

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were published in the Federal Register in March 2009.

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: 200-463

Pioneer Product: NADA 013-149
Trade Name: Amprolium-P 9.6% Oral Solution
Ingredients: Amprolium
Sponsor: IVX Animal Health, Inc.
Approval Date: February 12, 2009
Status: OTC
Route: Oral
Species: Growing chickens, turkeys, and laying hens
Drug Form: Oral solution
Concentration: Each milliliter of solution contains 96 milligrams (mg) amprolium (9.6 percent solution).
Indications: The treatment of coccidiosis in growing chickens, turkeys, and laying hens
Tolerance: In the edible tissues and in eggs of chickens and turkeys: 1 part per million (ppm) in uncooked liver and kidney and 0.5 ppm in uncooked muscle tissue. In eggs: 8 ppm in egg yolks, and 4 ppm in whole eggs.
Withdrawal: zero withdrawal period
Exclusivity: None
Patent: None

21 CFR 520.100 74 FR 10483

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: 200-228

Trade Name: Phonedectin® Injection
Pioneer: NADA 128-409
Ingredients: Ivermectin
Sponsor: IVX Animal Health, Inc.
Approval Date: January 23, 2009

This supplement provides for the extension of persistent activity claims against parasites that are no longer protected by marketing exclusivity. Updating the Environmental Safety section and adding to the Residue Information section.

21 CFR 522.1192 74 FR 9049

NADA Number: 012-965

Trade Name: Tylan® 50 and Tylan® 200
Ingredients: Tylosin
Sponsor: Elanco Animal Health
Approval Date: February 24, 2009

The effect of the supplement provides for the scientific name of the organism *Actinomyces pyogenes* has been changed to *Arcanobacterium pyogenes*.

21 CFR 522.2640 74 FR 11643

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The following corrections or additions to the list were published in the Federal Register in March 2009.

NADA Number: 141-103

Trade Name: Sevoflo®
Ingredients: Sevoflurane
Sponsor: Abbott Laboratories
Approval Date: July 27, 2006

This final rule is to codify the supplemental NADA approval that provided for a revised induction dose which was not codified under the original. The supplemental approval dated July 27, 2006

21 CFR 529.2150 74 FR 10484

Supplemental Approvals

ANADA Number: 200-314

Trade Name: Pennchlor S®
Pioneer: NADA 035-805
Ingredients: Chlortetracycline, sulfamethazine
Sponsor: Pennfield Oil Company
Approval Date: February 19, 2009

The effect of the supplement provides for a change to the trademark symbol from ™ to ®.

ANADA Number: 200-391

Trade Name: Griseofulvin Powder
Pioneer: NADA 039-792
Ingredients: Griseofulvin
Sponsor: IVX Animal Health, Inc.
Approval Date: February 19, 2009

The effect of the supplement provides for updating the Warning statement to "**Do not use in horses intended for human consumption**".

Patents

NADA Number: 141-262

Patent Number: 6,222,320
Expiration Date: May 8, 2020

NADA Number: 141-263

Patent Number: 6,222,038
Expiration Date: April 21, 2015

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New Sponsor

New Sponsor: Medical Developments International Ltd.
P.O. Box 21
Sandown Village, 3171 VIC Australia

Drug Labeler Code: 025245

21 CFR 510.600 74 FR 9766

Transfer of Ownership

NADA 014-485

Previous Sponsor: Schering-Plough Animal Health Corp.
New Sponsor: Medical Developments International Ltd.

21 CFR 529.1455 74 FR 9766

Correction

In title 21 of the Code of Federal Regulations, part 558, revised as of April 1, 2008, on page 410, in §558.58 (e)(1)(iii), the entry for Bambermycins 1 to 3, in the column under "Limitations" remove "057926" and in its place add "016592"; in the column under "Sponsor", add "016592".

21 CFR 529.1455 74 FR 9766