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 November 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: 131-675

Trade Name: Safe-Guard®
Ingredients: Fenbendazole
Sponsor: Intervet Inc.
Approval Date: November 5, 2007

This supplemental application provides for removal of the sentence "There are no known contraindications to the use of the drug in cattle" from the cattle "Warning" statement, and the wording of the "Warning" statement for horses has been changed to "Do not use in horses intended for human consumption".

21 CFR 558.258 72 FR 66046

NADA Number: 141-224

Trade Name: Optaflexx®, Rumensin®, and Tylan®
Ingredients: Ractopamine hydrochloride, monensin USP, and tylosin phosphate
Sponsor: Elanco Animal Health, A Division of Eli Lilly & Co.
Approval Date: October 12, 2007

This supplemental application provides for increased level of monensin in combination Type C medicated feeds and a revision to bacterial pathogen nomenclature; specifically *Arcanobacterium (Actinomyces) pyogenes.*

21 CFR 558.500 72 FR 62571

NADA Number: 141-225

Trade Name: Optaflexx® and Rumensin®
Ingredients: Ractopamine hydrochloride and monensin USP
Sponsor: Elanco Animal Health, A Division of Eli Lilly & Co.
Approval Date: October 30, 2007

This supplemental application provides for revised dosing for the combined use of ractopamine hydrochloride and monensin USP for cattle fed in confinement for slaughter, based on the December 1, 2006, supplemental approval for Rumensin® (under NADA 095-735), which provided for an increase in the upper dosage limit in cattle being fed in confinement for slaughter.

21 CFR 558.500 72 FR 65667

NADA Number: 141-246

Trade Name: Aquaflor®
Ingredients: Florfenicol
Sponsor: Schering-Plough Animal Health Corp.
Approval Date: October 26, 2007
Exclusivity: 7 years

This supplemental application provides for the addition of an indication for the control of mortality in freshwater-reared salmonids due to furunculosis associated with *Aeromonas salmonicida.*

21 CFR 558.261 72 FR 65886

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 November 2007.

Supplemental Approvals, cont.

NADA Number: 065-440

Trade Name: Aureomycin®
Ingredients: Chlortetracycline hydrochloride
Sponsor: Fort Dodge Animal Health, Division of Wyeth Holdings Corp.
Approval Date: October 18, 2007

This supplemental application provides for a revision to bacterial pathogen nomenclature; specifically under the indications for Swine, *Hemophilus* spp. to *Actinobacillus pleuropneumoniae* and for Calves, Beef Cattle, and Non-lactating Diary Cattle *Hemophilus* spp. to *Histophilus* spp. This supplemental approval changed the "Residue Warning" section to read: "Do not administer to chickens, growing turkeys, swine, and cattle with 24 hours of slaughter".

21 CFR 520.445b 72 FR 63987

ANADA Number: 200-437

Trade Name: Noromectin®
Ingredients: Ivermectin
Sponsor: Norbrook Laboratories, Ltd.
Approval Date: October 5, 2007

This supplemental application adds claims for an extension of persistent effectiveness against *Oesophagostomum radiatum* from 14 to 28 days and for *Trichostrongylus axei* and *Cooperia punctata* from 14 to 21 days.

21 CFR 522.1192 72 FR 62771

Patent Number Addition

NADA Number: 141-244

Patent number: 6,936,592
Expiration Date: May 29, 2018

Patent number: 6,861,412
Expiration Date: November 28, 2020

Change of Sponsor Address

NADA Numbers: 141-174, 141-178, 141-186

Sponsor Name: IDEXX Pharmaceuticals, Inc.

From: 4249-105 Piedmont Pkwy
Greensboro, NC 27410

To: 7009 Albert Pick Road
Greensboro, NC 27409

Drug Labeler Code: 065274

72 FR 63986, November 14, 2007

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 November 2007.

Notices

The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between FDA and the Association of American Feed Control Officials (AAFCO). The purpose of this MOU is to facilitate FDA's collaboration with AAFCO in the AAFCO New and Modified Ingredient Definition Process by clarifying the responsibilities of FDA and AAFCO in defining feed ingredients, in providing mechanisms for resolving disputes that may arise, and in providing mechanisms for modifying the ingredient definition process when required.

DATES: The Agreement became effective August 30, 2007

FOR FURTHER INFORMATION CONTACT: Sharon Benz, Division of Animal Feeds (HFV-220), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, 240-453-6864.

72 FR 65046, November 19, 2007

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The FDA solicits comments on the Animal Drug User Fees and Fee Waivers and Reductions 21 CFR Part 740 (OMB Control Number 0910-0540)-Extension. Fax written comments to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX 202-395-6974 or e-mailed to baguilar@omb.eop.gov by December 19, 2007. All comments should be identified with the OMB control number 0910-0540 and the FDA docket number: 2007N-0219.

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 65038, November 19, 2007

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The FDA solicits comments on the current Good Manufacturing Practice Regulations for Medicated Feeds 21 CFR Part 225 (OMB Control Number 0910-0152)-Extension. Fax written comments to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX 202-395-6974 or e-mailed to baguilar@omb.eop.gov by December 19, 2007. All comments should be identified with the OMB control number 0910-0540 and the FDA docket number: 2007N-0305.

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 65041, November 19, 2007

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The FDA solicits comments on the Animal Drug User Fee Cover Sheet, FDA Form 3546, (OMB Control Number 0910-0539)-Extension. Fax written comments to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX 202-395-6974 or e-mailed to baguilar@omb.eop.gov by December 20, 2007. All comments should be identified with the OMB control number 0910-0539 and the FDA docket number: 2007N-0220.

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 65342, November 20, 2007

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The FDA is announcing the availability of a revised guidance for industry (73) entitled "Stability Testing of New Veterinary Drug Substances and Medicinal Products (Revision) VICH GL3(R)." This revised guidance has been developed for veterinary use by the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary medicinal Products (VICH). This revised document is intended to provide guidance regarding the development of stability testing data for new animal drug applications (referred to as registration applications in the guidance) submitted to the European Union (EU), Japan, and United States.

Notices, cont.

This guidance document is also available on the FDACVM home page (http://www.fda.gov/cvm) and from the Division of Dockets Management web site (http://www.fda.gov/ohrms/dockets/default.htm). Submit written requests for single copies of the guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine (CVM), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your request.

Submit written comments regarding this publication to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the full title of the guidance and the docket number 2006D-013. Submit electronic comments on the guidance via the Internet at http://www.fda.gov/dockets/ecomments or http://www.regulations.gov.

FOR FURTHER INFORMATION CONTACT: Dennis Bensley, Center for Veterinary Medicine (HFV-140), Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, 301-827-6956, e-mail: dennis.bensley@fda.hhs.gov.

72 FR 65752, November 23, 2007

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The FDA is announcing the availability of a revised guidance for industry (93) entitled "Impurities in New Veterinary Medicinal Products (Revision) VICH GL11(R)." This revised guidance has been developed for veterinary use by the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary medicinal Products (VICH). This revised document is intended to assist in developing registration applications for approval of veterinary medicinal products submitted to the European Union (EU), Japan, and United States. The revised guidance addresses only those impurities in new veterinary medicinal drug products classified as degradation products.

This guidance document is also available on the FDACVM home page (http://www.fda.gov/cvm) and from the Division of Dockets Management Web site (http://www.fda.gov/ohrms/dockets/default.htm). Submit written requests for single copies of the guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine (CVM), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your request.

Submit written comments regarding this publication to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the full title of the guidance and the docket number 1999D-2145. Submit electronic comments on the guidance via the Internet at http://www.fda.gov/dockets/ecomments or http://www.regulations.gov.

FOR FURTHER INFORMATION CONTACT: Dennis Bensley, Center for Veterinary Medicine (HFV-140), Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, 301-827-6956, e-mail: dennis.bensley@fda.hhs.gov.

72 FR 65753, November 23, 2007

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The FDA is announcing the availability of a revised guidance for industry (92) entitled "Impurities in New Veterinary Drug Substances (Revision) VICH GL10(R)." This revised guidance has been developed for veterinary use by the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary medicinal Products (VICH). This revised document is intended to provide guidance for registration applicants on the content and qualification of impurities in new veterinary drug substances produced by chemical syntheses and not previously registered in a country, region, or member state.

This guidance document is also available on the FDACVM home page (http://www.fda.gov/cvm) and from the Division of Dockets Management Web site (http://www.fda.gov/ohrms/dockets/default.htm). Submit written requests for single copies of the guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine (CVM), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your request.

Submit written comments regarding this publication to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the full title of the guidance and the docket number 1999D-2215. Submit electronic comments on the guidance via the Internet at http://www.fda.gov/dockets/ecomments or http://www.regulations.gov.

FOR FURTHER INFORMATION CONTACT: Dennis Bensley, Center for Veterinary Medicine (HFV-140), Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, 301-827-6956, e-mail: dennis.bensley@fda.hhs.gov.

72 FR 65754, November 23, 2007