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 June 2007.

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: 141-077

Trade Name: Adspec®
Ingredients: Spectinomycin sulfate
Sponsor: Pharmacia & Upjohn Co., A Division of Pfizer, Inc.
Approval Date: May 10, 2007
Status: Rx

This supplemental application provides for minor revisions to the 500 mL bottle label and package insert. The package insert revised nomenclature for two bovine respiratory pathogens on labeling for Spectinomycin sulfate injectable solution. *Pasteurella haemolytica* and *Haemophilus somnus* was updated to *Mannheimia haemolytica* and *Histophilus somni.*

21 CFR 522.2121 *72 FR 31178*

NADA Number: 097-505

Trade Name: Lincomix® 20 and Lincomix® 50
Ingredients: Lincomycin hydrochloride
Sponsor: Pharmacia & Upjohn Co., A Division of Pfizer, Inc.
Approval Date: May 23, 2007
Status: OTC

This supplemental application provides for the use of lincomycin in feed of swine weighing greater that 250 pounds and for the addition of reproductive and gastrointestinal cautionary statements for swine and a cautionary statement concerning species that should not be exposed to the product to the label.

21 CFR 558.325 *72 FR 33387*

Sponsor Information Change

Change of Address:

Watson Laboratories, Inc.
620 North 51st Ave.
Phoenix, AZ 85043-4705

To

Watson Laboratories, Inc.
311 Bonnie Circle
Corona, CA 92880

21 CFR 510.600 (c)

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 June 2007.

Patent Extension

NADA 141-217

Patent number: 4,937,234
Extension Period: 5 years
Expiration Date: August 10, 2013

Notice(s)

The Food and Drug Administration (FDA) has determined the regulatory review period for ZILMAX (NADA 141-258) and is publishing this notice. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that animal drug product.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy (HFD-305), Food and Drug Administration, 5630 Fisher Lane, rm. 1061, Rockville, MD 20857, 301-594-2041.

72 FR 30595, June 1, 2007

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The FDA solicits comments on the reporting requirements for the animal drug user fees, fee waivers and reductions. Submit written and electronic comments by August 13, 2007.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fisher Lane, Rockville, MD 20857, 301-827-1472

72 FR 32852, June 14, 2007

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The Food and Drug Administration (FDA) solicits comments on the hourly burden necessary to complete FDA Form 3546, "Animal Drug User Fee Cover Sheet." Submit written and electronic comments by August 14, 2007.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fisher Lane, Rockville, MD 20857, 301-827-1472

72 FR 33232, June 15, 2007

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The Food and Drug Administration (FDA) is announcing the availability for comments of a revised draft guidance for industry (143) entitled "Revised Draft Guidance for Industry on Pharmacovigilance of Veterinary Medicinal Products: Controlled List of Terms: (VICH GL30). This revised draft guidance, which updates a draft guidance on the same topic for which a notice of availability was published in the Federal Register of February 6, 2002 (the 2002 guidance), has been developed for veterinary use by the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicial Products (VICH). This draft VICH guidance document describes the specific data elements to be used for the submission and exchange of spontaneous adverse event reports (AERs) between marketing authorization holders (MAHs) and regulatory authorities (RAs). Submit written and electronic comments by July 23, 2007.

FOR FURTHER INFORMATION CONTACT: Lynn Post, Center for Veterinary Medicine (HFV-210), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9062, e-mail: lynn.post@fda.hhs.gov.

72 FR 34262, June 21, 2007