Medicated Products

- Type A medicated article
- Type B medicated feed
- Type C medicated feed

Medicated Feed Parentage

Medicated Products

The Veterinarian and Medicated Feed: Roles

What is changing
Introduction

New Rule

FDA Organization Overview

Agenda
- Introduction
  - Medicated Feeds, Water, GFI 209 and GFI 213
- Overview of the New Rule
  - Background
  - Definitions
  - Major Provisions
  - General Requirements
  - Veterinarian Requirements
- Important dates
  - October 1, 2015
  - January 1, 2017
- Conclusions

Approved New Animal Drugs and Their Uses

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21 CFR 500

21 CFR 558

21 CFR 520

Oral

21 CFR 500

Animal Drugs, Feeds, and Related Products

21 CFR 558

New Animal Drugs for Use in Animal Feeds

OTC

Rx

VFD

Guidance For Industry 209

Explains Judicious Use of Medically Important Antimicrobial New Animal Drugs

Guidance For Industry 213

Explains the Timing and Manner of Acting per 213

Introduction

21 CFR 500

Animal Drugs, Feeds, and Related Products

21 CFR 520

New Animal Drugs for Use in New Animal Drugs

Water

21 CFR 558

New Animal Drugs for Use in Animal Feeds

OTC

VFD

Background

With passing the ADAA in 1996, Congress created a new regulatory category for certain animal drugs used in animal feed called veterinary feed directive drugs or VFD drugs

FDA has determined that some new animal drugs, vital to animal health, should be approved for use in animal feed but only if such medicated feeds are used under the professional supervision of a licensed veterinarian in the course of the veterinarian’s practice

What is VFD?

VFD is a drug

A “veterinary feed directive (VFD) drug” is a new animal drug intended for use in or on animal feed which is limited by an approved, conditionally approved application, or index and for use only under the professional supervision of a licensed veterinarian who authorizes such use by a lawful veterinary feed directive.

VFD is a document

A “veterinary feed directive” is a written (nonverbal) statement issued by a licensed veterinarian in the course of the veterinarian’s professional practice that orders the use of a VFD drug or combination VFD drug in or on an animal feed, and this written statement authorizes the client (the owner of the animal or animals or other caretaker) to obtain and use animal feed bearing or containing a VFD drug or combination VFD drug to treat the client’s animals only in accordance with the approved, conditionally approved application, or index.
A "distributor" means any person who distributes a medicated feed containing a VFD drug to:

- another distributor, or
- the client-recipient of a VFD.

A "combination VFD drug" means a combination veterinary feed directive (VFD) drug intended for use in or on animal feed which is limited by an approved application and can be used only under the professional supervision of a licensed veterinarian when authorized by a lawful VFD.

New Rule – “Veterinary feed directive drugs” (21 CFR 558.6)

(a) General requirements related to veterinary feed directive (VFD) drugs
(b) Responsibilities of the veterinarian issuing the VFD
(c) Responsibilities of any person who distributes an animal feed containing a VFD drug or a combination VFD drug

New Rule - General Requirements (21 CFR 558.6(a))

- Animal feed bearing or containing a VFD drug or a combination VFD drug (a VFD feed or combination VFD feed) may be fed to animals only by or upon a lawful VFD issued by a licensed veterinarian.

VFD Feed → Animals

VFD Required
Animal feed bearing or containing a VFD drug or a combination VFD drug (a VFD feed or combination VFD feed) may be fed to animals only by or upon a lawful VFD issued by a licensed veterinarian.

A VFD feed or combination VFD feed must not be fed to animals after the expiration date on the VFD.

Use and labeling of a VFD drug or a combination VFD drug in feed is limited to the approved, conditionally approved, or indexed conditions of use. Use of feed containing this veterinary feed directive (VFD) drug in a manner other than as directed on the labeling (extralabel use) is not permitted.

All involved parties (the veterinarian, the distributor, and the client) must retain a copy of the VFD for 2 years. The veterinarian must retain the original VFD in its original form (electronic or hardcopy). The distributor and client copies may be kept as an electronic copy or hardcopy.

All labeling and advertising for VFD drugs, combination VFD drugs, and feeds containing VFD drugs or combination VFD drugs must prominently and conspicuously display the following cautionary statement:

“Caution: Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian.”

Repository of Blue Bird labels: http://www.fda.gov/AnimalVeterinary/Products/AnimalFoodFeeds/MedicatedFeed/BlueBirdLabels/default.htm

(1) In order for a VFD to be lawful, the veterinarian issuing the VFD must:

- be licensed to practice veterinary medicine
- be operating in the course of the veterinarian’s professional practice and in compliance with all applicable veterinary licensing requirements, and in the context of a VCPR (State or Federal)

http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm460406.htm
New Rule – Veterinarian Responsibilities
(21 CFR 558.6(b))

(1) In order for a VFD to be lawful, the veterinarian issuing the VFD must:
- be licensed to practice veterinary medicine
- be operating in the course of the veterinarian’s professional practice and in compliance with all applicable veterinary licensing requirements, and in the context of a VCPR (State or Federal)

(2) Issues a VFD in compliance with the conditions for use approved, conditionally approved, or indexed for the VFD drug or combination VFD drug

(3) Includes fully and accurately all required information

(4) Includes the following optional information

Information Required on VFD

1. Vet’s and client’s names/address/telephone
2. The premises at which the animals specified in the VFD are located
3. Date of VFD issuance
4. VFD expiration date
5. The name of the VFD drug
6. Species and production class of the animals to be fed the VFD feed
7. The approximate number of animals to be fed by the expiration date of the VFD
8. The indication for which the VFD is issued
9. Drug level and duration of use
10. Withdrawal time/special instructions/cautions
11. Number of refills (if permitted by the drug approval)
12. The statement: “Use of feed containing this veterinary feed directive (VFD) drug in a manner other than as directed on the labeling (extralabel use) is not permitted”
13. An affirmation of intent for combination VFD drugs
14. Veterinarian’s electronic or written signature

Information Optional on VFD

1. More specific description of the location of treated animals (e.g., pen…)
2. The approximate age/weight range of the animals
3. Any other information the veterinarian deems appropriate to identify the animals specified in the VFD

VFD Example

VFD Rule – Veterinarian Responsibilities
(21 CFR 558.6(b))

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(2) Issues a VFD in compliance with the conditions for use approved, conditionally approved, or indexed for the VFD drug or combination VFD drug

(3) Includes fully and accurately all required information

(4) Includes the following optional information

(5) Includes the drug-specific information for each VFD drug used in the combination
VFD Rule – Veterinarian Responsibilities
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2. Issues a VFD in compliance with the conditions for use approved, conditionally approved, or indexed for the VFD drug or combination VFD drug
3. Includes fully and accurately all required information
4. Includes the following optional information
5. Includes the drug-specific information for each VFD drug used in the combination
6. Affirms the VFD drug(s) may be used alone or in an approved combination with over-the-counter drug(s)

Affirms his/her intent on VFD

1. This VFD only authorizes the use of the VFD drug(s) cited in this order and is not intended to authorize the use of such drug(s) in combination with any other animal drug(s).
2. This VFD authorizes the use of the VFD drug(s) cited in this order in any FDA-approved, conditionally approved, or indexed combination(s) in medicated feed that contains the VFD drug(s) as a component.
3. This VFD authorizes the use of the VFD drug(s) cited in this order in any FDA-approved, conditionally approved, or indexed combination(s) in medicated feed that contains the VFD drug(s) as a component.

VFD example

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VFD example
(i) "This VFD only authorizes the use of the VFD drug(s) cited in this order and is not intended to authorize the use of such drug(s) in combination with any other animal drug(s)."

(ii) "This VFD authorizes the use of the VFD drug(s) cited in this order in the following FDA-approved, conditionally approved, or indexed combination(s) that contains the VFD drug(s) as a component or in any FDA-approved, conditionally approved, or indexed combination medicated feed containing the VFD drug(s) as a component."

(iii) "This VFD authorizes the use of the VFD drug(s) cited in this order in any FDA-approved, conditionally approved, or indexed combination(s) in medicated feed that contains the VFD drug(s) as a component."

If a VFD drug is not approved in a combination, only first of the three statements could be included on the VFD order.

VFD Rule – Veterinarian Responsibilities

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   - issues a VFD in compliance with the conditions for use approved, conditionally approved, or indexed for the VFD drug or combination VFD drug
   - includes fully and accurately all required information
   - includes the following optional information
   - includes the drug-specific information for each VFD drug used in the combination
   - affirms whether the VFD drug(s) may be used alone or in an approved combination with over-the-counter drug(s)
   - issues VFD in writing (nonverbally)
VFD Rule — Veterinarian Responsibilities
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3. Includes fully and accurately all required information
4. Includes the following optional information
5. Includes the drug-specific information for each VFD drug used in the combination
6. Affirms whether the VFD drug(s) may be used alone or in an approved combination with over-the-counter drug(s)
7. Issues VFD in writing (nonverbally)
8. VFD could be hardcopy or electronic and must be sent to the distributor
9. Provides a copy to the client

VFD — where do I transmit it

- VFD is a written (non verbal) statement and can be hardcopy or electronic
- If the VFD is transmitted electronically, the veterinarian is not required to send the original in hardcopy to the distributor
- The veterinarian keeps the original VFD

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New Rule — Distributors Responsibilities
(21 CFR 558.6(c))

- is permitted to fill a VFD only if the VFD contains all the required information
- is permitted to distribute an animal feed containing a VFD drug or combination VFD drug only if it complies with the terms of the VFD and is manufactured and labeled in conformity with the approved, conditionally approved, or indexed conditions of use for such drug

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- must keep records of the receipt and distribution of all medicated animal feed containing a VFD drug for 2 years

In addition to other applicable recordkeeping requirements found in this section, if the distributor manufactures the animal feed bearing or containing the VFD drug, the distributor must also keep VFD feed manufacturing records for 1 year in accordance with part 225 of this chapter. Such records must be made available for inspection and copying by FDA upon request.

Distributors Record Keeping

New Rule – Distributors Responsibilities
(21 CFR 558.6(c))

- must notify FDA prior to the first time it distributes animal feed containing a VFD drug. The notification is required once per distributor and must include the following information:
  1. The distributor’s complete name and business address;
  2. The distributor’s signature or the signature of the distributor’s authorized agent; and
  3. The date the notification was signed.

- must also notify FDA within 30 days of any change in ownership, business name, or business address. The notifications must be submitted to:
  Food and Drug Administration,
  Center for Veterinary Medicine,
  Division of Animal Feeds (HFV-220),
  7519 Standish Pl.
  Rockville, MD 20855
  FAX: 240-453-6882

A distributor is permitted to distribute a VFD feed to another distributor only if the originating distributor (consignor) first obtains a written (nonverbal) acknowledgment letter, as defined in § 558.3(b)(11), from the receiving distributor (consignee) before the feed is shipped. Consignor distributors must retain a copy of each consignee distributor’s acknowledgment letter for 2 years.
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**Drugs approved for feed use**

- Amprolium
- Amprolium and ethopabate
- Apramycin
- Avilamycin
- Bacitracin methylenedisalicylate
- Bacitracin zinc
- Bambermycins
- Carbadox
- Chlortetracycline
- Chlortetracycline and sulfamethazine
- Clopidol
- Decoquinate
- Diclazuril
- Dichlorvos
- Efrotomycin
- Erythromycin
- Famphur
- Fenbendazole
- Florfenicol
- Halofuginone
- Hygromycin B
- Iodinated casein
- Ivermectin
- Laidlomycin
- Lasalocid
- Lincomycin
- Maduramicin
- Melengestrol
- Mibolerone
- Monensin
- Morantel tartrate
- Narasin
- Neomycin sulfate
- Nequinate
- Nicarbazin
- Novobiocin
- Nystatin
- Oleandomycin
- Oxytetracycline
- Oxytetracycline and neomycin
- Penicillin
- Poloxalene
- Poloxalene free-choice liquid Type C feed
- Pyrantel
- Ractopamine
- Robenidine
- Salinomycin
- Semduramicin
- Sulfadimethoxine, ormetoprim
- Sulfamerazine
- Sulfaquinoxaline
- Thiabendazole
- Tiamulin
- Tilmicosin
- Tylosin
- Tylvalosin
- Tylosin and sulfamethazine
- Virginiamycin
- Zilpaterol
- Zoalene

**Important Dates**

- **New rule published**: June 3, 2015
- **New rule goes into effect**: October 1, 2015
- **Target date for completion of OTC to VFD conversion**: January 1, 2017

**What should happen?**

- **2000 rule**: At this time will apply only to drugs that are already approved as VFD (avilamycin, florfenicol, and tilmicosin)
- The veterinarian issues VFD according to the new rule
- Keeps the original VFD
- Follows up with no hard copy
- Affirms his/her intent...

**What happened?**

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Conclusions

- Veterinary Feed Directive is an invaluable tool in ensuring proper use of antimicrobial drugs in animal feed
- Veterinarians are key in minimizing the potential for rise in antimicrobial resistance
- New rule clarifies and updates the old rule
- VFD – where the veterinary practice meets medicated feed

Where to look for more information