

Extralabel Use of Medicated Feeds for Minor Species

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Overview

In December of 2016 the Center for Veterinary Medicine of the FDA issued a revised Compliance Policy Guide (CPG) in which the extralabel use of approved drugs in medicated feed may be considered for minor species.

Minor species are defined as animals other than cattle, horses, swine, chickens, turkeys, dogs, and cats. Extralabel use of medicated feed may be considered for treatment of minor species when there are no approved treatment options available and the health of animals is threatened, and suffering or death would result from failure to treat the affected animals.

When Extralabel Use is Allowed

For a veterinarian to authorize the extralabel use of medicated feed in minor species, they must meet the following criteria:

1. Have a valid Veterinary Client Patient Relationship (VCPR)
 - a. Veterinarian has assumed responsibility for making medical judgments and the client has agreed to follow the instructions of the veterinarian
 - b. Veterinarian has sufficient knowledge of the animals to initiate a diagnosis
 - c. Practicing veterinarian is readily available for follow-up in the case of adverse reactions and has recently seen or is personally acquainted with the care of the animals by virtue of examination of the animals and/or by timely visits to the premises
2. Limit the extralabel use to:
 - a. A minor species not listed in the approved drug labeling or the use indications for that minor species not listed in the labeling
 - b. A medication approved for use in animal feed
 - c. Use in a minor species similar to the species for which the medicated feed is approved
 - i. Aquaculture is limited to medicated feeds approved for use in aquatic species
 - ii. Avian species are limited to medicated feeds approved for use in avian species
 - iii. Mammalian species are limited to medicated feeds approved for use in mammalian species
 - d. Farmed or confined minor species
 - e. Therapeutic treatment and not production (claim) purposes
 - f. Non-promotional use (no advertising of the medicated feed for an extralabel use)

Minor Species VFDs and Documentation

For drugs requiring a Veterinary Feed Directive (VFD), the veterinarian must:

1. Complete a separate written recommendation to the client including the medical rationale and the withdrawal period with copies maintained by the veterinarian and client for 2 years
2. Complete a VFD consistent with the approved labeling for the indication (write for a major species and indication) and in special instructions note:
 - a. "This VFD is being issued in accordance with CPG 615.115"
 - b. The actual species for which the medicated feed is intended, and
 - c. The withdrawal time associated with the extralabel use if different than the labeled withdrawal time as already reflected on the VFD.

GlobalVetLINK's electronic VFD system, FeedLINK®, includes a minor species feature to assist veterinarians with completing a VFD for minor species in accordance with CPG 615.115. Visit www.globalvetlink.com to learn more.

To view the full CPG 615.115 from the FDA CVM, visit:

fda.gov/downloads/iceci/compliancemanuals/compliancepolicyguidancemanual/ucm529668.pdf