Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 2008 list were published in the Federal Register in January 2008.

New Approval(s)

NADA Number: 141-281

Trade Name:	AVIAX® II Type A Medicated Article
Ingredients:	Semduramicin
Sponsor:	Phibro Animal Health
Approval Date:	December 3, 2007
Status:	OTC
Route:	Oral
Species:	Broiler Chickens
Drug Form:	Type A medicated article
Concentration:	5.0% Semduramicin (as semduramicin sodium biomass): 22.7 g/lb or 50g/kg
Indications:	For the prevention of coccidiosis caused by *Eimeria tenella, E. acervulina, E. maxima, E. brunetti, E. necatrix,* and *E. mitis.*
Tolerance:	400 parts per billion (ppb) in liver and 130 ppb in muscle
Withdrawal:	Zero withdrawal period
Exclusivity:	3 years

21 CFR 558.4, 21CFR558.555, 21CFR556.597

ANADA Number: 200-383

Trade Name:	ClindaRobe™ Capsules
Ingredients:	Clindamycin hydrochloride
Sponsor:	Novopharm Ltd.
Approval Date:	December 19, 2007
Status:	Rx
Route:	Oral
Species:	Dogs
Drug Form:	Capsules
Concentration:	25 mg, 75 mg, 150 mg capsule
Indications:	For the treatment of infections caused by susceptible strains of the designated microorganisms in the specific conditions listed: Skin infections (wounds and abscesses) due to coagulase positive staphylococci (*Staphylococcus aureus* or *Staphylococcus intermedius*). Deep wounds and abscesses due to *Bacteroides fragilis*, *Prevotella melaninogenicus*, *Fusobacterium necrophorum*, and *Clostridium perfringens.* Dental infections due to *Staphylococcus aureus*, *Bacteroides fragilis*, *Prevotella melaninogenicus*, *Fusobacterium necrophorum*, and *Clostridium perfringens.* Osteomyelitis due to *Staphylococcus aureus*, *Bacteroides fragilis*, *Prevotella melaninogenicus*, *Fusobacterium necrophorum*, and *Clostridium perfringens.*

21 CFR 520.446

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 2008 list were published in the Federal Register in January 2008.

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: 141-036

Trade Name:	Pirsue®
Ingredients:	Pirlimycin Hydrochloride
Sponsor:	Pharmacia & Upjohn Co., A Division of Pfizer, Inc.
Approval Date:	December 12, 2007
Tolerance:	2.4 µg/g in liver, 0.4 µg/mL in milk
Withdrawal:	Milk: 36-hour milk discard after the last treatment regardless of treatment duration. Following infusion twice at a 24-hour interval, treated animals must not be slaughtered for 9 days. Following any extended duration of therapy (more than two infusions at a 24-hour interval, up to 8 consecutive days), animals must not be slaughtered for 21 days.
Exclusivity:	3 years

This supplemental application extends the dosage regimen for intramammary infusion in lactating dairy cattle to daily treatment for up to 8 days and qualifies the product for an additional exclusivity period of 3 years for the extended duration regimen.

21 CFR 526.1810, 21CFR 556.515 73 FR 811

NADA Number: 141-230

Trade Name:	Previcox®
Ingredients:	Firocoxib
Sponsor:	Merial Ltd.
Approval Date:	December 18, 2007
Exclusivity:	3 years

This supplemental application provides for the addition of a new indication for the control of postoperative pain and inflammation associated with soft-tissue surgery in dogs and qualifies the product for an additional exclusivity period of 3 years for the new indication.

21 CFR520.928 73 FR 2808

ANADA Number: 200-308

Pioneer Product:	101-479
Trade Name:	Flunixin Injection
Ingredients:	Flunixin meglumine
Sponsor:	Norbrook Laboratories, Ltd.
Approval Date:	December 19, 2007

This supplemental application adds claims for intravenous injection in lactating dairy cattle to control pyrexia associated with acute bovine mastitis.

21 CFR 522.970 73 FR 2808

Supplemental Approvals, cont.

NADA Number: 097-222

Trade Name: Cefa-Lak® and Today®
Ingredients: Cephapirin sodium
Sponsor: Fort Dodge Animal Health, Division of Wyeth.
Approval Date: December 20, 2007

This supplemental application provides for the following labeling changes requested by the sponsor for both products: Add the phrase "Not for Human Use", add the statement "Restricted Drug (California) - Use Only as Directed", add the copyright statement "© 2006 Ford Dodge Animal Health. All Rights Reserved", revise the "Warning" section header to "Residue Warnings", and add the compressed arrows at the sides of the "Residue Warnings" section. The insert, syringe label, and carton were also reformatted.

21 CFR 526.365 73 FR 3181

Patent Addition(s)

NADA Number: 141-036

Patent number: 6,648,851
Expiration Date: March 5, 2022

NADA Number: 141-230

Patent number: 6,541,646
Expiration Date: Oct 8, 2019

Patent Extension

NADA Number: 141-258

Patent number: 4,900,735
Extension Period: 1 year
Expiration Date: December 11, 2009

New Sponsor

Sponsor Name: Novopharm Ltd.

30 Novopharm Ct.
Toronto, Ontario, Canada M1B 2K9

Drug Labeler: 043806

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 2008 list were published in the Federal Register in January 2008.

Labeling Revisions

NADA Number: 033-157

Trade Name: SPECTAM® Scour-Halt®
Ingredients: Spectinomycin
Sponsor: IVX Animal Health, Inc.
Effective Date: January 16, 2008

This supplemental application provides for the trademark ™ to be changed to a registered trademark ®.

NADA Number: 129-034

Trade Name: Disal™
Ingredients: Furosemide
Sponsor: Boehringer Ingelheim Vetmedica, Inc.
Effective Date: January 31, 2008

This supplemental application provides for the registered trademark ® to be changed to a trademark ™.

Notices

The Food and Drug Administration (FDA) is announcing its intention to schedule and hold a public meeting early in 2008 to obtain input from stakeholder groups, including, but not limited to, the Association of American Feed Control Officials (AAFCO), veterinary medical associations, animal health organizations, and pet food manufacturers for the development of ingredient, processing, and labeling standards to ensure the safety of pet food. These standards were mandated by the FDA Amendments Act of 2007 (FDAAA). Date, Time, and Location: The date, time, and location for the 2008 public meeting will be announced in a subsequent notice that will be published in the Federal Register a later date.

Public comments related to this notice (Docket number: 2007N-0487) may be submitted in writing to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 or electronically to either http://www.fda.gov/dockets/ecomments or http://www.regulations.gov.

FOR FURTHER INFORMATION CONTACT: Walther Osborne, Center for Veterinary Medicine (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, 240-276-9024, FAX: 240-276-9101, or e-mail: walter.osborne@fda.hhs.gov.

73 FR 1225, January 7, 2008

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The FDA is providing notice that effective January 15, 2008, the public will no longer be able to submit electronic comments to its Dockets through FDA's Web site. Electronic comments to FDA's Dockets may continue to be submitted through the Federal eRulemaking Portal. In recent months, FDA has alerted the public through our published Federal Register documents that after the transition date, electronic submissions will only be accepted by FDA through Federal Dockets Management System (FDMS) at http://www.Regulations.gov. Please note that the process for submitting written comments to FDA's Dockets will remain the same.

FOR FURTHER INFORMATION CONTACT: The Division of Dockets Management Public Room (HFA-305), Food and Drug Administration, 5630 Fisher Lane, 1061, Rockville, MD 20852, 301-827-6860, or 301-827-6870.

73 FR 2264, January 14, 2008

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Notices, cont.

At the request of the Commissioner of Food and Drugs (the Commissioner), the Institute of Medicine (the IOM) conducted a study of the use of FDA's advisory committees. In its final report, one of the IOM's recommendations was for the agency to publish an annual tentative schedule of its meetings in the Federal Register. This publication implements the IOM's recommendation. The tentative schedule for forthcoming meetings of the FDA's public advisory committee meetings for 2008 may be viewed at: http://www.fda.gov/oc/advisory/default.htm. Up-to-date schedule information may also be obtained by calling the Advisory Committee Information Line at 1-800-741-8138.

FOR FURTHER INFORMATION CONTACT: Theresa L. Green, Advisory Committee Oversight and Management Staff (HF-4), Food and Drug Administration, 5600 Fisher Lane, Rockville, MD 20857, 301-827-1220.

73 FR 2507 January 15, 2008

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The FDA is announcing the availability of a risk assessment on animal cloning. FDA's Center for Veterinary Medicine (CVM) developed this risk assessment to evaluate the health risks to animals involved in the process of cloning and to evaluate the food consumption risks that may result from edible products derived from animal clones or their progeny. FDA is also announcing the availability of a risk management plan that sets out measures the FDA will use to manage those risks. In addition, FDA is announcing availability of guidance for industry 179. This guidance describes FDA's recommendations regarding the use of edible products from animal clones and their progeny in human food or in animal feed.

To obtain single copies of any of these documents submit a written request to: Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Please include a self-addressed, adhesive label with your request. Electronic access to these documents is available at: http://www.fda.gov/cvm/cloning.htm. Comments related to these documents (Docket number: 2003N-0573) may be submitted in writing to: Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 or electronically to: http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Larisa Rudenko, Center for Veterinary Medicine (HFV-100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8245, e-mail: clones@cvm.fda.gov.

73 FR 2923, January 16, 2008