

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were published in the Federal Register in February 2010.

Original 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: 141-301

Trade Name: Topmax™ and Coban®
Ingredients: Ractopamine hydrochloride and monensin, USP
Sponsor: Elanco Animal Health, A Division of Eli Lilly
Approval Date: December 11, 2009
Status: OTC
Route: Oral
Species: Finishing tom and hen turkeys
Drug Form: Type A Medicated Articles for manufacture of 2-way combination Type C medicated feeds
Concentration: Ractopamine hydrochloride: 9 grams ractopamine hydrochloride activity per pound in the Type A medicated article.
Monensin, USP: 90 grams monensin, USP activity per pound in the Type A medicated article.
Indications: For increased rate of weight gain and improved feed efficiency in finishing tom turkeys fed for the last 14 days prior to slaughter, and for the prevention of coccidiosis in growing turkeys caused by *Eimeria adenoeides*, *E. meleagritidis* and *E. gallopavonis*.
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, and for the prevention of coccidiosis in growing turkeys caused by *Eimeria adenoeides*, *E. meleagritidis* and *E. gallopavonis*.
Tolerance: The tolerance for ractopamine in turkey liver is 0.45 ppm. A tolerance for residues of monensin in turkeys is not required.
Withdrawal: Zero days
21 CFR 558.500 75 FR 5887

ANADA Number: 200-478

Trade Name: Albac® 50 plus Nicarb®
Pioneer: Baciferm® plus Nicarb®
Ingredients: Bacitracin zinc plus nicarbazin
Sponsor: Alpharma, Inc.
Approval Date: January 21, 2010
Status: OTC
Route: Oral
Species: Broiler Chickens
Drug Form: Type A Medicated Article
Concentration: Bacitracin zinc – 50 g/lb; Nicarbazin – 113.5 g/lb
Indications: As an aid in preventing outbreaks of cecal (*Eimeria tenella*) and intestinal (*E. acervulina*, *E. maxima*, *E. necatrix*, *E. brunetti*) coccidiosis, and for increased rate of weight gain and improved feed efficiency in broiler chickens
Tolerance: A withdrawal period of 4 days has been established for Nicarb®; nicarbazin in broiler chickens
Withdrawal: A tolerance of 4 parts per million (ppm) is established for residues of nicarbazin in uncooked chicken muscle, liver, skin, and kidney
The tolerance for residues of bacitracin from zinc bacitracin or bacitracin methylene disalicylate in uncooked edible tissues of chickens and eggs is 0.5 ppm
21 CFR 558.366 75 FR 7555