# Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 2006 list were published in the Federal Register in November 2006.

## New Approvals

### NADA Number: 141-257

Trade Name: Iverhart Max™
Ingredients: Ivermectin, pyrantel pamoate, praziquantel
Sponsor: Virbac Animal Health
Approval Date: October 13, 2006
Status: Prescription only
Route: Oral
Species: Dogs
Drug Form: Chewable Tablets
Concentration:

| *Tablet size* | *Ivermectin* | *Pyrantel Pamoate* | *Praziquantel* |
|---|---|---|---|
| Toy | 34 mcg | 28.5 mg | 28.5 mg |
| Small | 68 mcg | 57 mg | 57 mg |
| Medium | 136 mcg | 114 mg | 114 mg |
| Large | 272 mcg | 228 mg | 228 mg |

Indications: For use in dogs to prevent canine heartworm disease by eliminating the tissue stage of heartworm larvae (*Dirofilaria immitis*) for a month (30 days) after infection and for the treatment and control of roundworms (*Toxocara canis*, *Toxascaris leonina*), hookworms (*Ancylostoma caninum*, *Uncinaria stenocephala*, *Ancylostoma braziliense*) and tapeworms (*Dipylidium caninum*, *Taenia pisiformis*).
Exclusivity: 3 years

*21CFR 520.1199*

### ANADA Number: 200-365

Pioneer Product: 101-777
Trade Name: Glycopyrrolate Injectable
Ingredients: Glycopyrrolate
Sponsor: IVX Animal Health, Inc.
Approval Date: October 2, 2006
Status: Prescription only
Route: Intravenous, intramuscular or subcutaneous in dogs; intramuscular in cats
Species: Dogs and cats
Drug Form: Sterile solution
Concentration: 0.2 mg/mL
Indications: As a preanesthetic anticholinergic agent in dogs and cats

*21CFR 522.1066*

## ANADA Number: 200-379

| | |
|---|---|
| Pioneer Product: | 200-113 |
| Trade Name: | Neomycin Liquid |
| Ingredients: | Neomycin sulfate |
| Sponsor: | Sparhawk Laboratories, Inc. |
| Approval Date: | October 24, 2006 |
| Status: | OTC |
| Route: | Oral |
| Species: | Cattle, swine, sheep, and goats |
| Drug Form: | Solution |
| Concentration: | Each mL contains neomycin sulfate (commercial grade) 200 mg equivalent to 140 mg neomycin |
| Indications: | For the treatment and control of colibacillosis (bacterial enteritis) caused by *Escherichia coli* susceptible to neomycin sulfate in cattle, swine, sheep, and goats. |
| Tolerance: | 7.2 parts per million (ppm) in kidney (target tissue) and fat, 3.6 ppm in liver, 1.2 million in muscle, and 0.15 ppm in milk. |
| Withdrawal: | 1 day for cattle, 2 days for sheep, and 3 days for swine and goats. |

*21CFR 520.1485, 21 CFR 556.430*

# 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.

## ANADA Number: 200-320

| | |
|---|---|
| Pioneer Product: | 134-314 |
| Trade Name: | Equell™ |
| Ingredients: | Ivermectin |
| Sponsor: | Virbac AH, Inc. |
| Approval Date: | October 24, 2006 |

This application provides for incorporating CVM requested changes to the label's "WARNING" and "INDICATIONS" sections and to add expired three-year exclusivity claims.

*21CFR 520.1192*

## NADA Number: 96-298

| | |
|---|---|
| Trade Name: | Bovatec® 91 |
| Ingredients: | Lasalocid |
| Sponsor: | Alpharma, Inc. |
| Approval Date: | October 20, 2006 |

This application provides for use of lasalocid, Bovatec 91 Type A medicated article, in the free-choice cattle feeds containing 1440, 150 or 1088 g lasalocid/ton, respectively.

*21CFR 558.311*

## NADA Number: 140-863

Trade Name: Paylean® 9 & Paylean® 45
Ingredients: Ractopamine hydrochloride
Sponsor: Elanco Animal Health, A Division of Eli Lilly & Co.
Approval Date: April 25, 2006
Exclusivity: 3 years

This application provides for the replacement of the current indication and dosage with a new indication that allows use in pigs weighing in excess of 240 lb and a new dose range of 4.5 to 9.0 grams per ton. Additionally, this supplement updates the caution statement to reflect new animal safety data.

*21CFR 558.500*

## NADA Number: 141-172

Trade Name: Paylean® and Tylan®
Ingredients: Ractopamine hydrochloride and Tylosin phosphate
Sponsor: Elanco Animal Health, A Division of Eli Lilly & Co.
Approval Date: October 20, 2006

This application provides for the combined use of ractopamine hydrochloride and tylosin phosphate in swine in excess of 240 lb and reduces the maximum dose of ractopamine hydrochloride to 10 ppm (9 g/ton).

*21CFR 558.500*

# Suitability Petition Action

Number: SP 06P-0093/PRC1
Sponsor: ECO Animal Health
Petition: Request permission to file an ANADA for a generic new animal drug which differs from the pioneer product, Merial's Ivomec® (ivermectin) 1% Injection, NADA 128-409 by the following characteristics: The proposed generic drug product would contain twice the strength of the pioneer product (2%) and would be intended to deliver the same amount of active ingredient per pound of body weight in a dose volume one-half of the pioneer's product.

Action: Denied

# Change of Sponsor Name

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

Drug labeler code: 062794

## Technical Amendments

The Food and Drug Administration (FDA) is amending the animal drug regulations to correct an inadvertent error in the conditions of use of bambermycins free-choice cattle feeds. This action is being taken to improve the accuracy of the animal drug regulations.

2. In Sec. 558.95, revise the last sentence of paragraph (d)(4)(iii)(d) to read as follows:

Sec. 558.95 Bambermycins.

* * * * *
(d) * * *
(4) * * *
(iii) * * *
(d) * * * Daily bambermycins intakes in excess of 20 mg/head/day have not been shown to be more effective than 20 mg/head/day.
* * * * *

*71 FR 65053, November7, 2006*

**************************************

The Food and Drug Administration (FDA) is correcting a document amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) that appeared in the Federal Register of September 1, 2006 (71 FR 51995). FDA is correcting the date of approval of an ANADA for a generic lincomycin injectable solution which was drafted in error. This correction is being made to improve the accuracy of the Federal Register.

1. On page 51995, in the third column, in the third sentence of the SUPPLEMENTARY INFORMATION section, the date of NADA approval ``July 27, 2006'' is corrected to read ``August 2, 2006''.

*71 FR 65052-65053, November 7, 2006*

**************************************

The Food and Drug Administration (FDA) is amending the animal drug regulations to simplify the organization of special labeling requirements for formulations (Type A medicated articles, Type B and Type C medicated feeds) containing monensin sodium. This action is being taken to improve the clarity of the regulations.

On October 28, 2004, FDA approved a supplemental new animal drug application (sNADA 95-735) filed by Elanco Animal Health for RUMENSIN (monensin sodium) Type A medicated article adding use in a new class of cattle (dairy cows) for increased milk production efficiency (69 FR 68783, November 26, 2004). On December 15, 2005, FDA approved another supplement to NADA 95-735 for use in dairy cow component feeding systems (71 FR 1689, January 11, 2006). The approval of each of these new conditions of use resulted in the amendment of the animal drug regulations for monensin in Sec. 558.355 (21 CFR 558.355).

Since these approvals for use of monensin in dairy cow feeds as well as beef cattle feeds, FDA has become aware of confusion regarding which statements on the approved Type A medicated article labeling also appear on the approved representative labeling (Blue Bird labeling) for Type B and Type C medicated feeds for each class of cattle. At this time, the regulations are being amended in Sec. 558.355 to simplify the organization of special labeling requirements for formulations (Type A medicated articles, Type B and Type C medicated feeds) containing monensin sodium. This action is being taken to improve the clarity of the regulations.

*71 FR 66231-66232, November 14, 2006*

**************************************

## Notice(s)

The Food and Drug Administration (FDA) solicits comments on an information collection to meet specified requirements for submitting adequate and well-controlled studies to provide substantial evidence of effectiveness for a new animal drug.

Submit written or electronic comments on the collection of information by January 2, 2007.

Submit electronic comments on the collection of information to: http://www.fda.gov/dockets/ecomments. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with docket number 2006N-0431.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1472.*71*

*FR 64535-64536, November 2, 2006*

**********

The Food and Drug Administration (FDA) solicits comments on extending OMB approval on the existing reporting requirements for the information collection activity entitled ``How to Use E-mail to Submit a Notice of Intent to Slaughter for Human Food Purposes."

Submit electronic comments on the collection of information to: http://www.fda.gov/dockets/ecomments. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with docket number 2006N-0435.

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.

Submit written or electronic comments on the collection of information by January 8, 2007.

*71 FR 65532-65533, November 8, 2006*

**********

The Food and Drug Administration (FDA) solicits comments on extending Office of Management and Budget (OMB) approval on the existing reporting requirements relating to how one may submit information electronically to the Center for Veterinary Medicine (CVM), using e-mail.

Submit electronic comments on the collection of information to: http://www.fda.gov/dockets/ecomments. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with docket number 2006N-0432.

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.

Submit written or electronic comments on the collection of information by January 8, 2007.

*71 FR 65533-65534, November 8, 2006*

**********

## Notice(s) – cont'd

The Food and Drug Administration (FDA) solicits comments on extending OMB approval of existing reporting requirements for the information collection activity on guidance for industry on ``How to Use E-Mail to Submit a Study Protocol."

Submit electronic comments on the collection of information to: http://www.fda.gov/dockets/ecomments. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with docket number 2006N-0436.

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.

Submit written or electronic comments on the collection of information by January 8, 2007.

*71 FR 65534-65535, November 8, 2006*

**********

The Food and Drug Administration (FDA) solicits comments on extending Office of Management and Budget (OMB) approval of existing reporting requirements on electronic submission of requests for meetings, in person or via teleconference, to discuss with animal drug sponsors studies to be conducted and how to meet the statutory requirements for drug approval under the Federal Food, Drug, and Cosmetic Act. Requests for meetings about new animal drug submissions were previously submitted on paper copy to the Center for Veterinary Medicine (CVM).

Submit electronic comments on the collection of information to: http://www.fda.gov/dockets/ecomments. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with docket number 2006N-0434.

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.

Submit written or electronic comments on the collection of information by January 8, 2007.

*71 FR 65535-65536, November 8, 2006*

**********

The Food and Drug Administration (FDA) solicits comments on extending the Office of Management and Budget (OMB) approval on the existing reporting requirements for the information collection activity entitled ``How to Use E-Mail to Submit a Notice of Final Disposition of Animals Not Intended for Immediate Slaughter."

Submit electronic comments on the collection of information to: http://www.fda.gov/dockets/ecomments. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with docket number 2006N-0433.

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.

Submit written or electronic comments on the collection of information by January 8, 2007.

*71 FR 65827-65828, November 9, 2006*

**********

## Notice(s) – cont'd

Proposed collection of information; Medicated Feed Mill License Applications

The Animal Drug Availability Act (ADAA) of October 9, 1996, amended section 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b) to replace the system for the approval of specific medicated feed with a general licensing system for feed mills. Before passage of the ADAA, medicated feed manufacturers were required to obtain approval of Medicated Feed Applications (MFAs) in order to manufacture certain types of medicated feeds. An individual approved MFA was required for each and every applicable medicated feed. The ADAA streamlined the paperwork process for gaining approval to manufacture medicated feeds by replacing the MFA system with a facility license for each medicated feed manufacturing facility. Implementing regulations are at part 515.

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.

Fax written comments on the collection of information by December 14, 2006

*71 FR 66335, November 14, 2006*

**********

## Notice(s) – cont'd

The Food and Drug Administration (FDA) announces the availability of draft guidance for industry (136) entitled ``Protocols for the Conduct of Method Transfer Studies for Type C Medicated Feed Assay Methods.'' This draft guidance provides our recommendations for protocols for conducting the transfer study of a single-laboratory validated Type C medicated feed assay method to laboratories that have no experience with the test method.

Submit written or electronic comments on this draft guidance by January 29, 2007, to ensure their adequate consideration in preparation of the final document. General comments on agency guidance documents are welcome at any time.

Submit written requests for single copies of the draft guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit written comments 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 draft guidance and the docket number found in brackets in the heading of this document. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

*71 FR 66335-66336, November 14, 2006*

**********

The Food and Drug Administration (FDA) This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Transmissible Spongiform Encephalopathies Advisory Committee. General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues. Date and Time: The meeting will be held on December 15, 2006, from 8 a.m. to 3:30 p.m.

*71 FR 69134-69135, November 29, 2006*