



From:

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To: [REDACTED] Telephone: [REDACTED] Fax: [REDACTED] Email: [REDACTED]	Re: Clinacox® 0.5% Premix, BMD® 110 G, Safe-Guard® Premix 20% Case Id: ON-032621-22810 Date of Response: Mar 29, 2021 8:06:09 AM
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Case Information:

Date Submitted Mar 26, 2021 12:54:00 PM
Species Turkeys
Number of Animals 13000
Location of Animals
Reason for Use

Additional Information The total length of time that diclazuril (1ppm) and bacitracin (55ppm) are in the feed is 70 days.

Drugs Administered

Drug Trade Name	Generics	Route	Dose	Diseases
Clinacox® 0.5% Premix	• diclazuril	Oral - Feed	1 ppm (in feed) Continuously for 6 days	• Alimentary: coccidiosis
BMD® 110 G	• bacitracin	Oral - Feed	55 ppm (in feed) Continuously for 6 days	• Alimentary: necrotic enteritis - clostridium perfringens
Safe-Guard® Premix 20%	• fenbendazole	Oral - Feed	16 ppm (in feed) Continuously for 6 days	• Alimentary: endoparasites - ascarids • Alimentary: endoparasites - heterakis

Response and Recommendation: 24 hours

Diclazuril is approved for use in turkey feeds as an aid in the prevention of coccidiosis at 1 ppm to be fed from one day of age to a maximum of 14 weeks of age with a zero day withdrawal time. Recent changes in legislation removed all growth promotion claims on feed additive drugs in Canada. These changes resulted in no "on label" claim for bacitracin in turkeys. Bacitracin was approved for use in turkey feeds "as an aid in improving the rate of gain and feed efficiency" at 4.4 ppm to be fed to market weight with no withdrawal time. Based on very limited available information, it appears that the zero withdrawal time for bacitracin in turkeys in Canada was based on the very low oral bioavailability of this drug. Historically, when there was no Canadian MRL in turkeys, we recommended a very conservative meat withdrawal interval of 5 days when the bacitracin dose is increased up to 55 ppm in turkey feeds. The Canadian MRL for bacitracin in turkey tissues has now been established at 0.5 ppm (kidney, liver, muscle, and skin & fat) which is the same as the United States. Bacitracin is approved in the United States for use in turkeys at concentrations of 4.4- 55 ppm and 220 ppm with no withdrawal time. Since the MRLs for bacitracin in turkeys have not changed, it appears that doses up to 220 ppm will not result in violative residues. However, to comply with CgFARAD™ policy of recommending a "greatly extended" withdrawal interval for extralabel drug use in food animals, we recommend following a minimum 24 hours meat withdrawal interval for this use of bacitracin in turkeys. Fenbendazole (Safe-Guard® Premix 20%) is approved as a dewormer for growing turkeys in Canada at 16 ppm to be fed for 6 days with a withdrawal time of 24 hours. We are not aware of any interaction between these drugs that would require further extension of the withdrawal intervals. As such, we recommend following a withdrawal interval of at least 24 hours for this combination.

Therefore, the Canadian gFARAD recommends a withdrawal interval of 24 hours, which should be sufficient so that detectable residues are not found. Furthermore, this recommendation for residue avoidance does not address the risks of developing or transmitting antimicrobial resistance from treated animals to other animals or humans following the extralabel use of this antimicrobial. Because the Canadian gFARAD withdrawal recommendation is not an official withdrawal time and is based on data that has not been reviewed nor approved by the Veterinary Drugs Directorate or the Canadian Food Inspection Agency, responsibility for residue violations rests with the attending veterinarian.

To review this request in CgFARAD:

<https://farad.usask.ca/cgfarad/vet/viewRequest?id=22810&lang=en>