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 July 2008.

Labeling Revisions

NADA Number: 035-157

Trade Name: Gallimycin® PFC
Ingredients: Erythromycin
Sponsor: Cross Vetpharm Group, Ltd.
Effective Date: July 11, 2008

This supplemental application provides for the letters "PFC" to be added to the right of Gallimycin®.

Patent Information Corrections

NADA Number: 141-218

Patent Number:	Currently Listed Patent Expiration Date:	Corrected Patent Expiration Date:
5,741,512	April 27, 2010	August 30, 2011
5,866,159	August 30, 2011	September 13, 2009
5,916,589	March 6, 2017	September 13, 2009
5,962,014	March 6, 2017	September 13, 2009
5,962,017	April 27, 2015	September 13, 2009
6,007,840	March 6, 2017	September 13, 2009
6,258,808	June 26, 2012	June 25, 2012

Trade Name: Atopica®
Ingredients: Cyclosporine
Sponsor: Novartis Animal Health US, Inc.

NADA Number: 141-267

Patent Number 4,910,214
Corrected Expiration Date: July 15, 2013
Trade Name: Dexdomitor®
Ingredients: Dexmedetomidine hydrochloride
Sponsor: Orion Corp.

The original listed expiration date had expired, so the patent was removed from the active list.

Patent Removal

NADA Number: 131-310

Patent Removed: 5,214,035
Trade Name: Regu-Mate®
Ingredients: Altrenogest
Sponsor: Intervet Inc.

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 2007 list were published in the Federal Register in July 2008.

Patent Information Update

NADA Number: 141-244

Patent Number	6,420,536
Expiration Date Update:	May 24, 2019
Trade Name:	Draxxin®
Ingredients:	Tulathromycin
Sponsor:	Pfizer, Inc.

Patent Term Extension

NADA Number: 141-258

Patent Number	4,900,735
Expiration Date Update:	December 11, 2012
Trade Name:	Zilmax®
Ingredients:	Zilpaterol hydrochloride
Sponsor:	Intervet Inc.

New Patent

NADA Number: 141-285

Patent Number	7,378,408
Expiration Date Update:	September 4, 2023
Trade Name:	Convenia®
Ingredients:	Cefovecin sodium
Sponsor:	Pfizer, Inc.

Actions Taken by FDA Center for Veterinary Medicine

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Final Rule

The Food and Drug Administration (FDA) is issuing an order prohibiting the extralabel use of cephalosporin antimicrobial drugs in food-producing animals. FDA is issuing this order based on evidence that extralabel use of these drugs in food-producing animals will likely cause an adverse event in humans and, as such, presents a risk to the public health. FDA is concerned that the extralabel use of cephalosporins in food-producing animals is likely to lead to the emergence of cephalosporin-resistant strains of foodborne bacterial pathogens. If these drug-resistant bacterial strains infect humans, it is likely that cephalosporins will no longer be effective for treating disease in those people.

DATES: This rule becomes effective October 1, 2008. Submit written or electronic comments on this document by September 2, 2008.

COMMENTS, identified with the docket number FDA-2008-N-0326, may be submitted by any of the following methods:
Electronically at the Federal eRulemaking Portal : http://www.regulations.gov,
By fax at: 301-827-6870,
In writing (paper, disk or CD-ROM formats) by mail/hand delivery/courier at: Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville MD 20852.
Email submissions will not be accepted.

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 38110 July 3, 2008

Notices

The FDA is announcing the availability of a draft guidance for industry entitled “Providing Regulatory Submissions in Electronic Format - Drug Establishment Registration and Drug Listing.” This draft guidance document establishes a Pilot Program for industry to voluntarily submit drug establishment registration and drug listing information in an electronic format that FDA can process, review, and archive. The document provides guidance on what required and FDA-recommended information related to drug establishment registration and drug listing to submit and on how to electronically prepare and submit the information to FDA.

DATES: Although you can comment on any guidance at any time, to ensure that the agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance, including comments regarding proposed collection of information, by September 9, 2008

COMMENTS: Any comments submitted should include the Docket number: FDA-2005-N-0464. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061,Rockville, MD 20852. Submit electronic comments to http://www.regulations.gov.

COPIES of this draft guidance (Docket number: FDA-2005-N-0464) may be obtained as follows:
By mailing a request to: Office of Critical Path Programs (HF-18), Office of the Commissioner, Food and Drug Administration, 5600 Fisher Lane, Rockville, MD 20857. Please include a self-addressed adhesive label with your request;
By calling the Office of Critical Path Programs at: 301-827-1512; or
Via the Internet using one of the following URLs: http://www.fda.gov/cder/guidance/index.htm, http://www.fda.gov/cber/guidelines.htm, http://www.fda.gov/cvm/guidance/guidance.html, or http://www.regulations.gov.

FOR FURTHER INFORMATION CONTACT: Lonnie Smith, Office of Critical Path Programs (HF-18), Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-0011.

73 FR 39964 July 11, 2008

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 2007 list were published in the Federal Register in July 2008.

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