Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 2001 list were published in the Federal Register in April 2001.

New Approvals

NADA Number: 141-156

Trade Name:	Amprol® plus BMD®
Ingredients:	Amprolium, bacitracin methylene disalicylate
Sponsor:	Alpharma, Inc.
Approval Date:	February 12, 2001
Status:	Over-the-counter
Route:	Oral
Species:	Chickens (replacement)
Drug Form:	Type A Medicated Articles to make two-way combination drug Type C medicated feeds.
Concentration:	Amprolium: 25% as a Type A Medicated Article Bacitracin methylene disalicylate: 10, 25, 30, 40, 50, 60, or 75 grams of bacitracin methylene disalicylate activity per pound of Type A Medicated Article.
Indications:	For the development of active immunity to coccidiosis, and for increased rate of weight gain and improved feed efficiency.
Tolerance:	21CFR 556.70 Bacitracin: Tolerances for residues of bacitracin in uncooked edible tissues and eggs of chickens are established at 0.5 part per million. The acceptable daily intake for total residues of bacitracin is 0.05 milligram per kilogram of body weight per day. 21CFR 556.50 Amprolium: Tolerances for residues of amprolium are established at 1 part per million in uncooked liver and kidney, 0.5 part per million in uncooked muscle, 8 parts per million in egg yolks, and 4 parts per million in whole eggs.
Withdrawal:	Zero days

21CFR 558.55

NADA Number: 141-142

Trade Name:	Amprol® plus BMD® plus 3-Nitro®
Ingredients:	Amprolium, bacitracin methylene disalicylate, roxarsone
Sponsor:	Alpharma, Inc.
Approval Date:	February 16, 2001
Status:	Over-the-counter
Route:	Oral
Species:	Chickens (replacement)
Drug Form:	Type A Medicated Articles to make three-way combination drug Type C medicated feeds.
Concentration:	Amprolium: 25% as a Type A Medicated Article Bacitracin methylene disalicylate: 10, 25, 30, 40, 50, 60, or 75 grams of bacitracin methylene disalicylate activity per pound of Type A Medicated Article. Roxarsone: 45.4, 90, 227, or 360 grams of roxarsone activity per pound of Type A Medicated Article.
Indications:	For the development of active immunity to coccidiosis, as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organism susceptible to bacitracin, and for increased rate of weight gain, improved feed efficiency, and improved pigmentation.
Tolerance:	21CFR 556.70 Bacitracin: Tolerances for residues of bacitracin in uncooked edible tissues and eggs of chickens are established at 0.5 part per million. The acceptable daily intake for total residues of bacitracin is 0.05 milligram per kilogram of body weight per day. 21CFR 556.50 Amprolium: Tolerances for residues of amprolium are established at 1 part per million in uncooked liver and kidney, 0.5 part per million in uncooked muscle, 8 parts per million in egg yolks, and 4 parts per million in whole eggs. 21CFR 556.60 Arsenic (roxarsone): Tolerances for residues of combined arsenic from roxarsone are established at 0.5 part per million in uncooked muscle tissue, 2 parts per million in uncooked edible by-products, and 0.5 part per million in eggs.
Withdrawal:	5 days

21CFR 558.55, 558.76, and 558.530

NADA Number: 141-172

Trade Name:	Paylean® plus Tylan®
Ingredients:	Ractopamine hydrochloride, tylosin phosphate
Sponsor:	Elanco Animal Health, A Division of Eli Lilly & Co.
Approval Date:	February 20, 2001
Status:	Over-the-counter
Route:	Oral
Species:	Swine (finishing, 150 – 240 pounds)
Drug Form:	Type A Medicated Articles to make Type C medicated feeds.
Concentration:	Ractopamine hydrochloride: 9 grams of ractopamine hydrochloride activity per pound of Type A Medicated Article. Tylosin Phosphate: 10, 40 or 100 grams of tylosin activity per pound of Type A Medicated Article.
Indications:	For increased rate of weight gain, improved feed efficiency, increased carcass leanness, and prevention and/or control of porcine proliferative enteropathies (ileitis).
Tolerance:	21CFR 556.570 Ractopamine: A tolerance is established for residues of ractopamine hydrochloride parent in edible swine tissues of 0.05 part per million in muscle and 0.15 part per million in liver. 21CFR 556.740 Tylosin: A tolerance of 0.2 part per million is established for negligible residue of tylosin in uncooked fat, muscle, liver, and kidney in swine.
Withdrawal:	Zero days

21CFR 558.500 and 558.625

Supplemental Approvals

NADA Number: 096-298

This supplemental application provides for establishing tolerances for residues in chickens, turkeys and sheep liver and adding an acceptable daily intake (ADI).

Trade Name:	Avatec®
Ingredients:	Lasalocid sodium
Sponsor:	Alpharma, Inc.
Approval Date:	February 20, 2001
Status:	Over-the-counter
Route:	Oral
Species:	Chickens (broilers), turkeys (growing), sheep
Drug Form:	Type A Medicated Article to make Type C medicated feeds.
Concentration:	Type A Medicated Article containing 90.7 grams lasalocid activity per pound.
Indications:	**Chickens:** For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima.* **Turkeys:** For the prevention of coccidiosis caused by *Eimeria meleagrimitis, E. gallopavonis,* and *E. adenoeides.* **Sheep:** For the prevention of coccidiosis caused by *Eimeria ovina, E. crandallis, E. ovinoidalois, (E. ninakohlyakimovae), E. parva,* and *E. intricata.*
Tolerance:	21CFR 556.347 Lasalocid: An acceptable daily intake (ADI) of 0.01 milligram per kilogram of body weight per day for lasalocid is established. Chickens: A tolerance is established for residues of 1.2 parts per million for parent lasalocid in skin with adhering fat (target tissue) and 0.4 part per million in liver. Turkeys: A tolerance is established for residues of 0.4 part per million for parent lasalocid in skin with adhering fat and in liver (target tissue). Sheep: A tolerance is established for residues of 1.0 part per million for parent lasalocid in liver.
Withdrawal:	Zero days

21CFR 556.347

NADA Number: 140-338

This supplemental application provides for the addition of a new species (goat).

Trade Name:	Naxcel® Sterile Powder
Ingredients:	Ceftiofur sodium
Sponsor:	Pharmacia & Upjohn Company
Approval Date:	March 7, 2001
Status:	Prescription only
Route:	Intramuscular
Species:	Goats
Drug Form:	Powder for reconstitution
Concentration:	50 milligram per milliliter of resulting solution
Indications:	For the treatment of respiratory disease (pneumonia) associated with *Mannheimia haemolytica (Pasteurella haemolytica)* and *Pasteurella multocida* in goats.
Tolerance:	21CFR 556.113 Ceftiofur: A tolerance is established for residues of ceftiofur as follows: 1 part per million in muscle, 2 parts per million in liver, 8 parts per million in kidney (target tissue) and 100 parts per billion.
Withdrawal:	Zero days

21CFR 522.313 and 556.113

NADA Number: 130-435

This supplemental application provides for a revised withdrawal time of oxytetracycline hydrochloride soluble powder in the drinking water of turkeys and swine.

Trade Name:	Oxytet Soluble, Tetravet-CA
Ingredients:	Oxytetracycline hydrochloride
Sponsor:	Alpharma, Inc.
Approval Date:	November 29, 2000
Status:	Over-the-counter
Route:	Oral
Species:	Chickens, turkeys, swine
Drug Form:	Powder
Concentration:	25.6 grams, 102.4 grams, 512 grams, or 648 grams per packet
Indications:	**Chickens:** 200 to 400 milligrams per gallon for control of infectious synovitis caused by *Mycoplasma synoviae*, susceptible to oxytetracycline. 400 to 800 milligrams per gallon for control of respiratory disease (CRD) and air sac infections caused by *Mycoplasma gallisepticum* and *Escherichia coli*, susceptible to oxytetracycline and for control of fowl cholera caused by *Pasteurella multocida*, susceptible to oxytetracycline. **Turkeys:** 200 to 400 milligrams per gallon for control of hexamitiasis caused by *Hexamita meleagridis*, susceptible to oxytetracycline. 400 milligrams per gallon for control of infectious synovitis caused by *Mycoplasma synoviae*, susceptible to oxytetracycline. 25 milligrams per pound body weight in growing turkeys for control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis), susceptible to oxytetracycline. **Swine:** 10 milligrams per pound body weight for the control and treatment of the following diseases in swine: Bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis*, susceptible to oxytetracycline. For breeding swine: Leptospirosis (reducing the incidence of abortions and shedding of leptospira) caused by *Leptospira pomona*, susceptible to oxytetracycline.
Tolerance:	21CFR 556.500 Oxytetracycline: Tolerances are established for the sum of residues in tissues of swine, chickens and turkeys as follows: 2 parts per million in muscle, 6 parts per million in liver, 12 parts per million in fat and kidney.

Withdrawal: Chickens: zero days
Turkeys: zero days
Swine: zero days

21CFR 520.1660d

Change of Sponsor

NADA Number: 200-141

From Inhalon Pharmaceuticals, Inc.
To: Minrad, Inc.
836 Main St., 2d floor
Buffalo, NY 14202
Drug labeler code: 060307

Withdrawals

NADA Number: 141-017

Trade Name: SaraFlox® WSP
Sponsor: Abbott Laboratories
Date: April 30, 2001

NADA Number: 141-018

Trade Name: SaraFlox® Injection
Sponsor: Abbott Laboratories
Date: April 30, 2001

Suitability Petition Action

Number: 01P-0066/CP1
Sponsor: First Priority, Inc.
Petition: Request permission to file an ANADA for a generic new animal drug, ivermectin/pyrantel pamoate, which differs from the pioneer product, Heartgard™ Plus (ivermectin/pyrantel pamoate), Merial Limited's NADA 140-971 by the following characteristic: Ivermectin/pyrantel pamoate generic is a compressed chewable tablet and Heartgard™ Plus is an 'extruded' chewable tablet.
Action: Approved on April 9, 2001

Number: 01P-0124/CP1
Sponsor: First Priority, Inc.
Petition: 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.
Action: Approved on April 11, 2001

Number: 01P-0045/CP1
Sponsor: Bimeda, Inc.
Petition: 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.
Action: Approved on April 20, 2001