Understanding “Free Choice” and “Hand Fed” Feeds Which Include Chlortetracycline

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Overview

As the new VFD labels come into effect, a common question is the status of “free choice” and “hand fed” feeds, especially in relation to medicated mineral feeds.

Free choice is defined as “a method of feeding livestock in which various feeds are kept constantly available and the feeders (animals) are allowed to balance their own diet.”

Hand fed, on the other hand, is a designation assigned in the drug approval process in which feed is required to be fed daily in order for the animals to be observed each day when there is concern for adverse drug reactions.

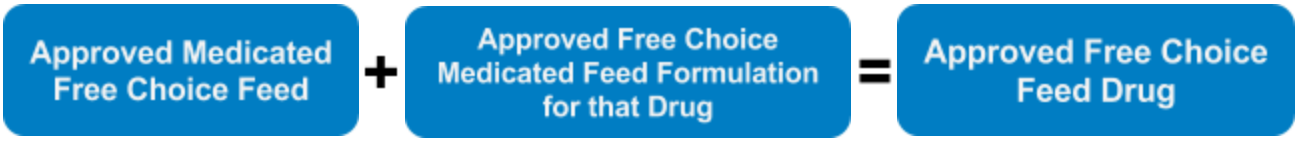
Feeding Method	Definition
Free Choice	Feed is kept constantly available, animals balance their own diet
Hand Fed	Fed daily in order for the animal to be observed daily

There is only one approved chlortetracycline indication for free choice feeds:
“Beef and non-lactating dairy cattle: As an aid in control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline when delivered in a free-choice feed.”

There are four **proprietary** FDA approved free choice feed formulations and one **public** FDA approved free choice feed formulation containing the approved chlortetracycline free choice indication for control of active cases of Anaplasmosis. All other indications and formulations are to be hand fed (fed daily).

It is illegal for a veterinarian to fill out a VFD for a label application of a feed drug knowing that it will be used in another manner (e.g., dose, duration, indication, or feeding practices). It is illegal for a distributor to distribute feed based on a VFD knowing that the intended use is different than on the VFD. It is illegal for the recipient of the VFD to use the feed in any manner than as authorized on the VFD.

Regardless of personal opinions on these new drug labels, previous practices, and the associated VFD process, it is important that all beef cattle veterinarians be on the same page regarding the regulatory situation.



For more detailed and technical information, please see the full article.

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Free Choice Feeds
A mineral feed (or any feed) may only be labeled as a free choice feed when both the drug label and the feed formulation have been approved for this indication by the Food and Drug Administration Center for Veterinary Medicine (FDA/CVM).

In the case of a free choice feed, the intake is determined by the feed formulation, and the animal's intake of that formulation, rather than by the amount provided each day. In other words, the intake of the drug (the dose) is determined by the feed ingredients, the formulation of these ingredients, and the concentration of the drug. Therefore, the formulation of a free choice feed must be approved by the Food and Drug Administration Center for Veterinary medicine. This approval includes manufacturing and intake considerations. Below is the list of the drug approval and the formulations which may be used in free choice feeds containing chlortetracycline.

Drug Approval
There is only one approved chlortetracycline indication for free choice feeds.

> "Beef and non-lactating dairy cattle: As an aid in control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline when delivered in a free-choice feed. Free-choice feed must be manufactured under a feed mill license utilizing an FDA-approved formulation. (Exception: a medicated feed mill license is not required to manufacture the 6000 g/ton free choice mineral feed formulation published at 21 CFR §558.128(e) (6))"

Free choice feed approvals which contain the above approved chlortetracycline approval: (there are 5)

These are the four FDA approved, **proprietary**, free choice feed formulations containing the approved chlortetracycline free choice indication for control of active cases of Anaplasmosis. **Must** be manufactured by a federally licensed feed mill according to the proprietary formulation. Simply including chlortetracycline in a feed at this concentration does not create an approved formulation.

8000 g/ton medicated mineral feed (ADM)
6000 g/ton medicated mineral feed (Ridley USA)
5000 g/ton pressed block product (Purina)
700 g/ton pressed block product (Ridley USA)

This is the one FDA approved, **public**, free choice feed formulation containing the approved chlortetracycline free choice indication for control of active cases of Anaplasmosis. **No requirement to** be manufactured by a federally licensed feedmill. This is the published formulation referenced in the label indication above.

6000 g/ton public formulation (Zoetis)

Hand Fed Feeds
This term is the source of confusion as we move into the VFD era. From a regulatory standpoint, the designation “hand fed” on a feed drug label is added during the approval process when there is concern for adverse drug reactions, and the feed is required to be fed daily in order for the animals to be observed daily. It refers to the drug, not the formulation. This designation is most commonly applied to a feed to be fed on pasture.

In common industry use, the terms “hand fed” and “limit fed” have been used to described feeds fed on a daily basis, whether once or multiple times a day. This is an understanding of the terms based on how the feed is fed (at least once daily).

What This Means
Regardless of how “hand fed” is interpreted in common use, it is clear that the term “hand fed” is not the same as free choice, and that the term free choice stands out alone as having an approved drug label provided in an approved feed formulation. Both the drug and the formulation must be approved for the free choice application. The same approved free choice drug may be marketed in multiple approved free choice formulations.

In the past, unapproved medicated mineral formulations have been manufactured and marketed as “free choice” feeds without regulatory intervention. Regardless of wording on the feed tag, these formulations were clearly meant to be fed in a free choice manner. In these cases, the term “free choice” not based on and FDA approval.

Regardless of terminology, feeding a medicated mineral feed other than in a manner of daily feeding meets the definition of free choice, and the drug and formulation must be approved for such use. If an unapproved drug regimen, and/or an unapproved free choice feed formulation are used to manufacture a medicated mineral feed (or any feed) with the intended use of being fed in a free choice manner, then that drug and the feed are considered adulterated by the FDA/CVM.
When the term “hand fed” is affixed to a feed label, it indicates that the feed is to be fed to the animals on a daily basis. This term gives no special regulatory status to the medicated feed other than clarifying that it is not a free choice feed. Also, the term does not refer to the method of handling the feed bag by hand, as in “hand feeding every week”. Adding “hand fed” to the feed tag does not change the label of the feed drug contained in the feed, but such addition could confuse the user leading to a possible extra-label drug use situation.

The following are illegal acts which apply to any feed.

1. It is illegal for a veterinarian to write a VFD for use in any animal species for any other indication than on the drug label. In the case of minor species, FDA CVM Compliance Policy Guide 615.115 outlines where special instructions and an accompanying document may be used to authorize extralabel use in specific circumstances. This extralabel use process does not apply to major species such as cattle, swine, chickens, or turkeys, and extralabel use in these major species is prohibited.
2. It is illegal to fill out a VFD for a label application of a feed drug, knowing that it will be used in another manner (e.g., dose, duration, indication, or feeding practices)
3. It is illegal for a distributor to distribute feed based on a VFD knowing that the intended use is different than on the VFD.
4. It is illegal for the recipient of the VFD to use the feed in any manner than as authorized on the VFD.
5. It is illegal to feed a Type A medicated article or a Type B medicated feed (a premix) as a Type C final feed.

Clarification on chlortetracycline labels: A good example of the exact wording for chlortetracycline approved indications is the Aureomycin® VFD form. Got to this website and go to the sixth VFD form (Aureomycin VFD final form beef cattle): https://www.zoetisus.com/products/vfd/index.aspx. (This is not an endorsement of this specific product.)

If a mineral product is citing any other indication than #5 on the Zoetis Aureomycin VFD form, by definition, there cannot be an approved free choice formulation because that indication is not approved for free choice (free choice feed approval = free choice drug approval + free choice feed formulation approval). Even for a 6000 g/ton formulation, if they are not using one of the approved formulations, then a veterinarian cannot write a VFD for free choice feeding for control of active infections of anaplasmosis. Also, just including an approved drug per label does not automatically make a free choice feed (such as a mineral) legal.

Common feed formulations to deliver 350 mg/head per day have been 2800 g CTC/ton for stockers and 5600 g CTC/ton for cows. For example, #2 on the above referenced VFD form could be provided in this manner by being fed daily. The higher concentration could be fed to achieve 0.5 mg CTC/lb of bodyweight for indication #4 on the above referenced VFD form, when fed daily. Neither these label indications, or the 2800 g/ton or 5600 g/ton formulations, are approved for free choice feeds.

There has been confusion that the free choice label (#5 on the VFD form) is for 0.5 to 2.0 mg/lb of chlortetracycline per day and therefore a veterinarian can authorize this dose with subsequent formulation by a feed manufacturer in any desired formulation. The discussion above shows why this is an untrue statement; only an approved free choice drug label in an approved formulation may be fed in a free choice manner.

Some may consider an attempt to authorize the free choice feeding of an unapproved formulation by including a statement such as “to be fed as a free choice feed” in the special instructions box. This inclusion would create an invalid VFD authorizing illegal extralabel use, unless the label indication on the VFD is for an approved free choice feed drug indication and this is an approved free choice feed formulation for this drug indication.

If authorizing another brand of chlortetracycline, steps should be taken to assure that the label indications are in fact equivalent (as in including all of the indications of the above label, especially concurrent feeding approvals). No brand of chlortetracycline has free choice formulation approvals other than described on the Aureomycin VFD form cited above.

In summary:
Approved free choice feed drug **+** approved free choice medicated feed formulation for that drug **=** Approved medicated free choice feed