



Food Animals Residue Avoidance and Depletion Program

June 8, 2011

FDA ANNOUNCES SUSPENSION OF ROXARSONE FOR USE IN FOOD ANIMALS*

The FDA announced today that all domestic sales of roxarsone, an arsenic-based animal drug that is manufactured and sold by Alpharma LLC, will be halted within 30 days. Roxarsone, which is sold as a stand-alone product (3-NITRO[®]) as well as numerous combination products, is currently approved for use in chickens, turkeys and pigs. The major indications for roxarsone use in food animals are prevention of coccidiosis, improved weight gain (growth promoter) and improved pigmentation (poultry).

REASON FOR THIS ACTION: FDA scientists found increased levels of inorganic arsenic (As) in the livers of chickens treated with 3-Nitro[®] relative to levels in livers of the untreated chickens. While organic forms of arsenic, including roxarsone, are generally considered to be safe for human consumption, inorganic arsenic is more harmful and has been reported to be a human carcinogen.

WHICH PRODUCTS ARE AFFECTED: Roxarsone is an active ingredient in more than 70 animal drug products that are currently marketed for use in food animals (see list below). The voluntary suspension applies to all roxarsone-containing animal drug products, however at present, the FDA action does **not** apply to any other arsenic-based animal drugs. The following is a partial list of roxarsone-containing animal drugs affected by this action:

3-Nitro W	Biocox [®] / 3-Nitro [®] / Flavomycin [®]	Monteban Plus Roxarsone
3-Nitro-10, -20, -50, -80	Bio-Cox [®] / Albac [®] / 3-Nitro [®]	Monteban [®] plus Flavomycin [®] plus 3-Nitro [®]
Albac + Coban + 3-Nitro	BMD + Avatec + 3-Nitro	Nicarb [®] / 3-Nitro [®] / Lincomix [®]
Amprol + Roxarsone + Bambermycins	BMD + Monteban + Roxarsone	Nicarbazine Roxarsone Premix
Amprol HI-E / Albac / 3-Nitro	ChlorMax [™] / Bio-Cox [®] / 3-Nitro [®]	Nicarmix 25 [®] / 3-Nitro [®]
Amprol HI-E / Albac / 3-Nitro	ChlorMax [™] / Sacox [®] / 3-Nitro [®]	Nicarmix 25 [®] / 3-Nitro [®] / Lincomix [®]
Amprol HI-E, Bambermycins and Roxarsone	Clinacox plus 3-Nitro	Pennchlor [™] / Bio-Cox [®] / 3-Nitro [®]
Amprol [®] / BMD [®] / 3-Nitro [®]	Clinacox [™] + BMD [®] + 3-Nitro [®]	Ren-O-Sal
Amprolium & Roxarsone & Bambermycins	Coban / Albac / 3-Nitro	Robenz [®] Plus Roxarsone
Aureomycin + Bio-Cox + Roxarsone	Coban + 3-Nitro + BMD	ROBENZ [®] plus BMD [®] plus 3-NITRO [®]
Avatec + 3-Nitro + Bacitracin Zinc	Coban + 3-Nitro + Stafac	Rofenaïd plus Roxarsone
Avatec + Lincomycin + 3-Nitro Broiler	Coban and 3-Nitro	Roxarsone
Avatec and 3-Nitro	Coban, BMD, and 3-Nitro	Sacox / 3-Nitro
AVATEC plus 3-NITRO	Coban [®] / 3-Nitro [®] -10 / Baciferm [®] Premix	Sacox [®] / 3-Nitro [®] / Aureomycin [®]
Avatec [®] / 3-Nitro [®] / Albac [®]	Coyden 25 [®] / Albac [®] / 3-Nitro [®]	Sacox [®] / 3-Nitro [®] / Baciferm [®]
Avatec [®] / 3-Nitro [®] / Flavomycin [®]	Deccox [®] / 3-Nitro [®] / Albac [®]	Sacox [®] / 3-Nitro [®] / BMD [®]
Avatec [®] / Fortracin / 3-Nitro [®] Broiler Premix	Deccox [®] / Albac [®] / 3-Nitro [®]	Sacox [®] / 3-Nitro [®] / Flavomycin [®]
Aviax [™] / 3-Nitro [®]	Deccox [®] / BMD [®] / 3-Nitro [®]	Sacox [®] / Albac [®] / 3-Nitro [®]
Aviax [™] / BMD [®] / 3-Nitro [®]	Decoquinat + 3-Nitro	Sacox [®] / Albac [®] / 3-Nitro [®]
Aviax [™] / Stafac [®] / Roxarsone	Flavomycin [®] + 3-Nitro + Zoalene	Sacox [®] / Lincomix [®] / 3-Nitro [®]
Bio-Cox	Flavomycin [®] + 3-Nitro [®] + Coban [®]	Sacox [®] / Stafac [®] / 3-Nitro [®]
Bio-Cox + 3-Nitro	Lincomix / Amprol Plus / Roxarsone	Salinomycin (BIO-COX [®]) plus Roxarsone
Bio-Cox + 3-Nitro + Albac	Lincomix-Coban-Roxarsone	Stafac [®] + Bio-Cox [®] + 3-Nitro [®]
Bio-Cox + 3-Nitro + BMD	MAXIBAN and 3-NITRO	STENOROL [®] / 3-NITRO [®]
Bio-Cox + Roxarsone + Lincomix	MAXIBAN and BMD and 3-NITRO	Stenorol [®] plus 3-Nitro [®] plus BMD [®]
Bio-Cox [®] / 3-Nitro [®] / Baciferm [®]	Monensin + Bacitracin MD + Roxarsone	Zinc Bacitracin & Amprol HI-E [®]

USEFUL LINKS:

- FDA Press Release: <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm258342.htm>
- Related Q & A: <http://www.fda.gov/AnimalVeterinary/SafetyHealth/ProductSafetyInformation/ucm258313.htm>
- FDA Reports: <http://www.fda.gov/AnimalVeterinary/SafetyHealth/ProductSafetyInformation/ucm257540.htm>

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