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 August 2008.

New Approval(s)

NADA Number: 141-288

Trade Name:	Excenel® RTU EZ Sterile Suspension
Ingredients:	Ceftiofur hydrochloride
Sponsor:	Pharmacia & Upjohn Co., a Division of Pfizer, Inc.
Approval Date:	July 1, 2008
Status:	Rx
Route:	Intramuscular (swine); subcutaneous (cattle)
Species:	Swine; cattle (beef, non-lactating dairy, and lactating dairy)
Drug Form:	Sterile suspension for injection
Concentration:	50 mg ceftiofur equivalents (CE)/mL
Indications:	For treatment and / or control of swine bacterial respiratory disease (swine bacterial pneumonia) associated with *Actinobacillus pleuropneumoniae, Pasteurella multocida, Salmonella* Choleraesuis and *Streptococcus suis*. For treatment of the following bacterial diseases in cattle: Bovine respiratory disease (BRD, shipping fever, pneumonia) associated with *Mannheimia haemolytica, Pasteurella multocida* and *Histophilus somni*.; Acute bovine interdigital necrobacillosis (foot rot, pododermatitis) associated with *Fusobacterium necrophorum* and *Bacteroides melaninogenicus*; and acute metritis (0 to 14 days post-partum) associated with bacterial organisms susceptible to ceftiofur.
Tolerance:	Swine: 0.25 ppm ceftiofur free acid equivalents as desfuroylceftiofur acetamide (DCA) in kidney, 3 ppm DCA in liver, and 2 ppm DCA in muscle. Cattle: 0.4 ppm DCA in kidney, 2 ppm DCA in liver, 1 ppm DCA in muscle, and 0.1 ppm DCA in milk.
Withdrawal:	Swine: 4 days Cattle: 3 days Milk: No milk discard times
Exclusivity:	3 years
Patent(s):	5,736,151 Expires: December 9, 2016

21 CFR 522.313b *73 FR 45611*

Supplemental Approval(s)

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: 140-854

Trade Name:	Synanthic® Bovine Dewormer Suspension
Ingredients:	Oxfendazole
Sponsor:	Fort Dodge Animal Health, Division of Wyeth
Approval Date:	July 7, 2008

This supplemental approval provides for changes to product labeling, including revision of the taxonomic name of *Cooperia mcmasteri* to *Cooperia surnabada* in the Indications section of the 9.06% and 22.5% suspension labeling. In addition the label withdrawal information has been edited to read: "Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age."

21 CFR 520.1630. *73 FR 45610*

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 August 2008.

NADA Number: 013-663

Trade Name: Cocciprol® 9.6% Oral Solution
Ingredients: Amprolium
Sponsor: Phibro Animal Health
Approval Date: July 8, 2008

This supplemental approval provides for label revisions associated with a previous change of sponsorship and other minor changes for amprolium concentrate solution to make medicated drinking water for chickens and turkeys for the treatment of coccidiosis. This product approval is also being codified for the first time.

21 CFR 520.100 73 FR 45610

NADA Number: 038-439

Trade Name: Terramycin™ 200 for Fish
Ingredients: Oxytetracycline dihydrate
Sponsor: Phibro Animal Health
Approval Date: July 6, 2008

This supplemental approval provides for the for use of oxytetracycline dihydrate in Type C medicated feeds for the control of mortality in freshwater-reared salmonids due to coldwater disease associated with *Flavobacterium psychrophilum*, the control of mortality in freshwater-reared *Oncorhynchus mykiss* due to columnaris disease associated with *Flavobacterium columnare* removal of the limitation on treating salmonids in water temperatures below 9°C, and the addition to the label of the previously approved indication for marking of skeletal tissue in Pacific salmon

21 CFR 558.500 73 FR 45874

Patent Number Extension

NADA Number: 141-230

Trade Name: Previcox® Chewable Tablets
Ingredients: Firocoxib
Sponsor: Merial Ltd.
Patent number: 5,981,576
Extension Period: 651 days
Expiration Date: July 22, 2018

Patent Information Correction

NADA Number: 141-207

Trade Name: A180® Antimicrobial Injection Solution
Ingredients: Danofloxacin mesylate
Sponsor: Pfizer, Inc.

Currently Listed Patent number: 5,811,103
Correct Patent Number: 5,811,130

Patent Number: 4,861,779
Currently Listed Patent Expiration Date: August 19, 2006
Correct Patent Expiration Date: August 29, 2006

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 August 2008.

Notice

The Food and Drug Administration (FDA) is extending the comment period for the order prohibiting the extralabel use of cephalosporin antimicrobial drugs in food-producing animals from September 2, 2008 to November 1, 2008. The effective date of this rule also is also changed from October 1, 2008 to November 30, 2008.

DATES: Submit written or electronic comments, identified by the docket identification number: FDA-2008-N-0326, on this ruling by November 1, 2008.

Electronic Submissions
Submit electronic comments in the following way:
via the Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Written Submissions
Submit written submissions in the following ways:
via FAX: 301-827-6870.
via Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal, as described previously,

For access to the docket to read background documents or comments received, go to http://www.regulations.gov and insert the docket number(s), found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Neal Bataller, Center for Veterinary Medicine (HFV-230), Food and Drug Administration, 7519 Standish Pl., Rockville, MD, 20855, 240-276-9200, e-mail: neal.bataller@fda.hhs.gov.

73 FR 48127 July 3, 2008

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