The following corrections or additions to the January 2004 list were published in the Federal Register in August 2004.

New Approvals

NADA Number: 141-211

Trade Name:	Mecadox® 10 / Terramycin® 50, 100, or 200
Ingredients:	Carbadox, oxytetracycline dihydrate base
Sponsor:	Phibro Animal Health
Approval Date:	July 21, 2004
Status:	Over-the-counter
Route:	Oral, via feed
Species:	Swine
Drug Form:	Type A Medicated Article to make two-way combination Type C medicated feed.
Concentration:	Carbadox 10 grams activity per pound of Type A Medicated Article; oxytetracycline 50, 100, or 200 grams activity per pound of Type A Medicated Article.
Indications:	For the treatment of bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis* susceptible to oxytetracycline, treatment of bacterial pneumonia caused by *Pasteurella multocida* susceptible to oxytetracycline, and increased rate of weight gain and improved feed efficiency.
Tolerance:	*21CFR 556.100* Carbadox: A tolerance of 30 parts per billion is established for residues of quinoxaline-2-carboxylic acid (marker residue) in liver (target tissue). *21CFR 556.500* Oxytetracycline: Tolerances are established for the sum of tetracycline residues including chlortetracycline, oxytetracycline and tetracycline, in tissues as follows: 2 parts per million in muscle, 6 parts per million in liver, and 12 parts per million in fat and kidney.
Withdrawal:	42 days

21CFR 558.115 & 558.450

NADA Number: 141-229

Trade Name:	Sedivet® 1% Injection
Ingredients:	Romifidine hydrochloride
Sponsor:	Boehringer Ingelheim Vetmedica, Inc.
Approval Date:	June 3, 2004
Status:	Prescription only
Route:	Intravenous
Species:	Horses
Drug Form:	Liquid (solution)
Concentration:	10 milligrams per milliliter
Indications:	For use as a sedative and analgesic to facilitate handling, clinical examinations, clinical procedure, and minor surgical procedures. Also used as a preanesthetic prior to the induction of general anesthesia.
Patent Number:	4,624,960 Expiration date: October 11, 2005
Exclusivity:	5 years

21CFR 522.2076

NADA Number: 141-230

Trade Name:	Previcox™		
Ingredients:	Firocoxib		
Sponsor:	Merial Ltd.		
Approval Date:	July 21, 2004		
Status:	Prescription only		
Route:	Oral		
Species:	Dogs		
Drug Form:	Tablet (chewable)		
Concentration:	57 or 227 milligrams per tablet		
Indications:	For the control of pain and inflammation associated with osteoarthritis in dogs.		
Patent number:	5,981,576	Expiration date:	October 9, 2016
	6,677,373		October 8, 2019
Exclusivity:	5 years		

21CFR 520.928

NADA Number: 141-232

Trade Name:	Simplicef™
Ingredients:	Cefpodoxime proxetil
Sponsor:	Pharmacia & Upjohn Co.
Approval Date:	July 22, 2004
Status:	Prescription only
Route:	Oral
Species:	Dogs
Drug Form:	Tablet
Concentration:	100 or 200 milligrams per tablet
Indications:	For the treatment of skin infections (wounds and abscesses) caused by susceptible strains of *Staphylococcus intermedius, Staphylococcus aureus, Streptococcus canis* (group G, β hemolytic), *Escherichia coli, Pasteurella multocida,* and *Proteus mirabilis.*
Exclusivity:	5 years

21CFR 520.370

NADA Number: 141-233

Trade Name:	Optaflexx™ / Rumensin® / Tylan® / MGA®
Ingredients:	Ractopamine hydrochloride, monensin sodium, tylosin phosphate, melengestrol acetate
Sponsor:	Elanco Animal Health A Division of Eli Lilly & Co.
Approval Date:	July 2, 2004
Status:	Over-the-counter
Route:	Oral, via feed
Species:	Cattle, heifers fed in confinement for slaughter
Drug Form:	Type A Medicated Articles to make dry four-way combination Type C medicated feeds.
Concentration:	Ractopamine hydrochloride 45.4 grams activity per pound of Type A Medicated Article, monensin sodium 80 grams activity per pound of Type A Medicated Article, tylosin phosphate 40 or 100 grams activity per pound of Type A Medicated Article, melengestrol acetate 200 or 500 milligrams activity per pound of Type A Medicated Article.
Indications:	For increased rate of weight gain, improved feed efficiency, increased carcass leanness, prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*, reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Actinomyces (Corynebacterium) pyogenes*, and suppression of estrus (heat) in heifers fed in confinement for slaughter for the last 28 to 42 days on feed.
Tolerance:	*21CFR 556.570* Ractopamine: The tolerances for residues of ractopamine are established as follows: 0.03 part per million in muscle and 0.09 part per million in liver. 21CFR 556.420 Monensin: A tolerance of 0.05 part per million is established for negligible residues in edible tissues. *21CFR 556.740* Tylosin: Tolerances are established for residues of tylosin in edible products as follows: 0.2 part per million (negligible residue) in uncooked fat, muscle, liver, and kidney. *21CFR 556.380* Melengestrol acetate: A tolerance of 25 parts per billion is established for residues of the parent compound, melengestrol acetate, in fat.
Withdrawal:	Zero days
Patent number:	4,690,951 Expiration date: September 1, 2007 5,643,967 July 1, 2014

21CFR 558.342, 558.355, 558.500, & 558.625

NADA Number: 141-234

Trade Name:	Optaflexx™ / Rumensin® / MGA®
Ingredients:	Ractopamine hydrochloride, monensin sodium, melengestrol acetate
Sponsor:	Elanco Animal Health A Division of Eli Lilly & Co.
Approval Date:	July 2, 2004
Status:	Over-the-counter
Route:	Oral, via feed
Species:	Cattle, heifers fed in confinement for slaughter
Drug Form:	Type A Medicated Articles to make three-way combination Type C medicated feeds.
Concentration:	Ractopamine hydrochloride 45.4 grams activity per pound of Type A Medicated Article, monensin sodium 80 grams activity per pound of Type A Medicated Article, melengestrol acetate 200 or 500 milligrams activity per pound of Type A Medicated Article.
Indications:	For increased rate of weight gain, improved feed efficiency, increased carcass leanness, prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*, and suppression of estrus (heat) in heifers fed in confinement for slaughter for the last 28 to 42 days on feed.
Tolerance:	*21CFR 556.570* Ractopamine: The tolerances for residues of ractopamine are established as follows: 0.03 part per million in muscle and 0.09 part per million in liver. *21CFR 556.420* Monensin: A tolerance of 0.05 part per million is established for negligible residues in edible tissues. *21CFR 556.380* Melengestrol acetate: A tolerance of 25 parts per billion is established for residues of the parent compound, melengestrol acetate, in fat.
Withdrawal:	Zero days
Patent number:	4,690,951 Expiration date: September 1, 2007 5,643,967 July 1, 2014

21CFR 558.342, 558.355, & 558.500

ANADA Number: 200-273

Pioneer Product:	098-989
Trade Name:	Vetro-Gen™ Veterinary Ophthalmic Ointment
Ingredients:	Gentamicin sulfate
Sponsor:	Altana, Inc.
Approval Date:	June 8, 2004
Status:	Prescription only
Route:	Topical
Species:	Dogs and cats
Drug Form:	Ointment
Concentration:	3 milligrams per gram
Indications:	For treatment of conjunctivitis caused by susceptible bacteria.

21CFR 524.1044c

ANADA Number: 200-358

Pioneer Product:	141-059
Trade Name:	Pennchlor / BMD
Ingredients:	Chlortetracycline hydrochloride, bacitracin methylene disalicylate
Sponsor:	Pennfield Oil Co.
Approval Date:	July 2, 2004
Status:	Over-the-counter
Route:	Oral, via feed
Species:	Swine
Drug Form:	Type A Medicated Articles to make Type B or Type C medicated feeds.
Concentration:	Chlortetracycline hydrochloride 40 grams activity per pound of Type A Medicated Article; Bacitracin methylene disalicylate 3 grams activity per pound of Type A Medicated Article.
Indications:	For increased rate of weight gain and improved feed efficiency; for treatment of bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline.
Tolerance:	*21CFR 556.150* Chlortetracycline: Tolerances are established for the sum of tetracycline residues in tissues of 2 parts per million in muscle, 6 parts per million in liver and 12 parts per million in fat and kidney. *21CFR 556.70 Bacitracin*: The tolerance for residues of bacitracin in uncooked edible tissues is 0.5 part per million.
Withdrawal:	Zero days

21CFR 558.76

ANADA Number: 200-364

Pioneer Product:	033-157
Trade Name:	SpecMed™ Scour-Chek™
Ingredients:	Spectinomycin dihydrochloride pentahydrate
Sponsor:	Cross Vetpharm Group Ltd.
Approval Date:	July 29, 2004
Status:	Over-the-counter
Route:	Oral
Species:	Swine under 4 weeks of age or weighing less than 15 pounds
Drug Form:	Liquid (solution)
Concentration:	50 milligrams per milliliter
Indications:	For the treatment and control of porcine enteric colibacillosis (scours) caused by *E. coli* susceptible to spectinomycin
Tolerance:	Not established
Withdrawal:	21 days

21CFR 520.2123c

Supplemental Approvals

This section displays the change(s) to the original approval. To read the complete approval please refer to 21CFR Parts 500 and the related Federal Register notices.

NADA Number: 140-338

This supplemental application provides for establishing a 4-day pre-slaughter withdrawal period in swine.

Trade Name:	Naxcel®
Ingredients:	Ceftiofur sodium
Sponsor:	Pharmacia & Upjohn Co.
Approval Date:	June 18, 2004
Status:	Prescription only
Route:	Intramuscular
Species:	Swine
Drug Form:	Powder for reconstitution
Concentration:	50 milligrams per milliliter
Indications:	For the treatment and control of swine bacterial respiratory disease (swine bacterial pneumonia) associated with *Actinobacillus (Haemophilus) pleuropneumoniae, Pasteurella multocida, Salmonella choleraesuis,* and *Streptococcus suis* type 2.
Tolerance:	*21CFR 556.113* Ceftiofur: Tolerances are established for residues of desfuroylceftiofur (marker residue) are: kidney (target tissue*)* 0.25 part per million, liver 3 parts per million, and muscle 2 parts per million.
Withdrawal:	4 days

21CFR 522.313

NADA Number: 140-890

This supplemental application provides for establishing a 4-day pre-slaughter withdrawal period in swine.

Trade Name:	Excenel® RTU
Ingredients:	Ceftiofur hydrochloride
Sponsor:	Pharmacia & Upjohn Co.
Approval Date:	June 18, 2004
Status:	Prescription only
Route:	Intramuscular
Species:	Swine
Drug Form:	Liquid (suspension)
Concentration:	50 milligrams per milliliter
Indications:	For the treatment and control of swine bacterial respiratory disease (swine bacterial pneumonia) associated with *Actinobacillus (Haemophilus) pleuropneumoniae, Pasteurella multocida, Salmonella choleraesuis,* and *Streptococcus suis* type 2.
Tolerance:	*21CFR 556.113* Ceftiofur: Tolerances are established for residues of desfuroylceftiofur (marker residue) are: kidney (target tissue*)* 0.25 part per million, liver 3 parts per million, and muscle 2 parts per million.
Withdrawal:	4 days

21CFR 522.314

NADA Number: 141-095

This supplemental application provides for an increased period of protection from reinfection with three species of internal parasites; *Cooperia oncophora, Dictyocaulus viviparus* from 21 days to 28 days, and *Cooperia punctata* from 28 days to 35 days following topical administration.

Trade Name:	Dectomax® Pour-On Solution for Cattle
Ingredients:	Doramectin
Sponsor:	Pfizer, Inc.
Approval Date:	June 30, 2004
Status:	Over-the-counter
Route:	Topical
Species:	Cattle
Drug Form:	Liquid (solution)
Concentration:	0.5%
Indications:	For treatment and control of gastrointestinal roundworms, lungworms, eyeworms, grubs, lice, mange mites and horn flies. To protect cattle from reinfection with *Cooperia oncophora*, *D. viviparus*, *Ostertagia ostertagi*, and *O. radiatum* for 28 days; and with *C. punctata*, and *Haemonchus placei* for 35 days after treatment.
Tolerance:	*21CFR 556.225* Doramectin: A tolerance of 100 parts per billion is established for parent doramectin (the marker residue) in liver (the target tissue) and 30 parts per billion in muscle of cattle.
Withdrawal:	45 days. Withdrawal not established for milk or pre-ruminating calves.
Exclusivity:	3 years

21CFR 524.770

NADA Number: 141-148

This supplemental application provides for the use of a single ingredient decoquinate and monensin Type A Medicated Articles to make a two-way Type B and Type C medicated feeds for cattle at a broader range of concentrations from 12.9 to 90.8 grams per ton of feed for decoquinate.

Trade Names:	Deccox® / Rumensin®
Ingredients:	Decoquinate, monensin sodium
Sponsor:	Alpharma, Inc.
Approval Date:	July 30, 2004
Status:	Over-the-counter
Route:	Oral, via feed
Species:	Cattle fed in confinement for slaughter
Drug Form:	Type A Medicated Articles to make Type B and Type C medicated feeds.
Concentration:	Decoquinate - 27.2 grams activity per pound of Type A Medicated Article; Monensin – 20, 30, 45, 60, 80, and 90.7 grams activity per pound of Type A Medicated Article
Indications:	For the prevention of coccidiosis caused by *Eimeria bovis* and *E. zuernii;* and improved feed efficiency in cattle being fed in confinement for slaughter.
Tolerance:	*21CFR 556.170:* Decoquinate: Tolerances are established for residues of decoquinate in the uncooked edible tissues as 1 part per million in skeletal muscle and 2 parts per million in other tissues. *21CFR556.420:* Monensin: A tolerance of 0.05 part per million for negligible residues of monensin in the edible tissues.
Withdrawal:	Zero days

21CFR 558.195

NADA Number: 141-214

This supplemental application provides for revised labeling. The sub-heading Small Strongyles, has been revised to separate the listing of adult species from the fourth-stage larvae. The label language has also been revised for treatment frequency; removing the eight week inter-treatment interval because treatment frequency should be based on a parasite control program designed specifically for each horse. A new precaution statement has also been added.

Trade Name: Zimermectin® Gold Paste
Ingredients: Ivermectin, praziquantel
Sponsor: Merial Ltd.
Approval Date: July 13, 2004
Status: Over-the counter
Route: Oral
Species: Horse

21CFR 520.1198

ANADA Number: 200-066

This supplemental application provides for a new packet size (9.87 ounces) and strength (1 gram per 2.73 powder).

Trade Name: Agrimycin® 166
Ingredients: Oxytetracycline hydrochloride
Sponsor: Agri Laboratories, Ltd.
Approval Date: July 13, 2004
Status: Over-the-counter
Route: Oral, via drinking water
Species: Chickens, turkeys, and swine
Drug Form: Powder (soluble)
Concentration: 1 gram oxytetracycline hydrochloride activity per 2.73 grams of powder

21CFR 520.1660d

Change of Sponsor

NADA Number: 138-255

From: Chemdex, Inc.
To: Sparhawk Laboratories, Inc.
12340 Santa Fe Trail Dr.
Lenexa, KS 66215
Drug labeler code: 058005

NADA Number: 138-657 ANADA Number: 200-315, 200-324

From: Veterinary Laboratories, Inc.
To: Sparhawk Laboratories, Inc.
12340 Santa Fe Trail Dr.
Lenexa, KS 66215
Drug labeler code: 058005

Actions Taken by FDA Center for Veterinary Medicine

Change of Sponsor's Address

Hess & Clark, Inc.
944 Nandino Blvd.
Lexington, KY 40511
Drug Labeler Code: 050749

Suitability Petition Action

Number:	04P-0372/CP1
Sponsor:	Intervet Inc.
Petition:	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 characteristic(s): The generic product will have a different dosage form (chewable tablet) from the pioneer.
Action:	Filed on August 20, 2004.

Final Rule

Pre-Submission Conferences:
The Food and Drug Administration (FDA) is issuing this final rule to amend its new animal drug regulations to implement a new provision of the Federal Food, Drug, and Cosmetic Act (the act). Under this new provision of the act, as amended by the Animal Drug Availability Act of 1996 (ADAA), any person intending to file a new animal drug application (NADA) or supplemental NADA or to investigate a new animal drug is entitled to one or more conferences with FDA to reach an agreement establishing a submission or investigational requirement. This final rule describes the procedures for requesting, conducting, and documenting such pre-submission conferences. This rule is effective November 1, 2004. For further information contact: Gail Schmerfeld, Center for Veterinary Medicine (HFV-100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-1796, e-mail: gschmer1@cvm.fda.gov.

Notice

PMF 5783 for Tylosin Tartrate

The Food and Drug Administration (FDA) is announcing the availability of effectiveness, target animal safety, human food safety, and environmental safety data that may be used in support of a new animal drug application (NADA) or supplemental NADA for use of tylosin tartrate for the control of American foulbrood (*Paenibacillus larvae*) in honeybees. The data, contained in Public Master File (PMF) 5783, were compiled under National Research Support Project 7 (NRSP-7), a national agricultural research program for obtaining clearances for use of new drugs in minor animal species and for minor uses. Sponsors of NADAs or supplemental NADAs may, without further authorization, reference the PMF 5783 to support approval of an application filed under Sec. 514.1(d). An NADA or supplemental NADA must include, in addition to reference to the PMF, animal drug labeling and other information needed for approval, such as: Data supporting extrapolation from a major species in which the drug is currently approved or authorized reference to such data; and data concerning manufacturing methods, facilities, and controls. Persons desiring more information concerning PMF 5783 or requirements for approval of an NADA or supplement may contact Joan C. Gotthardt, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7571, e-mail: jgotthar@cvm.fda.gov.

Guidance for Industry ``Waivers of In Vivo Demonstration of Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles.''

The Food and Drug Administration (FDA) is announcing the availability of a draft of Guidance for Industry #171 entitled ``Waivers of *In Vivo* Demonstration of Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles". This draft guidance describes the procedures that the agency recommends for the review of requests for waiver of in vivo demonstration of bioequivalence for generic soluble powder oral dosage form products and Type A medicated articles. Submit written or electronic comments on the draft guidance by October 18, 2004, to ensure their adequate consideration in preparation of the final document. General comments on agency guidance documents are welcome at any time. Written comments on the information collection provisions must be received by October 4, 2004.

Veterinary Medicine Advisory Committee Meeting

This notice announces a forthcoming meeting on October 13, 2004 of the Veterinary Medicine Advisory Committee of the Food and Drug Administration (FDA). The meeting will be open to the public. The meeting will be held at the DoubleTree Hotel, Plaza III, 1750 Rockville Pike, Rockville from 8:30 a.m. to 5 p.m. Contact Aleta Sindelar, Center for Veterinary Medicine (HFV-3), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-4515, e-mail: asindela@cvm.fda.gov for more information. The FDA Advisory Committee Information Line (1-800-741-8138 or 301-443-0572 in the Washington, DC area), code 3014512548, will have up-to-date information on this meeting.

The committee will discuss and make recommendations on the microbial food safety of an antimicrobial drug application currently under review for use in food-producing animals in accordance with the Center for Veterinary Medicine's Guidance for Industry #152. The background material for this meeting will be posted on the Internet no later than 1 business day before the meeting at http://www.fda.gov/cvm/default.html.