasteurella* spp. and *Haemophilus* spp.; bovine keratoconjunctivitis caused by *Moraxella bovis*; foot-rot and diphtheria caused by *Fusobacterium necrophorum*; bacterial enteritis (scours) caused by *Escherichia coli*; wooden tongue caused by *Actinobacillus lignieresii*; leptospirosis caused *by Leptospira pomona*; and wound infections and acute metritis caused by strains of staphylococci and streptococci organisms sensitive to oxytetracycline. Porcine: for the treatment of bacterial enteritis (scours, colibacillosis) caused by *Escherichia coli*; pneumonia caused by *Pasteurella multocida*; and leptospirosis caused by *Leptospira pomona*. Sows: as an aid in control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *Escherichia coli.*
Tolerance:	Chlortetracycline: *21CFR 556.150*: 2.0 ppm in muscle, 6.0 ppm in liver, and 12 ppm in fat and kidney is established for the sum of residues of the tetracyclines including chlortetracycline, oxytetracycline, and tetracycline in tissues of chickens, turkeys, ducks, swine, calves, beef cattle, nonlactating dairy cows, and sheep. Oxytetracycline: *21CFR 556.500*: 2.0 ppm in muscle, 6.0 ppm in liver, and 12 ppm in fat and kidney is established for the sum of residues of the tetracyclines including chlortetracycline, oxytetracycline, and tetracycline in tissues of cattle, beef calves, nonlactating dairy cattle, dairy calves, swine, sheep, chickens, turkeys, catfish, lobster, and salmonids. Tetracycline: *21CFR 556.720*: 2.0 ppm in muscle, 6.0 ppm in liver, and 12 ppm in fat and kidney is established for the sum of residues of the tetracyclines including chlortetracycline, oxytetracycline, and tetracycline in tissues of calves, swine, sheep, chickens, and turkeys.

This supplemental application provides for an increase in the tolerance level of oxytetracycline to 2.0 ppm in muscle, 6.0 ppm in liver, and 12 ppm in fat and kidney. The new tolerance levels are applicable to all approved tetracycline drugs listed under *21CFR 556*.

21CFR 556.150, 556.500, 556.720

NADA Number: 012-491

Trade Name :	TYLANâ 40, TYLANâ 100, TYLANâ 100 CAL
Ingredients:	Tylosin phosphate
Sponsor:	Elanco Animal Health
Approval Date:	11/08/96
Status:	Over-the-counter
Route:	Oral
Species:	Porcine (feeder pigs)
Drug Form:	Type A medicated article
Concentration:	TYLANâ 40: 40 g/lb TYLANâ 100: 100 g/lb TYLANâ 100 CAL: 100 g/lb
Indications:	For prevention and/or control of porcine proliferative enteropathies (ileitis) in swine associated with *Lawsonia intracellularis*.
Tolerance:	*21CFR 556.740*: 0.2 ppm (negligible residue) in uncooked fat, muscle, liver, and kidney.
Withdrawal:	Zero days
Exclusivity:	3 years

This supplemental application provides for adding a label indication for the prevention and/or control of porcine proliferative enteropathies (ileitis) by feeding tylosin phosphate at a level of 100 g/ton for 21 consecutive days.

21CFR 558.625

Change of Sponsor Name

From Hoechst-Roussel Agri-Vet Co. to Hoechst Roussel Vet.

From Fort Dodge Laboratories, Division of American Home Products Corp. to Fort Dodge Animal Health, Division of American Home Products Corp.

Change of Sponsor

NADA Number: 140-889

From A. H. Robins Co. to:

Biocraft Laboratories, Inc.
92 Route 46
Elmwood Park, NJ 07407.
Drug labeler code: 000332.

NADA Number: 065-107

From Mallinckrodt Veterinary, Inc. to:

Veterinary Specialties, Inc.
387 North Valley Ct.
Barrington, IL 60010.
Drug labeler code: 062925.

NADA Number: 140-857

From Pfizer, Inc. to:

Intervet, Inc.
P.O. Box 318
405 State St.
Millsboro, DE 19966.
Drug labeler code: 057926.