

Actions Taken by FDA Center for Veterinary Medicine

New Approvals

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

NADA Number: 141-255

Trade Name: 35% Perox-aid®
Ingredients: Hydrogen Peroxide
Sponsor: Eka Chemicals, Inc.
Approval Date: January 11, 2007
Status: OTC
Route: Immersion
Species: Freshwater-reared finfish eggs; and freshwater-reared salmonids, coolwater finfish and channel catfish
Drug Form: Liquid Solution
Concentration: 35% (w/w) weight in water
Indications: For the control of mortality in freshwater-reared finfish eggs due to saprolegniasis, for the control of mortality in freshwater-reared salmonids due to bacterial gill disease associated with *Flavobacterium branchiophilum*, and for the control of mortality in freshwater-reared coolwater finfish and channel catfish due to external columnaris disease associated with *Flavobacterium columnare* (*Flexibacter columnaris*)
Tolerance: None
Withdrawal: Zero days
Exclusivity: 7 years

21 CFR 529.1150
21CFR 510.600

NADA Number: 141-269

Trade Name: Revalor-XS
Ingredients: Trenbolone acetate and estradiol
Sponsor: Intervet, Inc
Approval Date: January 19, 2007
Status: OTC
Route: Subcutaneous implantation
Species: Steers fed in confinement for slaughter
Drug Form: Implant (pellet)
Concentration: One implant contains 200 mg trenbolone acetate and 40 mg estradiol
Indications: Increased rate of weight gain and improved feed efficiency for up to 200 days in steers fed in confinement for slaughter.
Tolerance: **21 CFR 556.739** Trenbolone: Not needed
21 CFR 556.240 Estradiol: In uncooked edible tissues of heifers, steers, and calves: 120 parts per trillion (ppt) for muscle, 480 ppt for fat, 360 ppt for kidney, 240 ppt for liver.
Withdrawal: None
Exclusivity: 3 years
Patents: Patent Number Expiration Date
6,498,153 March 22, 2019

21CFR 522.2477

Actions Taken by FDA Center for Veterinary Medicine

New Approvals, cont'd

NADA Number: 141-272

Trade Name: Reconcile®
Ingredients: Fluoxetine hydrochloride
Sponsor: Elanco Animal Health, A Division of Eli Lilly & Co.
Approval Date: January 19, 2007
Status: Rx
Route: Oral
Species: Dogs
Drug Form: Chewable tablets
Concentration: 8 mg, 16 mg, 32 mg, and 64 mg of Fluoxetine hydrochloride per tablet
Indications: The treatment of canine separation anxiety in conjunction with a behavior modification plan.
Exclusivity: 5 years

21CFR 522.980

ANADA Number: 200-415

Pioneer Product: 132-338
Trade Name: Gentamicin Sulfate Topical Spray
Ingredients: Gentamicin sulfate and betamethasone valerate
Sponsor: First Priority, Inc.
Approval Date: January 12, 2007
Status: Rx
Route: Topical
Species: Dogs
Drug Form: Liquid
Concentration: Each mL contains: gentamicin sulfate USP equivalent to 0.57 mg gentamicin base, betamethasone valerate, USP equivalent to 0.284 mg betamethasone
Indications: For the treatment of infected superficial lesions in dogs caused by bacteria susceptible to gentamicin

21CFR 522.1044f

Supplemental Approvals

This section describes change(s) to the original approval. For additional information refer to 21CFR Parts 500 and related Federal Register notices.

NADA Number: 138-993

Trade Name: MoorMan's® Cattle Minerals BT
Ingredients: Lasalocid sodium
Sponsor: ADM Alliance Nutrition
Approval Date: December 22, 2006

This application provides for an alternate strength of lasalocid (from Bovatec 68 to Bovatec 91 – 20% lasalocid activity) for Moorman's Cattle Mineral BT for pasture cattle (slaughter, stocker, feeder cattle and dairy and beef replacement heifers).

21CFR 558.311 72 FR 4955

Actions Taken by FDA Center for Veterinary Medicine

Supplemental Approvals, cont'd

ANADA Number: 200-272

Pioneer Product: 140-841
Trade Name: Noromectin®
Ingredients: Ivermectin
Sponsor: Norbrook Laboratories
Approval Date: January 19, 2007

This application provides for the addition of persistent activity claims that are no longer protected by three years marketing exclusivity that expired November 24, 2006.

21CFR 524.1193 72 FR 6464

NADA Number: 141-257

Trade Name: Iverhart Max™
Ingredients: Ivermectin/pyrantel pamoate/praziquantel
Sponsor: Virbac AH, Inc.
Approval Date: February 15, 2007
Exclusivity: 3 years

This application provides for removal of the following statement from the Precaution section of the package insert: "The effective use of this drug for the treatment and control of tapeworms has not been evaluated in dogs less than 15 pounds."

21CFR 520.1199 No FR Required

Addition of Patent Number

NADA Number: 141-269

<u>Patent Number:</u>	<u>Expiration Date:</u>
6,498,153	March 22, 2019

Extension of Patent Expiration Date

NADA Number: 141-207

<u>Patent Number:</u>	<u>Expiration Date:</u>
4,861,779	August 29, 2007

Addition of Sponsor

Eka Chemicals, Inc.

1775 West Oak Commons Ct.
Marietta, GA 30062-2254
Drug labeler code: 061088

Actions Taken by FDA Center for Veterinary Medicine

Notice(s)

The Food and Drug Administration (FDA) is announcing the availability of a draft compliance policy guide (CPG) entitled "Voluntary Self Inspection of Medicated Feed Manufacturing Facilities." This draft CPG is intended to provide guidance to the FDA field offices in prioritizing inspections of medicated feed manufacturing facilities for compliance with Current Good Manufacturing Practices for Medicated Feeds regulations (CGMP).

Submit written requests for single copies of this CPG to the Director, Division of Compliance Policy (HFC-230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

Submit written or electronic comments on this draft CPG by April 30, 2007 to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Land, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: For Technical Questions Concerning This CPG: Paul Bachman, Center For Veterinary Medicine (HFV-239). Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9225, e-mail: Paul.Bachman@fda.hhs.gov.

72 FR 6574, February 12, 2007

The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance.

The Center for Veterinary Medicine (CVM) accepts certain types of submissions electronically with no requirement for a paper copy. These types of documents are listed in public docket 1992S-0251 as required by 21 CFR 11.2. CVM's ability to receive and process information submitted electronically is limited by its current information technology capabilities and the requirements of the Electronic Records; Electronic Signatures final regulation. CVM's guidance entitled "Guidance for Industry 108: How to Submit Information in Electronic Format by E-Mail" outlines general standards to be used for the submission of any information by e-mail.

Fax written comments on the collection of information by March 16, 2007. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-6974.

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

72 FR 7045, February 14, 2007

The Food and Drug Administration (FDA) is announcing, that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance.

The Center for Veterinary Medicine (CVM) monitors the final disposition of investigational animals where such animals do not enter the human food chain immediately at the completion of the investigational study. CVM's monitoring of the final disposition of investigational food animals is intended to ensure that unsafe residues of new animal drugs do not get into the food supply. CVM issues a slaughter authorization letter to investigational new animal drug (INAD) sponsors that sets the terms under which investigational animals may be slaughtered (21 CFR 511.1(b)(5)). Also in this letter, CVM requests that sponsors submit a notice of final disposition of investigational animals not intended for immediate slaughter (NFDA). NFDAs have historically been submitted to CVM on paper. CVM's guidance on "How to Use E-mail to Submit a Notice of Final Disposition of Animals Not Intended for Immediate Slaughter" provides sponsors with the option to submit an NFDA as an e-mail attachment to CVM.

Fax written comments on the collection of information by March 16, 2007. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-6974.

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

72 FR 7046, February 14, 2007

Actions Taken by FDA Center for Veterinary Medicine

Notice(s), cont'd

The Food and Drug Administration (FDA) is announcing, that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance.

Section 512(d)(1)(E) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(d)(1)(E)), requires FDA to issue an order refusing to approve a new animal drug application (NADA), if there is a lack of substantial evidence that a new animal drug will have the effect it is purported or represented to have under the conditions of use prescribed in the proposed labeling. Therefore, substantial evidence must be submitted to us as part of the NADA to establish effectiveness of a drug. Section 21 CFR 514.4(a) specifies requirements for submitting adequate and well-controlled studies to provide substantial evidence of effectiveness for a new animal drug. This information collection requirement provides for submissions of substantial evidence of effectiveness information via electronic submissions to the Center for Veterinary Medicine (CVM).

Fax written comments on the collection of information by March 16, 2007. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-6974.

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

72 FR 7047, February 14, 2007

The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance.

Protocols for nonclinical laboratory studies (safety studies), are required under 21 CFR 58.120 for approval of new animal drugs. Protocols for adequate and well-controlled effectiveness studies are required under 21 CFR 514.117(b). Upon request by the animal drug sponsors, the Center for Veterinary Medicine (CVM), reviews protocols for safety and effectiveness studies that CVM and the sponsor consider to be an essential part of the basis for making the decision to approve or not approve an animal drug application or supplemental animal drug application. Establishing a process for acceptance of the electronic submission of protocols for studies conducted by sponsors in support of new animal drug applications (NADAs), is part of CVM's ongoing initiative to provide a method for paperless submissions. Sponsors may submit protocols to CVM in paper format. CVM's guidance on how to submit a study protocol permits sponsors to submit a protocol without data as an e-mail attachment via the Internet. CVM's guidance on how to submit a study protocol electronically implements provisions of the Government Paperwork Elimination Act (GPEA). The GPEA required Federal agencies, by October 21, 2003, to provide for the: (1) Option of the electronic maintenance, submission, or disclosure of information, if practicable, as a substitution for paper; and (2) use and acceptance of electronic signatures, where applicable.

Fax written comments on the collection of information by March 19, 2007. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-6974.

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

72 FR 7438, February 15, 2007

Actions Taken by FDA Center for Veterinary Medicine

Notice(s), cont'd

The Food and Drug Administration (FDA) is announcing, that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance.

The Center for Veterinary Medicine (CVM) holds meetings and /or teleconferences when a sponsor requests a presubmission conference under 21 CFR 514.5, or requests a meeting to discuss general questions. Generally, meeting requests are submitted to CVM on paper. However, CVM now allows registered sponsors to submit information electronically, and to request meetings electronically, if they determine this is more efficient and time saving for them. CVM's guidance "On How to Use E-Mail to Submit a Request for a Meeting or Teleconference to the Office of New Animal Drug Evaluation" provides sponsors with the option to submit a request for a meeting or teleconference as an e-mail attachment via the internet.

Fax written comments on the collection of information by March 19, 2007. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-6974.

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

72 FR 7441, February 15, 2007

The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance.

Section 512(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(j)) gives FDA the authority to set conditions under which animals treated with investigational new animal drugs may be marketed for food use. Under this authority, the Center for Veterinary Medicine (CVM), issues to a new animal drug sponsor (sponsors) a slaughter authorization letter that sets the terms under which investigational animals may be slaughtered. The United States Department of Agriculture (USDA) also monitors the slaughter of animals treated with investigational new animal drugs under the authority of the Meat Inspection Act (21 USC 601-95). Sponsors must submit slaughter notices each time investigational animals are presented for slaughter, unless this requirement is waived by an authorization letter (21 CFR 511.1(b)(5), 9 CFR 309.17). These notifications assist CVM and USDA in monitoring the safety of the food supply. Slaughter notices were previously submitted to CVM and USDA on paper (OMB No. 0910-0450). CVM's guidance on "How to Use E-Mail to Submit a Notice of Intent to Slaughter for Human Food Purposes" provides sponsors with the option to submit a slaughter notice as an e-mail attachment to CVM and USDA via the Internet. The electronic submission of slaughter notices is part of CVM's ongoing initiative to provide a method for paperless submissions.

Fax written comments on the collection of information by March 19, 2007.

To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-6974.

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

72 FR 7661, February 16, 2007
