

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 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: 141-203

Trade Name: Deramaxx®
Ingredients: Deracoxib
Sponsor: Novartis Animal Health US, Inc.
Approval Date: June 13, 2007
Patents: 5,756,529 Expires: September 29, 2015
5,892,053 Expires: May 25, 2015
5,910,597 Expires: May 25, 2015

This supplemental application provides for the addition of a 75 mg. tablet size.

21 CFR 520.538 72 FR 37437

NADA Number: 140-974

Trade Name: Ivomec® Premix for Swine
Ingredients: Ivermectin
Sponsor: Merial Ltd.
Approval Date: June 15, 2007

This supplemental application provides for the revision of the approved concentration of ivermectin in Type C medicated feed administered as a top dress to adult and breeding swine. The supplement also revises the "Caution" statements on each revised Type C Medicated Feed labels.

21 CFR 558.300 72 FR 37439

Regulatory Labeling Supplements

ANADA Number: 200-318

Pioneer Product: 140-841
Trade Name: Virbamec®
Ingredients: Ivermectin
Sponsor: Virbac Animal Health
Approval Date: July 6, 2007

This supplemental application provides for the addition of a new 10 Liter package size and updates to the labeling which include the speciation of *Cooperia* and updates to the Environmental Safety, Mode of Action, Residue Warning and Indications sections.

21 CFR 524.1193

NADA Number: 141-079

Trade Name: Ivomec® Eprinex®
Ingredients: Eprinomectin
Sponsor: Merial Ltd.
Approval Date: July 20, 2007

This supplemental application provides for the Eprinex trademark changed from TM to ®.

21 CFR 524.814

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Sponsor Information Change

Change of Sponsor Name:

Mylan Bertek Pharmaceuticals, Inc.
12720 Dairy Ashford
Sugar Land, TX 77478

Drug Labeler Code: 062794

To

UDL Laboratories, Inc.
12720 Dairy Ashford
Sugar Land, TX 77478

Drug Labeler Code: 051079

21 CFR 510.600 (c)

Notice(s)

The Food and Drug Administration (FDA) is announcing opportunity for public comment on paperwork associated with applications for new animal drugs. Specifically; paperwork involving presubmission conferences, new animal drug applications and supporting regulations and Guidance 152, and Form FDA 356V.

DATES: Submit written or electronic comments on the collection of information by September 7, 2007.

ADDRESSES: Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/ecomments>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

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 37242, July 9, 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 July 2007.

Notice(s), cont.

The FDA is announcing opportunity for public comment FDA's patent term restoration regulations on due diligence petitions for regulatory review period revision. Where a patented product must receive FDA approval before marketing is permitted, the Office of Patents and Trademarks may add a portion of the FDA review time to the term of a patent. Petitioners may request reductions in the regulatory review time if FDA marketing approval was not pursued with "due diligence."

DATES: Submit written or electronic comments on the collection of information by September 7, 2007.

ADDRESSES: Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/ecomments>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

72 FR 37243, July 9, 2007

The FDA is amending the regulations for food additives permitted (FAP) in feed to provide for the safe use of selenium yeast as a source of supplemental selenium in feed supplements for limit feeding for beef cattle and in salt mineral mixes for free-choice feeding for beef cattle.

FOR FURTHER INFORMATION CONTACT: Isabel W. Pocurull, Center for Veterinary Medicine (HFV-226), 7519 Standish Pl., Rockville, MD 20855, 240-276-6853.

72 FR 39562, July 19, 2007

The FDA is announcing the final rule designating of New Animal Drugs for Minor Uses or Minor Species. The Minor Use and Minor Species Animal Health Act of 2004 (MUMS act) amended the Federal Food, Drug, and Cosmetic Act (the act) to establish new regulatory procedures that provide incentives intended for the treatment of minor animal species and uncommon diseases in major animal species. At this time, FDA is issuing final regulations to implement the act. These regulations describe the procedures for designating a new animal drug as a minor use or minor species drug. Such designation establishes eligibility for the incentives provided by the MUMS act.

FOR FURTHER INFORMATION CONTACT: Bernadette Dunham, Center for Veterinary Medicine (HFV-50), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9090, e-mail: Bernadette.Dunham@fda.hhs.gov.

72 FR 41022, July 26, 2007