

## VFD Terminology



### Veterinary Feed Directive Terminology:

A helpful guide to understand the language used to write VFDs.

This document is designed to aid licensed veterinarians in writing complete and accurate Veterinary Feed Directives (VFDs). The definitions provided are taken from the Code of Federal Regulations (CFR) Title 21, Chapter 1, Subchapter E, Part 558, which is the Federal resource for VFD terminology.

#### The Code of Federal Regulations What is it?

- ➤ The Code of Federal Regulations (CFR) is the codification of the general and permanent laws published in the Federal Register by the executive departments and agencies of the Federal Government. Specifically, 21 CFR Part 515 Subpart A (21 CFR 558.3-558.6) is the legal framework that outlines how VFDs must be written and what is required both from the veterinarian and feed distributor.
- ➤ CFR Title 21, Chapter 1, Subpart E, Part 558 can be accessed from the following website: https://www.ecfr.gov/current/title-21/chapter-I/subchapter-E/part-558

#### Category I Drugs

<u>Category I Drugs</u> require either no withdrawal period at the lowest use level in each major species for which they are approved, or they are approved for use only in minor species.

#### Category II Drugs

- All drugs classified as <u>Category II drugs</u> are those that require a withdrawal period at the lowest use level for at least one major species for which they are approved. This general definition can be found in <u>21 CFR 558.3</u>, and information about specific VFD drugs and withdrawal times can be found in 21 CFR 558 Subparts A and B.
  - Category II Drugs also may be regulated on a "no-residue" basis or with a zero tolerance because of carcinogenic concern regardless of whether a withdrawal period is required in any species (major or minor).





#### Type A Medicated Article

- ➤ The most concentrated form of a drug, a <u>Type A medicated article</u> is never fed directly to animals. Its uses include:
  - The manufacture of another Type A medicated article.
  - The mixture with feed and/or feed ingredients to create a Type B medicated feed, which contains the VFD drug for distribution and further mixing on a farm or facility.
  - The creation of a ready-to-administer, Type C medicated feed, which contains the VFD drug.
- Category I, Type A medicated articles can be distributed to an animal producer/owner.
- Category II, Type A medicated articles cannot be distributed to an animal producer/owner. Only feed manufacturers that have a medicated feed mill license from the FDA can distribute a Category II, Type A medicated article (21 CFR Part 515).

#### Type B Medicated Feed

- ➤ A <u>Type B medicated feed</u> is a concentrated medicated feed that is made from the dilution of a Type A medicated article with a feed or feed ingredients. It, therefore, contains a lower drug concentration than a Type A medicated article.
- ➤ A Type B medicated feed is not fed to animals and is intended solely for the manufacture of other medicated feeds (Type B or Type C) through further mixing and/or dilution.
- Only feed manufacturers that have a medicated feed mill license from the FDA can manufacture a Type B medicated feed containing a Category II, Type A medicated article (21 CFR Part 515).





#### Type C Medicated Feed

- A <u>Type C medicated feed</u> is intended for use as the complete feed for the animal, or a Type C medicated feed may be fed top dressed or offered free choice in conjunction with other animal feed.
- A Type C medicated feed is manufactured by diluting a Type A medicated article or a Type B medicated feed with additional feed or feed ingredients.
- A Type C medicated feed may be further diluted to produce another Type C medicated feed.
- Only feed manufacturers that have a medicated feed mill license from the FDA can manufacture a Type C medicated feed containing a Category II, Type A medicated article (21 CFR Part 515).

#### Free-Choice Medicated Feed

- A Free-Choice, Type C Medicated Feed is one that is offered freely in conjunction with other animal feed, which ultimately allows the animal to balance their own diet (21 CFR 558.3(b)(4)).
- The Free-Choice feed is often placed in the feeding or grazing area, and is not intended to be consumed entirely at a single feeding (21 CFR 510.455).
- Examples include medicated blocks, mineral mixes, or liquid feed tank ("lick tank") supplements (21 CFR 510.455).
- ➤ The manufacture of Free-Choice medicated feeds is subject to good manufacturing practices outlined in (21 CFR Part 225), and may require an FDA feed mill license to produce.





#### Hand-Fed Medicated Feed

- A Hand-Fed medicated feed is a Type C medicated feed that may or may not compose the animal(s)' complete diet (Q&A: FDA Approved Free-Choice Feeding Options)
  - Linked here: <a href="https://www.fda.gov/animal-veterinary/development-approval-process/questions-and-answers-fda-approved-free-choice-feeding-options-anaplasmosis-control-cattle">https://www.fda.gov/animal-veterinary/development-approval-process/questions-anaphasmosis-control-cattle</a>
- Separate from Free-Choice medicated feeds, Hand-Fed feeding systems require:
  - Observation of the animal(s) being fed for adverse reactions
  - Daily feeding with the intention of providing the entire daily drug dose over a 24-hour period
  - Approved duration of use

#### Top Dress Medicated Feed

A Top Dress, Type C medicated feed is meant to be added on top of an animal's usual ration (21 CFR 558.3(b)(4)).

#### Major Species

Cattle, horses, swine, chickens, turkeys, dogs, and cats (21 CFR 516.3 "Major species").

#### Minor Species

Animals, other than humans, which are not major species such as: sheep, goats, llamas, alpacas, rabbits, and exotic species (e.g., fish, psittacine birds, etc.) (21 CFR 516.3 "Minor species").





#### Requirement of a Medicated Feed Mill License

- ➤ A feed manufacturing facility must possess an <u>FDA medicated feed mill license</u> to manufacture the following (21 CFR 510.455):
  - Type B or Type C medicated feed containing a Category II, Type A medicated article

#### OR

 All free-choice medicated feeds containing a Category II, Type A medicated article

#### OR

- Free-Choice medicated feeds from a Category I, Type A medicated article that utilize a specific proprietary formula and/or specifications
- The manufacture of the following types of feed are **exempt** from the required license, unless otherwise specified (21 CFR 558.4):
  - Type B or Type C medicated feed containing a Category I, Type A medicated article or containing Category I, Type B or Type C medicated feeds AND
  - Type B or Type C medicated feed containing Category II, Type B or Type C medicated feeds

#### AND

 A free-choice medicated feed containing a Category I, Type A medicated article that conforms to an FDA approved, public formulation and/or specifications as outlined in the CFR





#### Blue Bird Labels

- ➤ When a Type A medicated article is approved for a new animal drug application (NADA), the drug sponsors are required to submit what are called "Blue Bird Labels" (21 CFR 514.1(b)(3)(v)(b)).
- ➤ Blue Bird Labels are examples of Type B and Type C medicated feed labels.
  - They are created for manufacturers of medicated animal feeds.
  - The Blue Bird Labels act as a guide for the preparation of the final feed labels to be printed and distributed.
- Search for Blue Bird Labels to help with writing VFDs by searching the database on Animal Drugs @ FDA
  - Link here: <a href="https://animaldrugsatfda.fda.gov/adafda/views/">https://animaldrugsatfda.fda.gov/adafda/views/</a>