

Center for Veterinary Medicine Significant Approvals with Letters Issued and Publications in the Federal Register

CRITERIA

Letter Date Range From: 10/01/2000 To: 09/30/2001 Sort Order: Letter Date Ascending Count: 39

Letter Date	Publish Date	Submission ID	Applicant	Chemical	Species	Approval Type	Summary	Team
10/20/00	11/27/00	N 141175 A 0000	NOVARTIS ANIMAL HEALTH US INC	NITENPYRAM	CANINE, FELINE	NEW CHEMICAL ENTITY	Original approval for nitenpyram for the treatment of flea infestations on dogs, puppies, cats and kittens four weeks of age and older and 2 pounds body weight or greater.	HFV-112
11/16/00	12/29/00	N 141148 A 0000	ALPHARMA INC	DECOQUINATE, MONENSIN	BEEF CATTLE	NEW COMBINATION	Original approval for combination of decoquinatate and monensin in cattle feed for the prevention of coccidiosis caused by Eimeria bovis and E. zuernii, and for increased feed efficiency in cattle being fed in confinement for slaughter.	HFV-135
11/16/00	01/10/01	N 141149 A 0000	ALPHARMA INC	DECOQUINATE, MONENSIN SODIUM, TYLOSIN PHOSPHATE	BEEF CATTLE	NEW COMBINATION	Original approval for combination of decoquinatate, monensin and tylosin in cattle feed for the prevention of coccidiosis caused by Eimeria bovis and E. zuernii, for improved feed efficiency, and for reduction of incidence of liver abscesses caused by Fusobacterium necrophorum and Actinomyces pyogenes in growing-finishing cattle being fed in confinement for slaughter.	HFV-135
11/24/00	04/10/01	C 002243 A 0000	STERIGENICS INTERNATIONAL INC	IRRADIATION		NEW FOOD ADDITIVE PETITION	New Food Additive Petition for approval to irradiate various animal feeds for microbial control	HFV-222
11/29/00	04/30/01	N 130435 C 0061	ALPHARMA INC	OXYTETRACYCLINE HYDROCHLORIDE	CHICKEN, SWINE, TURKEY	NEW TOLERANCE/WITHDRAWAL PERIOD	Supplemental approval for oxytetracycline hydrochloride to remove an existing withdrawal period in turkeys and swine from 5 days and 13 days, respectively, to zero days based on new tolerances set for oxytetracycline in turkeys and swine.	HFV-135
12/05/00	01/24/01	N 141174 A 0000	BLUE RIDGE PHARMACEUTICALS INC	IVERMECTIN	FELINE	NEW DOSAGE FORM	Original approval for ivermectin for the treatment of adult ear mite (Otodectes cynotis) infestations in cats and kittens four weeks of age or older	HFV-112
12/05/00	01/04/01	N 141177 A 0000	SCHERING PLOUGH ANIMAL HEALTH CORP	CLOTRIMASOLE, GENTAMICIN SULFATE, MOMETASONE FUROATE MONOHYDRATE	CANINE	NEW COMBINATION	Original approval of gentamicin sulfate, mometasone furoate, and clotrimazole as an Otic Suspension for the treatment of otitis externa associated with yeast (Malassezia pachydermatis) and/or bacteria susceptible to gentamicin in dogs	HFV-112
12/07/00	01/24/01	A 200292 E 0001	MED PHARMEX INC	IVERMECTIN	EQUINE	ORIGINAL GENERIC	Original generic approval for ivermectin for the treatment and control of large strongyles, small strongyles, hairworms, pinworms, roundworms (ascarids), intestinal threadworms, large-mouth stomach worms, bots, lungworms, summer sores and cutaneous onchocerciasis	HFV-102
12/13/00	03/08/01	N 141163 C 0001	NOVARTIS ANIMAL HEALTH	MILBEMYCIN OXIME SOLUTION	FELINE	NEW SPECIES/CLASS	Supplemental approval for milbemycin oxime for treatment of ear mite infestations in cats and kittens four weeks of age and older. The supplement lowered the age limitation of the product from 8 to 4 week old kittens and to allow a repeat treatment if necessary.	HFV-110
12/27/00	03/08/01	A 200193 C 0009	PHOENIX SCIENTIFIC INC	CLINDAMYCIN HYDROCHLORIDE	CANINE, FELINE	NEW SPECIES/CLASS	Supplemental generic approval for clindamycin for therapy of wounds, abscesses, dental infections, and osteomyelitis in dogs; and for therapy of wounds, abscesses, and dental infections in cats.	HFV-102
12/27/00	03/05/01	A 200228 E 0010	PHOENIX SCIENTIFIC INC	IVERMECTIN	BEEF CATTLE, EXOTIC/ZOO/WILDLIFE, SWINE	ORIGINAL GENERIC	Original approval for ivermectin for the treatment and control of gastrointestinal nematodes, lungworms, grubs, lice, and mites in cattle; for the treatment and control of gastrointestinal roundworms, lungworms, lice, and mites in swine; for the treatment and control of grubs in American bison; and for the treatment and control of warbles in reindeer.	HFV-102
12/28/00	03/05/01	A 200299 E 0001	MED PHARMEX INC	IVERMECTIN	BEEF CATTLE	ORIGINAL GENERIC	Original generic approval for ivermectin for the effective control and treatment of gastrointestinal roundworms, lungworms, cattle grubs, mites, lice, horn flies	HFV-102

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01/02/01	03/05/01	N 141140 A 0000	ALPHARMA INC	BACTIRACIN METHYLENE DISALICYLATE, MONENSIN	CHICKEN	ADAA, NEW SPECIES/CLASS	New combination approval for monensin with BMD as an aid in preventing coccidiosis caused by Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati, and E. maxima, and for increased rate of weight gain and improved feed efficiency in replacement chickens intended for use as cage layers, and as an aid in preventing necrotic enteritis caused/complicated by Clostridium spp or other organisms susceptible to bacitracin in broiler/replacement chickens intended for use as cage layers	HFV-128
01/03/01	02/09/01	A 200281 E 0005	BLUE RIDGE PHARMACEUTICALS INC	PYRANTEL PAMOATE	CANINE	ORIGINAL GENERIC	Original generic approval for pyrantel pamoate for the removal of large roundworms (ascarids) (Toxocara canis; Toxascaris leonina) and Hookworms (Ancylostoma caninum; Uncinaria stenocephala) in dogs and puppies and to prevent reinfection of Toxocara canis in puppies and adult dogs and in lactating bitches after whelping.	HFV-102
01/12/01	03/05/01	A 200154 C 0016	PENNFIELD OIL CO	OXYTETRACYCLINE DIHYDRATE	BEEF CATTLE, SWINE	NEW ROUTE OF ADMINISTRATION	Supplemental approval of oxytetracycline hydrochloride for addition of the subcutaneous administration of oxytetracycline injectable solution in beef cattle, non-lactating dairy cattle and calves, and the addition of pre-ruminating (veal) calves	HFV-102
02/02/01	03/05/01	N 104646 C 0041	ELANCO ANIMAL HEALTH CO	MONENSIN, TYLOSIN	BEEF CATTLE	ADAA, NEW COMBINATION, NEW INDICATION	Supplemental approval letter for adding the coccidiosis claim to the monensin + tylosin combination.	HFV-126
02/12/01	04/19/01	N 141156 A 0000	ALPHARMA INC	AMPROLIUM, BACITRACIN METHYLENE DISALICYLATE	CHICKEN	ADAA, NEW SPECIES/CLASS	Original approval for amprolium plus bacitracin methylene disalicylate for the development of active immunity to coccidiosis, and for increased rate of weight gain and improved feed efficiency in replacement chickens.	HFV-128
02/16/01	04/23/01	N 141142 A 0000	ALPHARMA INC	AMPROLIUM, BACITRACIN METHYLENE DISALICYLATE, ROXARSONE	CHICKEN	ADAA, NEW COMBINATION	Original combination approval for amprolium, bacitracin methylene disalicylate, roxarsone for development of active immunity to coccidiosis, as an aid in the prevention of necrotic enteritis caused or complicated by Clostridium spp. or other organisms susceptible to bacitracin, and for increased rate of weight gain, improved feed efficiency, and improved pigmentation in replacement chickens.	HFV-128
02/20/01	04/18/01	N 096298 C 0277	ALPHARMA INC	LASALOCID	BEEF CATTLE, CHICKEN, DAIRY CATTLE, EXOTIC/ZOO/WILDLIFE, MINOR AVIAN, MINOR RUMINANT, TURKEY	NEW TOLERANCE/WITHDRAWAL PERIOD	Supplemental approval to establish an acceptable daily intake of 0.01 mg/kg/day, revised safe concentrations in chickens of 2.0 ppm in muscle, 6.0 ppm in liver, and 12 ppm in skin/fat, and revised safe concentrations in sheep of 2.0 ppm in muscle, 6.0 ppm in liver, and 12 ppm in kidney and fat, and a safe concentration in turkeys of 6.0 ppm in liver, 2.0 ppm in muscle, and 12 ppm in skin/fat for lasalocid used to prevent coccidiosis in chickens, growing turkeys, and sheep.	HFV-128
02/20/01	04/30/01	N 141172 E 0001	ELANCO ANIMAL HEALTH CO	RACTOPAMINE HYDROCHLORIDE, TYLOSIN PHOSPHATE	SWINE	NEW COMBINATION	Original combination approval for ractopamine hydrochloride plus tylosin phosphate for increased weight gain, improved feed efficiency and increased carcass leanness in finishing swine fed a complete ration containing at least 16% crude protein from 150 lb (68kg) to 240 lb (109 kg) body weight, and for prevention and/or control of porcine proliferative enteropathies (ileitis) associated with Lawsonia intracellularis.	HFV-128
03/07/01	04/30/01	N 140338 C 0122	PHARMACIA AND UPJOHN CO	CEFTIOFUR SODIUM	BEEF CATTLE, CANINE, CHICKEN, DAIRY CATTLE, EQUINE, MINOR RUMINANT, SWINE	NEW MINOR SPECIES	Supplemental approval for ceftiofur sodium (NAXCEL Sterile Powder) for the treatment of bacterial pneumonia associated with Pasteurella haemolytica and Pasteurella multocida in goats. The product was previously approved for use in cattle, sheep, swine, day-old chickens, day-old turkey poults, horses, and dogs.	HFV-133
03/08/01	05/16/01	N 140942 E 0007	ELANCO ANIMAL HEALTH CO	BAMBERMYCINS, NARASIN, NICARBAZIN	CHICKEN	ADAA, NEW COMBINATION	Original combination approval for the use of narasin and nicarbazin in combination with bambarmycins for the prevention of coccidiosis caused by Eimeria necatrix E. tenella, E. acervulina, E. brunetti, E. mivati, and E. maxima, and for increased rate of weight gain and improved feed efficiency in broiler chickens	HFV-128
04/11/01	05/09/01	N 118980 C 0156	ELANCO ANIMAL HEALTH CO	NARASIN	CHICKEN	NEW TOLERANCE/WITHDRAWAL PERIOD	Supplemental approval to add tolerance of 480 ppb in abdominal fat for narasin to prevent coccidiosis caused by Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati, and E. maxima.	HFV-135

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04/18/01	05/29/01	N 141083 E 0004	ALPHARMA INC	BACITRACIN ZINC, LASALOID SODIUM	CHICKEN	NEW COMBINATION	Original combination approval for lasalocid plus bacitracin zinc for the prevention of coccidiosis caused by Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati, and E. maxima, and for increased rate of weight gain and improved feed efficiency in broiler chickens.	HFV-128
04/25/01	05/29/01	N 008622 C 0071	PFIZER INC	OXYTETRACYCLINE HYDROCHLORIDE	BEEF CATTLE, CHICKEN, DAIRY CATTLE, MINOR RUMINANT, SWINE, TURKEY	NEW TOLERANCE/WITHDRAWAL PERIOD	Supplemental approval for establishment of a zero-day withdrawal period for swine administered oxytetracycline at 10 mg/lb/day for 14 days.	HFV-133
04/27/01	07/10/01	A 200295 E 0002	PENNFIELD OIL CO	CHLORTETRACYCLINE HYDROCHLORIDE	BEEF CATTLE, CHICKEN, SWINE, TURKEY	HYBRID GENERIC	Original generic approval of chlortetracycline hydrochloride for Bacterial Pneumonia and Enteritis in Calves, beef cattle and nonlactating dairy cattle and swine; Control of complicating bacterial organisms associated with Bluecomb and Infectious Synovitis in Turkeys; and Chronic Respiratory Disease and Air-sac infection and for the control of mortality due to fowl cholera in growing chickens.	HFV-102
05/16/01	07/06/01	N 136742 C 0047	MERIAL LTD	CLORSULON	BEEF CATTLE	NEW TOLERANCE/WITHDRAWAL PERIOD	Supplemental approval to add a tolerance of 100 ppb in cattle and acceptable daily intake 8 micrograms/kg body weight/day for clorsulon used for the treatment of immature and adult liver fluke (Fasciola hepatica) in cattle.	HFV-135
05/30/01	07/09/01	A 200302 E 0004	BLUE RIDGE PHARMACEUTICALS INC	IVERMECTIN, PYRANTEL PAMOATE	CANINE	ORIGINAL GENERIC	Original generic approval for ivermectin and pyrantel pamoate for the prevention of canine heartworm (Dirofilaria immitis) disease and for the treatment and control of adult Toxocara canis, Toxascaris leonina, Ancylostoma caninum, Uncinaria stenocephala, and Ancylostoma braziliense	HFV-102
06/06/01	07/09/01	N 141189 A 0000	FORT DODGE ANIMAL HEALTH INC	MOXIDECTIN	CANINE	NEW DOSAGE FORM	Original approval for moxidectin for the prevention of heartworm disease caused by Dirofilaria immitis and for the treatment of existing larval and adult hookworm (Ancylostoma caninum) infections in dogs six months of age and older.	HFV-112
06/18/01	09/05/01	N 141099 C 0014	FORT DODGE ANIMAL HEALTH DIVISION OF AMERICAN HOME PRODUCTS	MOXIDECTIN	BEEF CATTLE, DAIRY CATTLE	NEW INDICATION	Supplemental approval for moxidectin for additional indications for gastrointestinal roundworms and new persistent activity indications of 14 days for Haemonchus placei and 28 days for Oesophagostomum radiatum. Moxidectin is now approved for approval was for the treatment and control of gastrointestinal roundworms, lungworms, cattle grubs, mites, lice and horn flies; and control infections and protect from reinfection with certain roundworms for varying periods after treatment.	HFV-135
07/11/01	09/05/01	N 141179 A 0000	ALPHARMA INC	BACITRACIN METHYLENE DISALICYLATE, LASALOCID SODIUM	TURKEY	ADAA, NEW COMBINATION	Original approval for lasalocid sodium and bacitracin methylene disalicylate for the prevention of coccidiosis caused by Eimeria meleagrimitis, E. Gallopavinus, and E. adenoeides, and for increased rate of weight gain and improved feed efficiency in growing turkeys.	HFV-128
07/19/01	08/21/01	N 141188 A 0000	BAYER CORP	PONAZURIL	EQUINE	NEW CHEMICAL ENTITY	Original approval for ponazuril for the treatment of equine protozoal myeloencephalitis (EPM) caused by Sarcocystis neurona in horses	HFV-114
07/25/01	09/11/01	N 096298 R 0284	ALPHARMA INC	LASALOCID	BEEF CATTLE, CHICKEN, DAIRY CATTLE, EXOTIC/ZOO/WILDLIFE, MINOR AVIAN, MINOR RUMINANT, TURKEY	ADAA	Supplemental approval for expanding the dose range in pasture cattle from 60-200 mg lasalocid/head/day to 60-300 mg lasalocid/head/day.	HFV-126
08/01/01	09/05/01	N 141151 C 0008	PFIZER INC	MARBOFLOXACIN	CANINE, FELINE	NEW SPECIES/CLASS	Supplemental approval to expand the indications to include use of marbofloxacin in cats. The prior approval was for treatment of skin and soft tissue infections, for the treatment of urinary tract infections in dogs.	HFV-112
09/07/01	12/05/01	A 200321 E 0001	FIRST PRIORITY INC	IVERMECTIN	EQUINE	ORIGINAL GENERIC	Original generic approval for the treatment and control of large strongyles, small strongyles, hairworms, pinworms, roundworms (ascarids), intestinal threadworms, large-mouth stomach worms, bots, lungworms, summer sores and cutaneous onchocerciasis	HFV-102

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09/17/01	11/26/01	A 200144 C 0016	BIMEDA INC	OXYTETRACYCLINE HYDROCHLORIDE	CHICKEN, SWINE, TURKEY	NEW TOLERANCE/WITHDRAWAL PERIOD	Supplemental approval to change the withdrawal period for turkeys and swine to zero days. The drug is approved for control of hexamitiasis, infectious synovitis, and of complicating bacterial organisms associated with bluecomb in turkeys; and for the control and treatment of bacterial enteritis caused by escherichia coli and salmonella choleraesuis in swine, and leptospirosis (reducing the incidence of abortions and shedding of leptospira) caused by leptospira pomona, in breeding swine	HFV-102
09/21/01	12/05/01	A 200318 E 0001	VIRBAC ANIMAL HEALTH INC	IVERMECTIN	BEEF CATTLE	ORIGINAL GENERIC	Original generic approval for ivermectin topical liquid for the effective control and treatment of gastrointestinal roundworms, lungworms, cattle grubs, mites, lice, and horn flies and to control infections of gastrointestinal roundworms for 14 days after treatment in cattle.	HFV-102
09/21/01	12/04/01	N 140951 C 0021	SCHERING PLOUGH ANIMAL HEALTH CORP	DICLAZURIL	CHICKEN, TURKEY	NEW SPECIES/CLASS	Supplemental approval for diclazuril Type A medicated article for the prevention of coccidiosis caused by Eimeria adenoeides, E. gallopavonis, and E. meleagrititis in growing turkeys.	HFV-135
09/27/01	12/05/01	N 141053 R 0065	PFIZER INC	CARPROFEN	CANINE	NEW DOSAGE	Supplemental approval to add flexibility in administration of the total daily dose of Rimadyl caplets. The drug may now be administered orally at 2 milligrams per pound of body weight once daily or 1 milligram per pound of body weight twice daily.	HFV-114

Center for Veterinary Medicine Summary Report of Approvals

	NADA	ANADA	Total
Original	14	8	22
Supplemental	13	3	16
Total	27	11	38

ACCEPTABLE DAILY INTAKE	0
ADAA	7
CLARIFIED MIXING INSTRUCTIONS	0
DESI	0
HYBRID GENERIC	1
NEW ASSAY LIMITS	0
NEW CHEMICAL ENTITY	2
NEW COMBINATION	9
NEW CONTAINER SIZE	0
NEW DOSAGE	1
NEW DOSAGE FORM	2
NEW FEED MIX RULES	0
NEW FOOD ADDITIVE PETITION	1
NEW FORMULATION	0
NEW INDICATION	2
NEW LIMITATION	0
NEW MINOR SPECIES	1
NEW ROUTE OF ADMINISTRATION	1
NEW SOURCE OF DRUG	0
NEW SPECIES/CLASS	6
NEW STRENGTH/CONCENTRATION	0
NEW TOLERANCE/WITHDRAWAL PERIOD	6
ORIGINAL GENERIC	7
REVISED LABELING	0
RX/OTC STATUS CHANGE	0
TECHNICAL CORRECTION	0
PUBLICATION OF AVAILABILITY OF DATA	0
UNCLASSIFIED	0