Extra Label Use of Feed Medications in Minor Species

In December of 2016, the Food & Drug Administration (FDA) issued Compliance Policy Guide Sec. 615.115 entitled "Extra label Use of Medicated Feeds for Minor Species" to provide a mechanism by which minor species may be treated via medicated feed. Minor species are defined by the FDA by exclusion. Minor species are animals other than the major species of cattle, swine, horses, chickens, turkeys, dogs and cats.

If the process and requirements outlined in CPG Sec. 615.115 **(https://www.fda.gov/media/71960/download)** are followed, a veterinarian may consider and authorize the extra label use of medicated feed in minor species. Several conditions are required for the consideration of extra label medicated feed use in minor species, including:

1. There are no approved treatment options available.
2. The health of the animals is threatened.
3. Failure to treat the animals would result in suffering or death.

Additionally, extra label drug use under CPG Sec. 615.115 is limited to the following situations:

1. Use of medicated feed in a minor species not listed on the label.
2. Use of medicated feed to treat a disease indication not listed on the label.

The actual Compliance Policy Guide issued by the FDA can be found **here**. The Veterinarian Considerations are on pages 6-8 of the CPG Sec. 615.115.

It is important to understand that this CPG from the FDA does not actually legalize the extra label use of medicated feeds. The FDA position regarding the use of extra label medicated feeds is one of regulatory discretion and that in general, they will not recommend or initiate enforcement when extra label use of medicated feed is consistent with and meets the requirements of their CPG Sec. 615.115.

Several other requirements must be met when using medicated feed in an extra label fashion in aquatic species:

1. Extra label use of medicated feed for aquaculture species is limited to feed medications approved for use in aquatic species.
2. An additional written authorization document of the medical rationale for extra label medication use must be prepared by the authorizing veterinarian and accompany the **VFD**.
3. An extended withdrawal period should be specified for extra label medicated feed usage to prevent violative residues.

To comply with CPG Sec. 615.115, a **VFD form** must be completed along with a **separate authorization form** providing the medical rationale justifying the extra label medication use. Additional statements must also be included in the special instructions box on the VFD. This form must state:

- This VFD is being issued in accordance with CPG Sec. 615.115.
- Species to be treated (no need to circle a disease/pathogen in the table on the VFD).
- Do not slaughter treated animals for human consumption for _____ days after completion of treatment.

Please refer to the referenced CPG for a full listing of expectations, conditions and requirements for extra label use of feed medications in minor species.

EXAMPLE AUTHORIZATION FORM

Extra label Use of Type C Medicated Feed for Minor Species

This is a recommendation to use VFD feed in accordance with FDA CPG Sec. 615.115.
(Keep this form with appropriate VFD; 2 years retention period post-expiration date.)

Veterinarian: _____ Client/Producer: _____

Address: _____ Address: _____

_____ _____

_____ _____

Phone:_____ Phone:_____

Email *(optional)*:_____ Email *(optional)*:_____

Fax *(optional)*:_____ Fax *(optional)*:_____

This document and the accompanying VFD authorize you to feed this VFD feed to:

- Animal/Species to be treated:_____
- Diagnosis:_____
- Drug/Product selected for therapy:_____
- Dose:_____
- Duration of treatment (# of days; feedings/day, etc.):_____
- Location of animals to be treated:_____
- Slaughter/Harvest withdrawal period (extended):_____
- Cautions/Warnings/Comments:_____

VFD Date of Issuance (Month/Day/Year):_____

VFD Expiration Date (*not to exceed 6 months after issuance*) (Month/Day/Year):_____

Adverse Event Statement: Please report any observed or suspected adverse reactions in animals treated with this medication to your veterinarian or manufacturer of the medicated feed drug.

Veterinarian's signature: _____

(1 copy to Veterinarian; 1 copy to Client/Producer)