

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 2009 list were published in the Federal Register in December 2008.

New Approval

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: 141-290

Trade Name: Topmax™ 9 Type A Medicated Article
Ingredients: Ractopamine hydrochloride
Sponsor: Elanco Animal Health, A Division of Eli Lilly & Co.
Approval Date: November 12, 2008
Status: OTC
Route: Oral
Species: Finishing tom and hen turkeys
Drug Form: Type A medicated articles for use in the manufacture of Type B and Type C medicated feeds
Concentration: 4.6 to 11.8 g/ton (5 to 13 ppm)
Indications: For increased rate of weight gain and improved feed efficiency in finishing tom turkeys fed for the last 14 days prior to slaughter.
For increased rate of weight gain and improved feed efficiency in finishing hen turkeys fed for the last 7 to 14 days prior to slaughter.
Tolerance: 0.45 parts per million (ppm) in liver (the target tissue) and 0.1 ppm in muscle
Withdrawal: zero withdrawal period
Exclusivity: 3 years
Patent: None

21 CFR 558.500, 21CFR 556.570 73 FR 72714

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: 200-424

Trade Name: Optaflexx, Heifermax 500, Rumensin, and Tylan
Pioneer: NADA 141-233
Ingredients: Ractopamine hydrochloride, melengestrol acetate, monensin, and tylosin phosphate
Sponsor: Ivy Laboratories, Division of Ivy Animal Health, Inc.
Approval Date: November 13, 2008

The effect of the supplement provides for an increased level of monensin in four-way combination Type C medicated feeds containing, ractopamine, melengestrol, monensin, and tylosin for heifers fed in confinement for slaughter; and a revision to bacterial pathogen nomenclature.

21 CFR 520.500 73 FR 75323

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The following corrections or additions to the January 2009 list were published in the Federal Register in December 2008.

NADA Number: 012-491

Trade Name: Tylan Type A medicated article
Ingredients: Tylosin phosphate
Sponsor: Elanco Animal Health, A Division of Eli Lilly & Co.
Approval Date: November 13, 2008
Exclusivity: 3 years

The effect of the supplement provides for use of tylosin tartrate in medicated drinking water for swine for 3 to 10 days followed by administration of tylosin phosphate in medicated swine feed for 2 to 6 weeks for the control of porcine proliferative enteropathies (PPE, ileitis) associated with *lawsonia intracellularis*.

21 CFR 558.625 73 FR 76946

NADA Number: 013-076

Trade Name: Tylan Soluble
Ingredients: Tylosin phosphate
Sponsor: Elanco Animal Health, A Division of Eli Lilly & Co.
Approval Date: November 13, 2008
Exclusivity: 3 years

The effect of the supplement provides for use of tylosin tartrate in medicated drinking water for swine for 3 to 10 days followed by administration of tylosin phosphate in medicated swine feed for 2 to 6 weeks for the control of porcine proliferative enteropathies (PPE, ileitis) associated with *lawsonia intracellularis*.

21 CFR 520.2640 73 FR 76946