



# Summary Report

## Veterinary Feed Directives

### 2017 – 2019 Q1



## Acronyms

<b>Acronym</b>	<b>Name</b>
<b>AUS</b>	Antimicrobial Use & Stewardship
<b>CA</b>	California
<b>CDFA</b>	California Department of Food and Agriculture
<b>CDPH</b>	California Department of Public Health
<b>CFR</b>	Code of Federal Regulations
<b>CFRP</b>	Commercial Feed Regulatory Program
<b>CPRA</b>	California Public Records Act
<b>FDA</b>	Federal Food and Drug Administration
<b>FAC</b>	Food and Agricultural Code
<b>GFI</b>	Guidance for Industry
<b>MIAD</b>	Medically Important Antimicrobial Drugs
<b>NIR</b>	Not Independently Reported
<b>SAFE</b>	Safe Animal Feed Education
<b>VFD</b>	Veterinary Feed Directive
<b>VMB</b>	Veterinary Medical Board
<b>VCPR</b>	Veterinary-Client-Patient Relationship

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## Executive Summary

California Senate Bill 27 (Hill, 2015), chaptered as Food and Agricultural Code (FAC) Sections 14400-14408, placed additional restrictions on medically important antimicrobial drugs (MIADs) used in livestock production and mandated the California Department of Food and Agriculture (CDFA) to gather information on sales within the state. To implement the provisions of this law CDFA established the Antimicrobial Use and Stewardship (AUS) program, which is a collaborative effort between the Animal Health and Food Safety Services Division and Inspection Services Division, to assist in collecting information to fulfill this mandate.

Since 2017, CDFA's AUS program has been working closely with the California feed industry in collecting data from animal feed facilities that have filed a letter of intent with the U.S. Food and Drug Administration (FDA) to manufacture, or distribute (sell) medicated animal feed containing MIADs, also known as veterinary feed directive (VFD) drugs (animal drugs intended for use in or on animal feed that require the supervision of a licensed veterinarian). The overarching purpose of the data collection is to support FDA's VFD final rule requirements pertaining to the use of VFD drugs in animal feed, further identify and mitigate antimicrobial resistance in food-producing animals, and to maintain a high standard in promoting public health and welfare.

This report is broken out into five main sections:

- Background
- VFD Compliance
- Data Summaries, Tables and Figures
- Data on 2018 Manufacturing and Distribution Reports
- Looking Forward

The background section introduces key information about the implementation of the FDA's VFD final rule and its influence on the enactment of California's laws on antimicrobial use in food-producing animals. This section further elaborates on how this California law went beyond the required federal regulations by allowing CDFA's AUS program to collect data on MIADs used in medicated feed, containing VFD drugs, from animal feed manufacturers and distributors. This law also protects all confidential information contained within the VFD orders. Following the details of the law and AUS program, the background continues the explanation of VFDs by identifying the differences between a VFD drug, VFD order, and VFD feed by providing legal definitions and online resources for more explanation. As the background section wraps up, short sections are included on compliance and licensing information for feed manufacturers and distributors to lawfully produce and/or sell VFD feed, the scope of reporting within this summary, data collection methods of VFD order information, data confidentiality, and a brief summary of the tables and figures.

The compliance section of this summary gives more in-depth explanation on the evolution of data collection processes from 2017 to 2018 and beyond, and how CDFA's VFD compliance plan adheres to FAC Sections 14400-14408 while providing the most accurate, transparent, and useful data possible for reporting. Furthermore, the

compliance section outlines the early development stages of moving beyond outreach and education efforts when analyzing discrepancies on VFD orders and how violations will be addressed moving forward.

Following the compliance section are figures and tables for the respective VFD orders. Each table has an individual dataset that gives the reader a visual representation of the collected, analyzed, and aggregated VFD order data. This representation of data categories includes: collection of total VFD orders, intended species, VFDs by indication, by drug type/drug combination on the VFD, and so on.

Additionally, the 2018 Manufacturing and Distribution Reports provides a brief summary of the feed produced and distributed and explains additional figures and tables. For a comprehensive list of categories represented please refer to the “Scope of Reporting” sub-section found in the background section.

Finally, this report concludes with looking forward and discusses CDFA’s next steps in working towards reducing antimicrobial resistance in animal agriculture through continuous education, outreach, and compliance measures with the regulated industry. Additionally, it describes how VFD data collection plays a critical role in establishing scientifically accurate, unbiased, and transparent communication with the public, while maintaining data confidentiality in accordance with FAC Section 14407. Most importantly this report clearly conveys CDFA’s dedication to continuous program improvement, and human and animal health.

## Background

In 2015, the U.S. Food and Drug Administration (FDA) enacted stricter requirements for administering MIADs to animals through feed and water. Known as the VFD final rule, these requirements went into effect in 2017 and can be found in Section 558 of Title 21 of the Code of Federal Regulations (CFR). California further supported this effort at the state level through the enactment of FAC Sections 14400-14408 and creation of the AUS program. CDFA has worked to develop AUS into a resource to help veterinarians, producers, manufacturers, distributors and the public gain a better understanding of the VFD final rule, as well as additional state requirements regarding the sale and use of MIADs. AUS also collaborates with CDFA’s Commercial Feed Regulatory Program (CFRP), which is responsible for enforcement of laws and regulations, and the Safe Animal Feed Education (SAFE) program that develops and administers outreach and education efforts for feed manufacturers and distributors.

### **Veterinary Feed Directives**

An important part of the VFD final rule is the mandatory supervision by a licensed veterinarian for any use of MIADs in feed. This means a licensed veterinarian must issue a written document (called a “VFD order”) to authorize use of a MIAD (called a “VFD drug”) in VFD feed. It is important to note that the term VFD, rather than VFD order, is often used to refer to a written order from a licensed veterinarian; however, this report exclusively uses the term VFD order. The following sections describe the distinctions between the terms VFD drug, VFD order and VFD feed.

**VFD Drug:** The condensed definition of VFD drug found in 21 CFR 558.3(6) is a drug that is intended for use in, or on, an animal feed, which must be authorized by a lawful VFD order. VFD drugs are different than other MIADs because they are specifically administered to treat the target animal through medicated feed as opposed to alternate routes of administration, such as treatment by injection or via water. All VFD drugs must be approved in 21 CFR 558.6 for the species and indication of use. A list of approved VFD drugs can be found on FDA's website: <https://www.fda.gov/animal-veterinary/development-approval-process/drugs-veterinary-feed-directive-vfd-marketing-status>.

**VFD Order:** A VFD (or VFD order, for the purposes of this report) is defined under 21 CFR 558.3(7) as a written (nonverbal) statement issued by a licensed veterinarian, pursuant to a veterinary-client-patient relationship, ordering the use of a VFD drug in or on an animal feed. It is important to note that a VFD order is ***not*** a prescription. A VFD order allows the client to obtain and use animal feed bearing or containing a VFD drug to treat the client's animals. VFD orders are also required when issuing the use of a combination VFD drug where one or more VFD drugs are used together, or one or more drugs are used together with at least one being a VFD drug. A VFD order is deemed invalid if it is not completed to the standards outlined in 21 CFR 558.6. Additionally, 21 CFR 558.6(b)3(v) specifies that VFD orders are valid for a maximum six-month period between issue date and expiration, unless the licensed veterinarian sees fit to determine the expiration date sooner than the six-month maximum.

**VFD Feed:** A VFD feed is an animal feed containing a VFD drug. A VFD order is required to purchase and feed, a VFD feed. VFD orders can only be filled by a feed manufacturing firm licensed to make medicated feed, or by a distributor. To legally manufacture and/or distribute VFD feed, firms must submit a letter of intent to FDA. There are three types of VFD feed:

- *Type A medicated articles* are the strongest, highest concentration of a VFD drug with or without a carrier such as corn, rice hulls or gluten. Type A medicated articles cannot be directly fed and are only used to make Type B or Type C medicated feeds.
- *Type B medicated feeds* are manufactured medicated feeds made by mixing a Type A medicated article with non-medicated feed for distribution to clients with instructions for further mixing on-farm until the appropriate dosage is achieved according to the VFD order. Type B medicated feeds cannot be directly fed.
- *Type C medicated feeds* are complete feeds, top dress feeds or free choice feeds that can be made from mixing non-medicated feed with a Type A medicated article until the dosage is at a level that is medically appropriate for the target animal's diagnosis and treatment in a ready-to-feed manner. Type C medicated feed can also be manufactured from a Type B medicated feed (see above) and then further mixed on-farm with non-medicated feed until achieving the medically appropriate dosage for the target animal's indicated treatment, per the issued instructions outlined by the veterinarian on the VFD order.



All clients must have a valid VFD order to obtain VFD feed containing a VFD drug for their animals regardless of whether the animals are used for food production. For the complete legal definitions of VFD drug, VFD order, and the types of VFD feed, please refer to the “Definitions” section of the Appendices. More information on VFD orders and VFD drugs in California can be found here: <https://www.fda.gov/animal-veterinary/development-approval-process/veterinary-feed-directive-vfd>.

## **Manufacturing and Distributing VFD Medicated Feed**

CDFA is the primary regulatory agency responsible for oversight of medicated feed under the authority of FAC Section 14902.5. CDFA’s CFRP enforces the laws and regulations that govern the manufacturing and distributing of livestock feed, including medicated feed, and oversees the licensing and inspection of firms. Federal law defines a distributor as any person who distributes a medicated feed containing a VFD drug to another person; such other person may be another distributor or the recipient of a VFD (21 CFR 558.3(b)(9)). Additionally, any feed mills manufacturing VFD feed or retail locations distributing VFD feed must file a letter of intent with FDA; more information on the FDA VFD letter of intent can be found here: <https://www.fda.gov/animal-veterinary/development-approval-process/veterinary-feed-directive-requirements-distributors-who-manufacture-vfd-feed>.

All feed mills manufacturing medicated feed are required to obtain a commercial feed license pursuant to FAC Section 15051(a). Manufacturers can sell VFD feed in bulk or in determined packaged amounts. Feed distributors only sell medicated feed commonly found in pre-packaged containers, as opposed to bulk amounts, that are typically in different weighted bags of feed, various sizes of buckets or small tubs. Manufacturers and distributors sell VFD feed in amounts appropriate to the number of animals being treated, and as outlined by the licensed veterinarian on the VFD order.

CDFA requests that both manufacturers and distributors report VFD information on a quarterly basis, including providing copies of any VFD orders that have been received through their firm. FAC Section 14406 gives CDFA the authority to request and receive copies of these VFD orders. For data reported quarterly, CDFA verifies data accuracy and completeness during routine firm inspections. Furthermore, federal law requires manufacturers and distributors to retain copies of all VFD orders for two years (21 CFR 558.6(a)(4)).

Information collected in 2018, through the laws outlined above, allowed CDFA to compare the total amounts of finished feed produced (provided to the CFRP) to VFD feed produced. The comparison reveals that VFD feed makes up 0.0910% of all finished feed reported. Whole grains and integrated feed manufacturers (feed mills that manufacture for their own animals) are exempt from finished feed tonnage, however, their VFDs are reflected within this report.

## **Scope of Reporting**

This report summarizes manufacturing and distribution data for California medicated feed containing a VFD drug or combination VFD drugs, by VFD order written by a licensed veterinarian.

Pursuant to 21 CFR 558.6(b)(3), each VFD order is required to clearly identify information such as veterinarian name, client name, animal premises address, species and production class, drug name, product name, dosage, duration of treatment, indication for treatment, number of animals to be treated, withdrawal period to prevent antimicrobial residues, combination drug use, and manufacturing or distributing firm of VFD medicated feed. The data included in this report covers the MIADs used to manufacture VFD medicated feed, the species the feed is administered to, and the indication for use as it falls into the category of “respiratory disease,” “gastrointestinal disease,” “both” or “other” as classified by AUS staff with the indication given on VFD orders.

Of the information required to be identified on the VFD order, categories that are being collected and reviewed include, but are not limited to:

- Total number of VFD orders
- Total number of locations where VFD orders are received
- Total number of veterinarians issuing VFD orders
- Target animal species receiving VFD orders
- VFD drug(s) issued
- Indication for VFD drug use
- Total pounds of VFD feed distributed
- Total tons of VFD feed produced

Data will be categorized into Not Independently Reported (NIR) when VFD orders issued to a single species or a single type of VFD drug represents less than 5%<sup>1</sup> of the total VFD orders collected in a year. Also, if a reported species on a VFD order, or the VFD drug(s), make up less than 5% of total manufactured or distributed medicated feed, it will be captured within the NIR category. The NIR category is designed to protect the confidentiality of producer information that may be easily reidentified based on rare or unique characteristics, such as when a VFD drug is used for only one species.

### **Protecting Confidential Information**

This report is designed to provide to the public a summary of information collected under FAC Division 7 Chapter 4.5. This information is being reported in a manner consistent with maintaining confidentiality of a business’ or individual’s information in accordance with FAC Section 14407.

All data collected is subject to extensive internal review prior to publication. If it is determined that summary information would identify, or have the potential to identify, an individual or business, the data is reported as “Other” or “Not Independently Reported.” The report includes a list of information that is included in the “Other” or “Not Independently Reported” categories.

Data collected under FAC Chapter 4.5 and Section 14902.5 is confidential and exempt under Section 14407 from release under the California Public Records Act (CPRA) (Government Code Chapter 3.5 commencing with Section 6250). As such, it will not be

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<sup>1</sup> Any data less than 5% as independently reported increase the likelihood of reidentification



disclosed to any person or government agency except to the Veterinary Medical Board (VMB), as appropriate.

### **Data Collection Methods**

Data on VFD drugs and VFD orders is continuously collected by AUS for quarterly quantitative analysis and aggregation. The manufacturing/distributing firm's VFD information is reviewed for completeness and, if necessary, additional information is requested by CDFA field investigators. Similarly, every VFD order received from a firm is cataloged into a data-organizing tool where the data can be analyzed and aggregated on a quarterly, bi-annual or annual basis for reporting and necessary compliance.

### **Description of Tables and Figures**

The information presented in the following tables and figures is based on quarterly collections of VFD orders and other manufacturer or distributor VFD information. Each data table has superscripts and a corresponding numbered list with explanation, including what is contained in the NIR data, underneath the table or figure. "Not Independently Reported" represents different categories in each table, and a table may have two separate NIRs within it. Reported independently and not independently will vary each year depending on numerous factors. Some factors may include, but are not limited to, disease outbreaks, environmental factors, different drugs being approved or used, firm location changes, etc. These extenuating factors between years may make it difficult to directly compare certain data in either table or figure form. Additionally, AUS will periodically receive updates or corrections to the information previously given in VFD orders after their original submission date. Should this occur, it may cause slight variations in the data provided for years already reported on.

## **Veterinary Feed Directive Compliance**

CDFA has developed a VFD compliance plan that adheres to FAC Sections 14400-14408. VFD compliance began in 2017 with CDFA staff visiting all California feed mills and distributors who may have been selling, or planning to sell, medicated feeds containing VFD drugs. These compliance efforts consisted of distribution of outreach materials regarding the proper handling of VFD orders and sale requirements of VFD feeds. Once SB 27 went into effect, CDFA staff prioritized and revisited the facilities on the FDA VFD intent list to validate its accuracy. During these visits, as allowed under FAC Section 14406, CDFA collected all VFD orders at manufacturers and distributors to ensure compliance. CDFA staff also provided individualized outreach and education to these facilities to guide them on how to check all VFD orders for completeness and accuracy, along with guidelines on maintaining proper record keeping. After the initial 2017 VFD order collection, it was determined that more information was needed from manufacturers and distributors to accurately illustrate total tons of VFD medicated feed produced and total pounds of packaged VFD medicated feed distributed.

All VFD information collected is documented and analyzed for accuracy and completeness. If errors are found, CDFA considers the appropriate action needed and addresses that discrepancy on a case-by-case basis. For example, CDFA will refer potential violation issues on VFD orders pertaining to the veterinarian to the VMB,

sharing all information in accordance with FAC Sections 14407 and 14408. With that said, CDFA has developed general outreach directed at veterinarians which identifies the common errors observed on VFD orders. Furthermore, the VFD order information is used to look for issues related to manufacturers and distributors. It is the intent of the program to begin with an outreach and education approach to compliance. Further enforcement actions may be taken for repeat violations.

As part of the VFD compliance plan, CDFA conducts annual audits, similarly to those conducted by FDA of all manufacturers and distributors on FDA's VFD intent list. Additionally, this validation measure allows CDFA to ensure firms are submitting all VFD orders and any additional manufacturing and/or distributing information. This process also allows CDFA staff to visit retailers who may have not historically sold VFD feed, but are still on the FDA VFD intent list, to ensure they have no VFD feed sales.

To assist with VFD compliance, FDA released a draft updated version of its Guidance for Industry (GFI) #120 in March 2019, which can be found here: <https://www.fda.gov/media/70173/download>. GFI #120 is a guide for the federal VFD regulations and includes common questions and answers that include sections for veterinarians, producers, manufacturers and distributors and is routinely updated on the AUS website.

Veterinary feed directive order summary  
 Reported for 2017 - 2019 (Q1)  
 Veterinary feed directive order data

**Table 1a**

	2017	2018	2019 Q1 <sup>1</sup>
<b>Total Number of VFD Orders<sup>2</sup></b>	639	634	218 <sup>6</sup>
<b>Number of VFD Collection Locations<sup>3</sup></b>	41	36	26
<b>Total Number of Locations VFD Orders Were Issued to<sup>4</sup></b>	298	287	167
<b>Total Number of Veterinarians Who Issued VFD Orders<sup>5</sup></b>	113	112	69

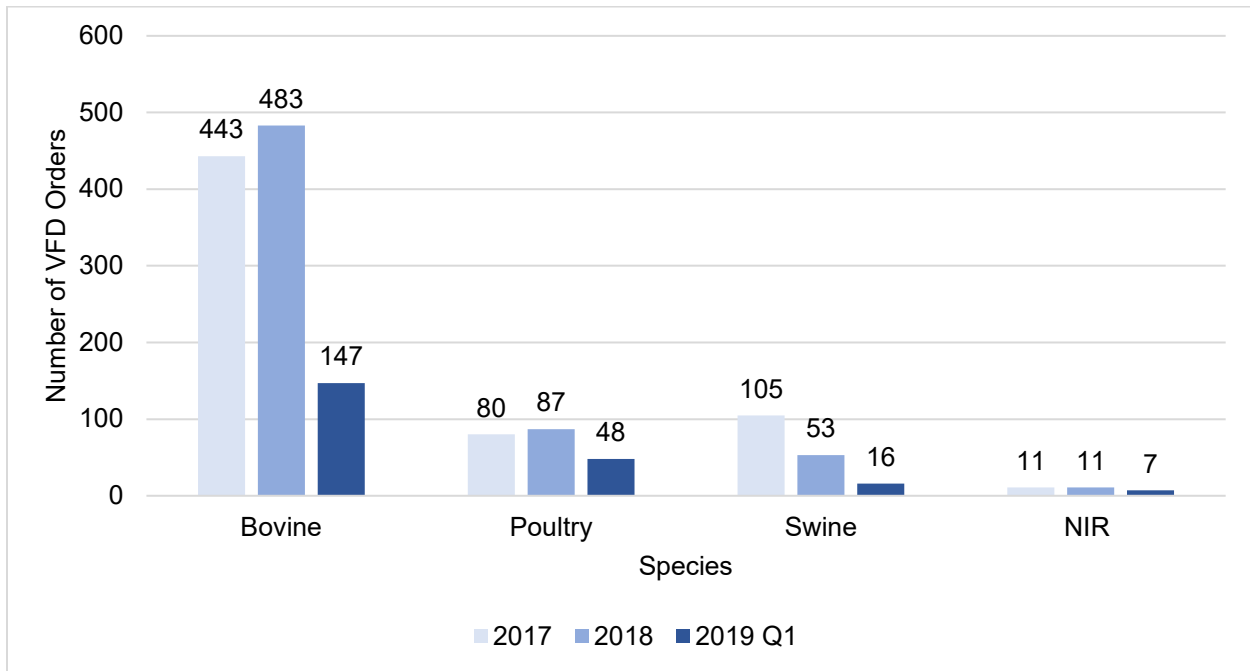
1. VFD orders collected for 2019 Q1 are quarter 1 – Jan. 1 to March 31 of 2019.
2. Total number of VFD orders received from manufacturers and distributors located in California (CA), that are listed on FDA's VFD intent list. The total number of VFD orders includes only CA locations where the VFD feed is intended to be fed.
3. Number of VFD collection locations is inclusive of all manufacturers and distributors in CA that received VFD orders.
4. Total number of locations VFD orders were issued represents the locations where the animals are housed.
5. Total number of veterinarians who issued VFD orders are licensed veterinarians who deemed that VFD feed should be used for treatment.
6. VFDs expire within 6 months from issue date; accordingly, quarterly numbers are not indicators of annual trends.

Number of VFD orders represented by intended species  
 Reported for 2017 - 2019 (Q1)  
 Veterinary feed directive order data

**Table 2a**

Species	2017	2018	2019 Q1
Bovine	443	483	147
Poultry	80	87	48
Swine	105	53	16
NIR <sup>1</sup>	11	11	7
<b>Total</b>	<b>639</b>	<b>634</b>	<b>218</b>

**Figure 2a**



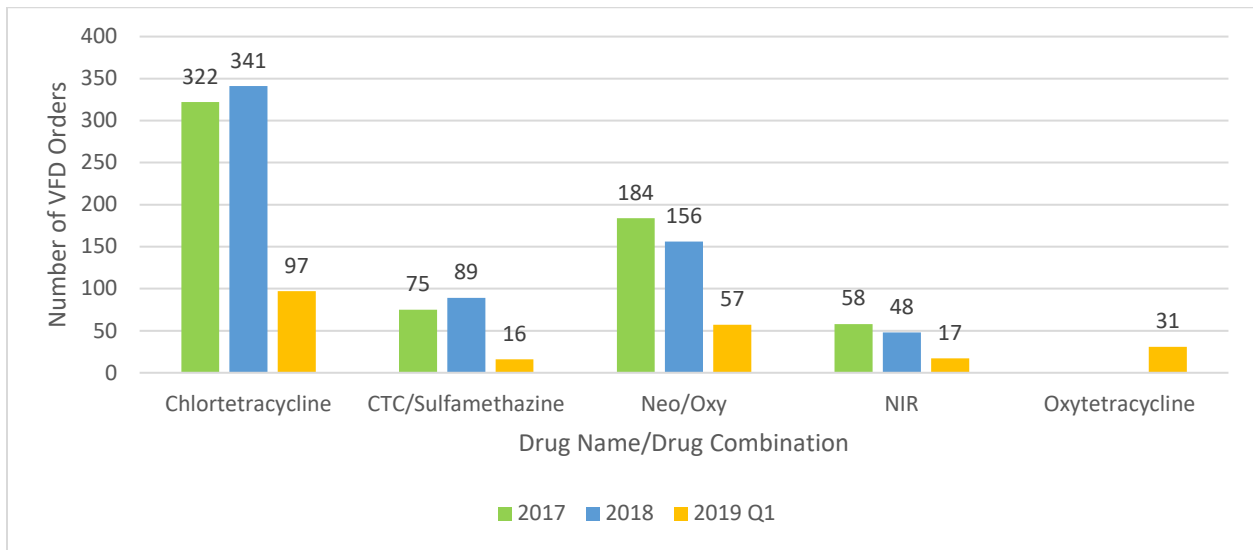
1. NIR = Not Independently Reported. This category includes Aquaculture, Caprine and Ovine. These species independently represent less than 5% of the total VFD orders.

Number of VFD orders represented by drug name  
Reported for 2017 - 2019 (Q1)  
Veterinary feed directive order data

**Table 3a**

Drug Name/Drug Combination Indicated on VFD Order	2017	2018	2019 Q1
Chlortetracycline	322	341	97
Chlortetracycline/Sulfamethazine <sup>1</sup>	75	89	16
Neomycin/Oxytetracycline <sup>2</sup>	184	156	57
NIR <sup>3</sup>	58	48	17
Oxytetracycline <sup>4</sup>	-	-	31
<b>Total</b>	<b>639</b>	<b>634</b>	<b>218</b>

**Figure 3a**



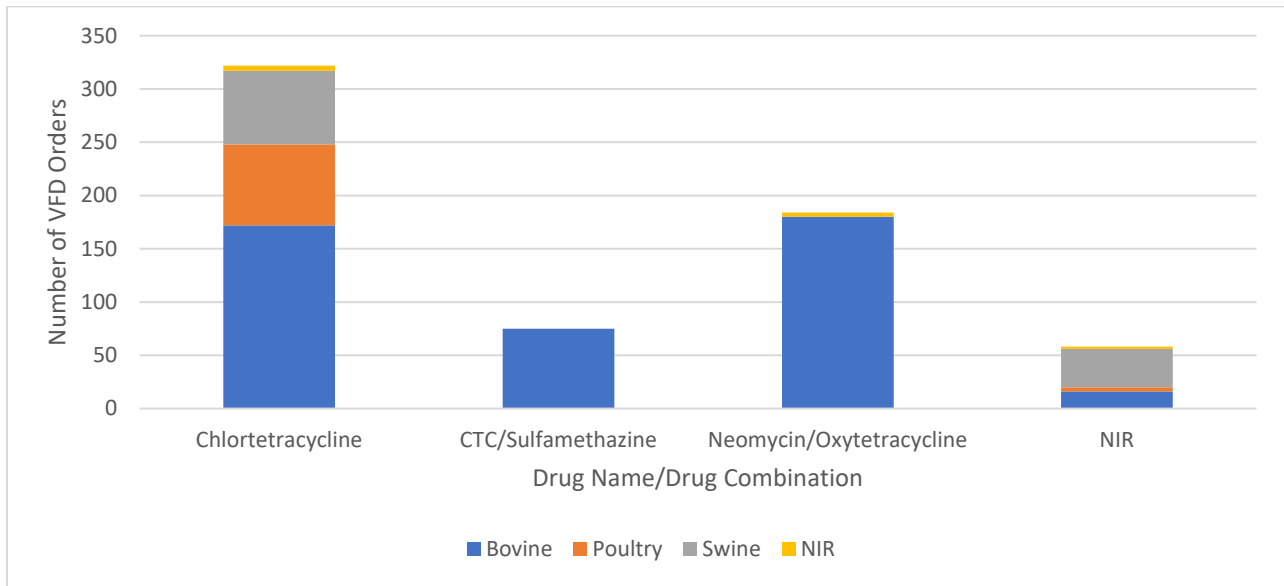
1. Chlortetracycline (CTC) with Sulfamethazine is represented as “CTC/Sulfamethazine” in figure.
2. Neomycin (Neo) with Oxytetracycline (Oxy) is represented as “Neo/Oxy” in figure.
3. NIR = Not Independently Reported. This category includes Chlortetracycline/Tiamulin, Florfenicol, Lincomycin, Oxytetracycline, Tiamulin, Tilmicosin, Tylosin and Virginiamycin (only represented in 2017). These drugs/combinations independently represent less than 5% of the total VFD orders collected.
4. Oxytetracycline is represented in 2019 Q1 due to higher number of VFD orders for specific non-combination drug and not in NIR.

Number of VFD orders by drug and intended species  
Reported for 2017  
Veterinary feed directive order data

**Table 4a**

2017					
Drug Name/Drug Combination Indicated on VFD Order	Bovine	Poultry	Swine	NIR <sup>1</sup>	Total
Chlortetracycline	172	76	69	5	322
Chlortetracycline/Sulfamethazine <sup>2</sup>	75	-	-	-	75
Neomycin/Oxytetracycline	180	-	-	4	184
NIR <sup>3</sup>	16	4	36	2	58
<b>Total</b>	<b>443</b>	<b>80</b>	<b>105</b>	<b>11</b>	<b>639</b>

**Figure 4a**



1. NIR = Not Independently Reported. This category for species includes Aquaculture, Caprine and Ovine. These species independently represent less than 5% of the total VFD orders.
2. Chlortetracycline (CTC) with Sulfamethazine is represented as “CTC/Sulfamethazine” in figure.
3. NIR = Not Independently Reported. This category for drug name/drug combinations independently represent Florfenicol, Lincomycin, Oxytetracycline, Tiamulin, Tilmicosin, Tylosin, Virginiamycin.

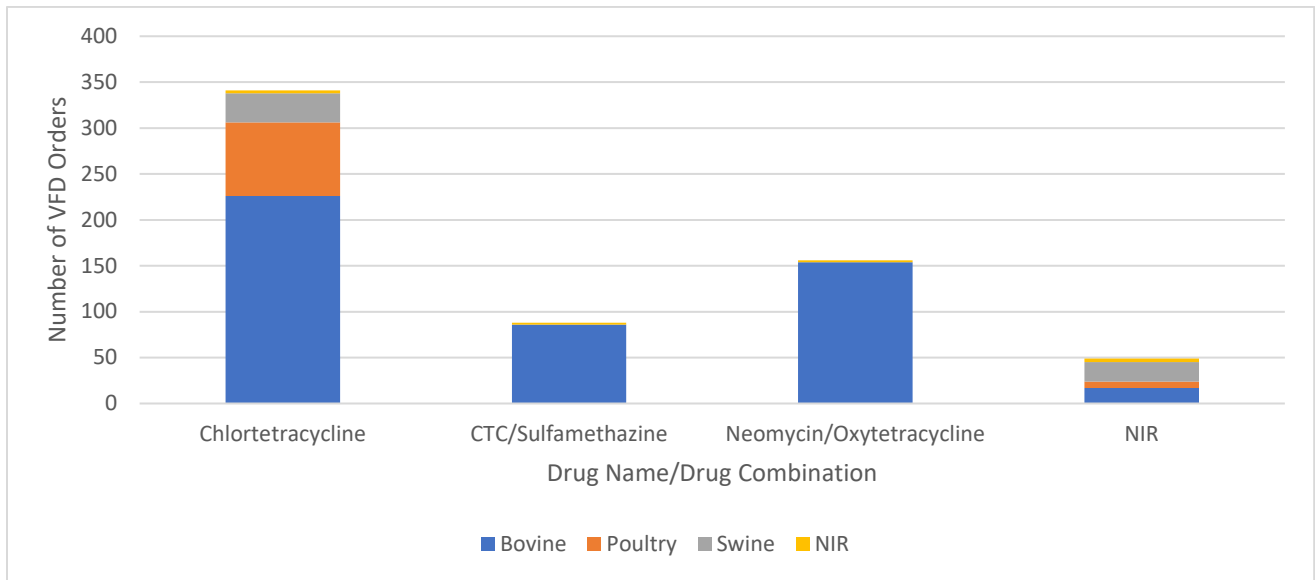


Number of VFD orders by drug and intended species  
Reported for 2018  
Veterinary feed directive order data

**Table 4b**

2018					
Drug Name/Drug Combination Indicated on VFD Order	Bovine	Poultry	Swine	NIR <sup>1</sup>	Total
Chlortetracycline	226	80	32	3	<b>341</b>
Chlortetracycline/Sulfamethazine <sup>2</sup>	86	-	-	2	<b>88</b>
Neomycin/Oxytetracycline	154	-	-	2	<b>156</b>
NIR <sup>3</sup>	17	7	21	4	<b>49</b>
<b>Total</b>	<b>483</b>	<b>87</b>	<b>53</b>	<b>11</b>	<b>634</b>

**Figure 4b**



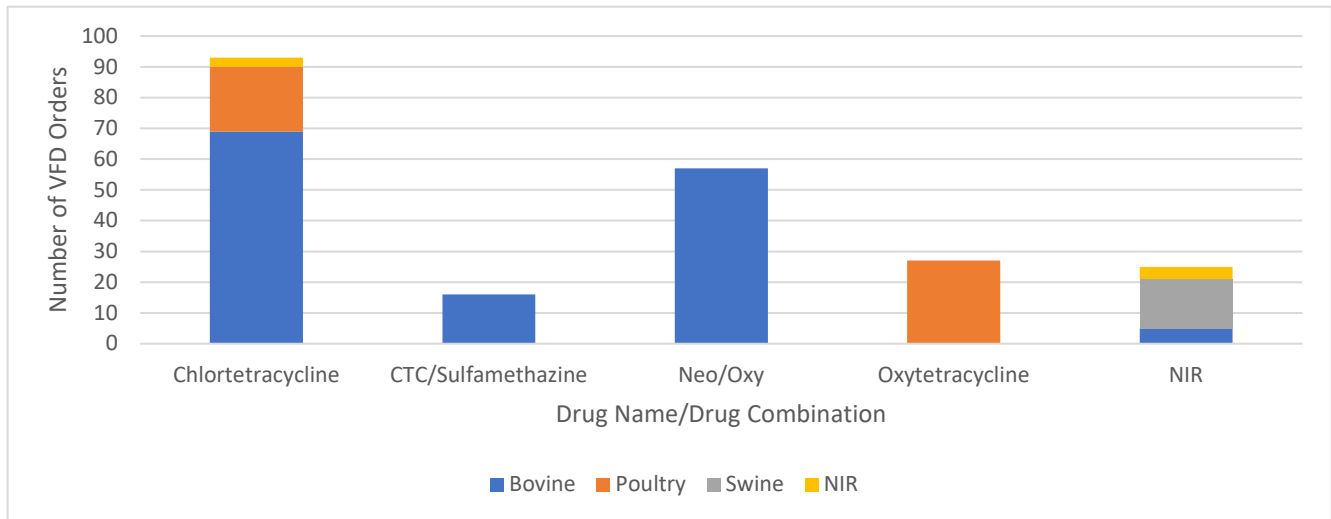
1. NIR = Not Independently Reported. This category for species includes Aquaculture, Caprine, Ovine. These species independently represent less than 5% of the total VFD orders.
2. Chlortetracycline (CTC) with Sulfamethazine is represented as “CTC/Sulfamethazine” in figure.
3. NIR = Not Independently Reported. This category for drug name/ drug combination independently represents Florfenicol, Lincomycin, Oxytetracycline, Tiamulin, Tilmicosin, Tylosin.

Number of VFD orders by drug and intended species  
Reported for 2019 (Q1)  
Veterinary feed directive order data

**Table 4c**

2019 Q1					
Drug Name/Drug Combination Indicated on VFD Order	Bovine	Poultry	Swine	NIR <sup>1</sup>	Total
Chlortetracycline	69	21	-	3	<b>93</b>
Chlortetracycline/Sulfamethazine <sup>2</sup>	16	-	-	-	<b>16</b>
Neomycin/Oxytetracycline <sup>3</sup>	57	-	-	-	<b>57</b>
Oxytetracycline	-	27	-	-	<b>27</b>
NIR <sup>4</sup>	5	-	16	4	<b>25</b>
<b>Total</b>	<b>147</b>	<b>48</b>	<b>16</b>	<b>7</b>	<b>218</b>

**Figure 4c**



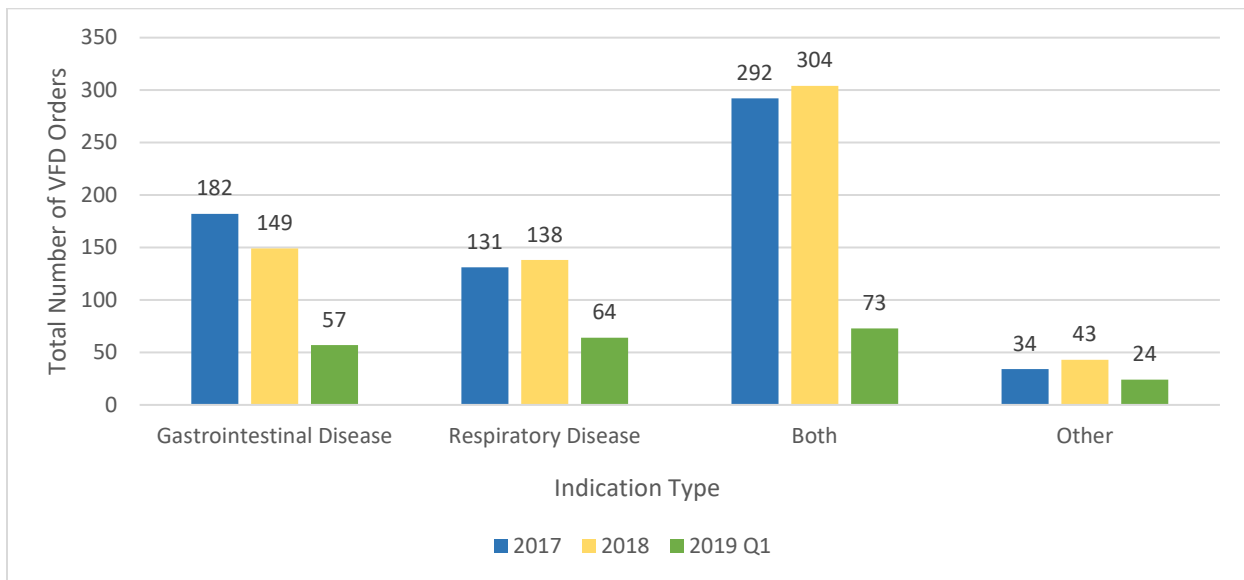
1. NIR = Not Independently Reported. This category for species includes Aquaculture, Caprine and Ovine. These species independently represent less than 5% of the total VFD orders.
2. Chlortetracycline (CTC) with Sulfamethazine is represented as “CTC/Sulfamethazine” in figure.
3. Neomycin (Neo) with Oxytetracycline (Oxy) is represented as “Neo/Oxy” in figure.
4. NIR = Not Independently Reported. This category for drug name/drug combination independently represents Florfenicol, Lincomycin, Tilmicosin, Tylosin.

Number of VFD orders by indication type  
Reported for 2017 - 2019 (Q1)  
Veterinary feed directive order data

**Table 5a**

Indication Type	2017	2018	2019 Q1
Gastrointestinal Disease <sup>1</sup>	182	149	57
Respiratory Disease <sup>2</sup>	131	138	64
Both <sup>3</sup>	292	304	73
Other <sup>4</sup>	34	43	24
<b>Total</b>	<b>639</b>	<b>634</b>	<b>218</b>

**Figure 5a**



1. Gastrointestinal (GI) Diseases include bacterial enteritis, bluecomb disease, coccidiosis, hexamitiasis, necrotic enteritis, porcine proliferative enteropathy, swine dysentery, swine ileitis and transmissible enteritis.
2. Respiratory diseases included bacterial pneumonia, chronic respiratory disease and respiratory disease.
3. “Both” is representative of two indications per VFD order, GI and Respiratory diseases.
4. “Other” diseases include abortions, anaplasmosis, columnaris disease, fowl cholera, infectious synovitis, jowl abscesses, leptospirosis, liver abscesses and vibronic abortions.

## **Compliance**

In 2017, CDFA staff began review of all VFD orders collected to ensure compliance. Any VFD orders found in error were reviewed with the manufacturer or distributor where they were collected. The manufacturers and distributors were educated on the requirements for manufacturing and/or distributing medicated feed containing a VFD drug. Through this effort, manufacturers and distributors began working closely with the issuing veterinarians on properly completing the VFD order prior to submission. These efforts continue through 2018 and 2019.

Beginning in 2018, CDFA began sharing any veterinarian-based issues with VMB in accordance with FAC Sections 14407 and 14408. CDFA staff conducted appropriate follow-up if the issue stemmed from a manufacturer or distributor. Other VFD compliance during 2017 and 2018 included the production of outreach, including documents directed at manufacturers, distributors, veterinarians and producers.

CDFA is conducting annual audits of all facilities on the FDA VFD intent list to validate accuracy of VFD information and ensure manufacturer/distributor compliance. CDFA Commercial Feed Regulatory Program staff perform regular inspections at firms that manufacture VFD medicated feed and monitor the feed manufacturing process, check medication logs and inventories, obtain samples and review production records. CDFA AUS staff also conducts annual compliance visits, similarly to those conducted by FDA, to all firms distributing VFD medicated feed.

## **Data on 2018 Manufacturing and Distribution Reports**

### **Summary of Data Collected**

Upon completion of the 2017 data analysis, it was determined that to ensure the most complete data reporting possible, additional information was required. Supplemental VFD information, allowed under state authority, was collected from manufacturing and distributing firms starting in 2018 (see table 6a and 7a).

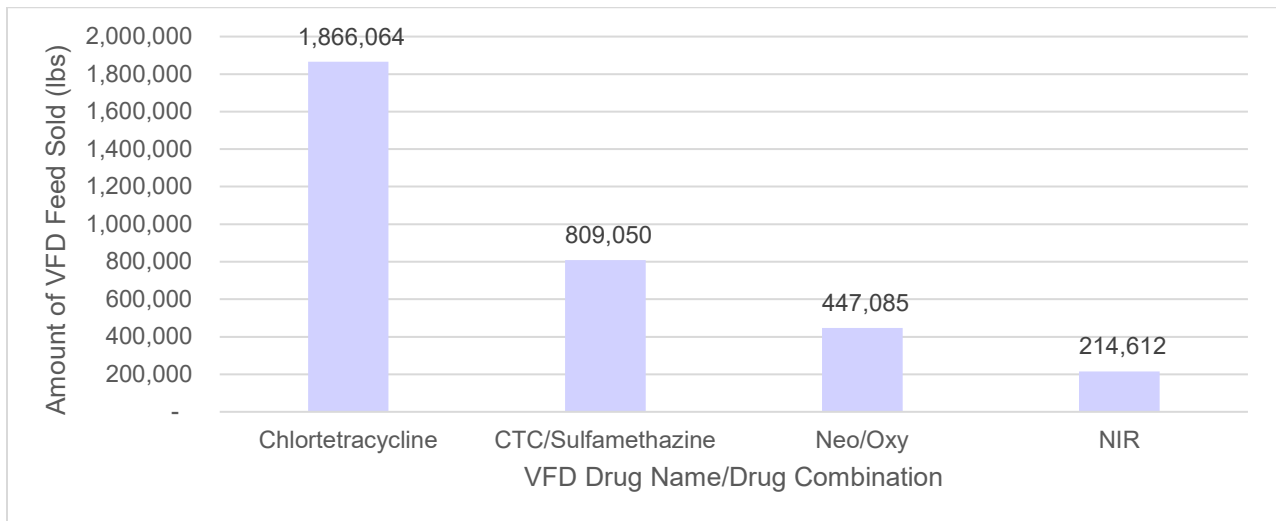
The data received from the manufacturer and distributor reports was entered into a data-organizing tool and is represented in the following tables and figures. The VFD feed represented in this data is reported as a Type B or Type C medicated feed only; this data does not include any Type A medicated articles. The distributor data is represented in pounds, due to distributors only selling VFD feed in predetermined amounts that are packaged in different weighted bags of feed, various sizes of buckets, or small tubs that generally weigh 50 pounds or less. If the data from a report was given in other measurements, like grams or ounces, it was converted to pounds for ease of reporting. Manufacturer data is reported in tons of VFD feed produced, as this feed is generally intended for large numbers of animals.

Amount of veterinary feed directive feed sold by distributors  
Reported for 2018  
Distributor report for amount of VFD feed sold data

**Table 6a**

	<b>Total pounds (lbs) of VFD feed sold<sup>1</sup></b>
<b>Drug Name/Drug Combination Used in VFD Feed</b>	<b>2018</b>
Chlortetracycline	1,866,064
Chlortetracycline <sup>2</sup> /Sulfamethazine	809,050
Neomycin/Oxytetracycline <sup>3</sup>	447,085
NIR <sup>4</sup>	214,612
<b>Total</b>	<b>3,336,811</b>

**Figure 6a**



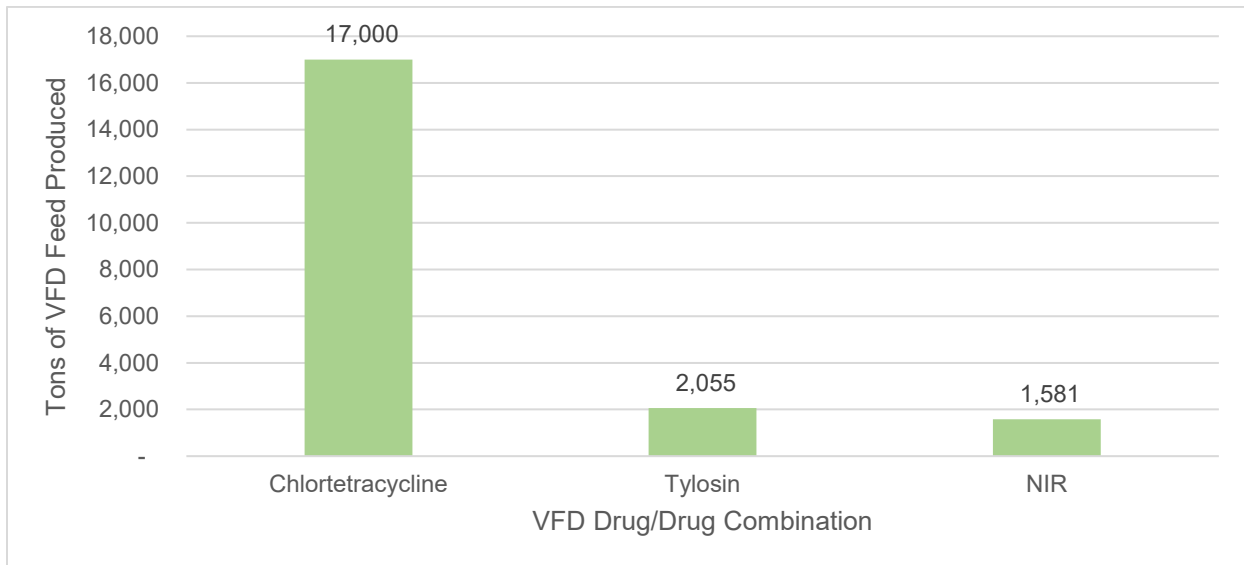
1. VFD feed drugs that were reported in kilograms (kg), grams (g), milligrams (mg) or ounces (oz) were converted to pounds (lbs).
2. Chlortetracycline (CTC) with Sulfamethazine is represented as “CTC/Sulfamethazine” in figure.
3. Neomycin (Neo) with Oxytetracycline (Oxy) is represented as “Neo/Oxy” in figure.
4. NIR = Not Independently Reported. This category includes CTC/ Tiamulin, Florfenicol, Lincomycin, Neomycin, Oxytetracycline, Spectinomycin, Sulfadimethoxine and Tiamulin. These drugs/combinations independently represent less than 5% of the total amount of drug sold by distributors.

Tons of medicated feed produced by manufacturers  
 Reported for 2018  
 Manufacturer report for tons of VFD feed produced data

**Table 7a**

	<b>Tons of VFD Feed Produced<sup>1</sup></b>
<b>Drug Name/Drug Combination Used in VFD Feed</b>	<b>2018</b>
Chlortetracycline	17,000
Tylosin	2,055
NIR <sup>2</sup>	1,581
<b>Total</b>	<b>20,636</b>

**Figure 7a**



1. Drugs that were reported in pounds (lbs) were converted to tons.
2. NIR = Not Independently Reported. This category includes CTC/Sulfamethazine, Lincomycin, Neo/Oxy, Oxytetracycline, Tiamulin and Tilmicosin. These drugs/combinations independently represent less than 5% of the total tons of VFD feed produced.



## Looking Forward

California is mandated to identify and work toward reducing antimicrobial resistance in animal agriculture. It is the intent of AUS to present VFD data and establish accurate, honest and transparent communication with the public while maintaining data confidentiality in accordance with FAC Section 14407. CDFA's AUS program has taken that initiative very seriously and continues to develop outreach and education materials to help veterinarians, producers, manufacturers, distributors and the public to know and understand the laws surrounding VFD orders, drugs and feed. By collecting, documenting and analyzing VFD orders, AUS has been able to create more knowledgeable programs and resources to assist industry participants to function successfully within the boundaries of the law, while also mitigating the risk of antimicrobial resistance and promoting public welfare.

Future AUS program efforts will utilize the VFD report information to assist in the development of the following projects:

- **AUS VFD Compliance Measures for:**
  - VFD feed manufacturers and distributors
  - Online sales
  - Annual visits to locations on FDA's VFD Intent List
  - Quarterly collection of VFD orders
- **AUS Stewardship for:**
  - Judicious use guidelines (ongoing)

This report is the result of efforts outlining the AUS program's commitment to utilizing collected information to make analytical, science-based decisions; maintain transparency in reporting; and focus on human and animal health. The overarching program goal is that the information contained in this report will provide publicly available and unbiased information to promote a better understanding when issuing, manufacturing, and distributing medicated feed containing VFD drugs.

# Appendices

## Definitions

“Antimicrobial” - referred broadly to drugs with activity against a variety of microorganisms including bacteria, viruses, fungi and parasites. Antimicrobial drugs that have specific activity against bacteria are referred to as antibacterial or antibiotic drugs. However, the broader term “antimicrobial,” commonly used in reference to drugs with activity against bacteria. (GFI #209)

“Antimicrobial Resistance” - the ability of bacteria or other microbes to resist the effects of a drug. Antimicrobial resistance, as it relates to bacterial organisms, occurs when bacteria change in some way that reduces or eliminates the effectiveness of drugs, chemicals or other agents designed to treat bacterial infections. (GFI #209)

“Antimicrobial Stewardship” - aim to optimize patient health and improve antimicrobial drug use in order to preserve the efficacy and ensure the availability of antimicrobials for years to come. (AUS Principles of Antimicrobial Stewardship)

“Commercial Feed” - includes all materials which are intended for use as feed or for mixing in feed except preparations which are manufactured or distributed for feeding to domestic pets, such as dogs, cats and birds. (FAC, Division 7, Chapter 6, Article 2, Section 14925)

“Distribute” - to offer for sale, sell, exchange or barter. (FAC, Division 7, Chapter 4, Article 1.5, Section 14209)

“Distributor” - means any person who distributes a medicated feed containing a VFD drug to another person. Such other person may be another distributor or the client-recipient of a VFD (21 CFR 558.3(b)(9)). As defined in the FD&C Act, the term “person” includes an individual, partnership, corporation, or association (section 201(e) of the FD&C Act (21 USC 321(e)). (FDA)

“Drug” - any of the following substances: (a) Any substance which is intended for use in the diagnosis, cure, mitigation, prevention, or treatment of disease. (b) Any substance, except food and water, which is intended to affect the structure or function of the body of any livestock. (FAC, Division 7, Chapter 4, Article 1.5, Section 14202)

“Finished Feed” - complete feed ready to be fed or further mixed on farm.

“Integrated Feed Mill” - facility that manufactures feed with the intent to feed only their own animals.

“Livestock” - all animals and poultry, including aquatic and amphibian species, that are raised, kept or used for profit. Livestock does not include bees or those species that are usually kept as pets, such as dogs, cats and pet birds. (FAC, Division 7, Chapter 4.5, Section 14400)

“Manufacture” - to grind, mix or further process a [commercial] feed. (FAC, Division 7, Chapter 6, Article 2, Section 14933)

“Major Species” - means cattle, horses, swine, chickens, turkeys. (FDA)

“Medically Important Antimicrobial Drug (MIAD)” - an antimicrobial drug listed in Appendix A of the federal Food and Drug Administration’s Guidance for Industry #152, including critically important, highly important, and important antimicrobial drugs, as that appendix may be amended. (FAC, Division 7, Chapter 4.5, Section 14400)

“Medicated Feed” - [commercial] feeds that contain drugs. (FAC, Division 7, Chapter 6, Article 2, Section 14934)

“Minor Species” - means livestock & avian species, that are not major species.

“Type A Medicated Article” - intended solely for use in the manufacture of another Type A medicated article or a Type B or Type C medicated feed. It consists of a new animal drug(s), with or without carrier (e.g., calcium carbonate, rice hull, corn, gluten) with or without inactive ingredients. (FDA)

“Type B Medicated Feed” - intended solely for the manufacture of other medicated feeds (Type B or Type C). It contains a substantial quantity of nutrients including vitamins and/or minerals and/or other nutritional ingredients in an amount not less than 25 percent of the weight. It is manufactured by diluting a Type A medicated article or another Type B medicated feed. (FDA)

“Type C Medicated Feed” - intended as the complete feed for the animal or may be fed “top dressed” (added on top of usual ration) on or offered “free-choice” (e.g., supplement) in conjunction with other animal feed. It contains a substantial quantity of nutrients including vitamins, minerals and/or other nutritional ingredients. It is manufactured by diluting a Type A medicated article or a Type B medicated feed. A Type C medicated feed may be further diluted to produce another Type C medicated feed. (FDA)

“Ton” - a net weight of 2,000 pounds avoirdupois. (FAC, Division 7, Chapter 6, Article 2, 14939)

“Veterinary-Client-Patient Relationship” - key elements include that the veterinarian engages with the client (i.e., the animal producer) to assume responsibility for making clinical judgments about patient (i.e., animal) health, have sufficient knowledge of the patient by virtue of patient examination and/or visits to the facility where the patient is managed, and provide for any necessary follow-up evaluation or care. (FDA)

“Veterinary Feed Directive” - 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. 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 conditions for use approved, conditionally approved, or indexed by the FDA (21 CFR 558.3(b)(7)). A VFD may also be referred to as a VFD order. (FDA)

“Veterinary Feed Directive Order” - refer to Veterinary Feed Directive definition.

“Veterinary Feed Directive Drug” - a drug intended for use in or on animal feed which is limited by an approved new animal drug application filed pursuant to section 512(b) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), a conditionally approved

application filed pursuant to section 571 of the FD&C Act, or an index listing pursuant to section 572 of the FD&C Act to use under the professional supervision of a licensed veterinarian (21 CFR 558.3(b)(6)). Use of animal feed bearing or containing a VFD drug (VFD feed) must be authorized by a lawful VFD (21 CFR 558.6(a)(1)). (FDA)

“Veterinary Feed Directive Feed” - refer to Type B and C Medicated Feeds definition.

## References

### Links

AUS Guidelines for Judicious Use –

[https://www.cdfa.ca.gov/ahfss/AUS/docs/Guidelines\\_Judicious\\_Use\\_of\\_Antimicrobials\\_Livestock.pdf](https://www.cdfa.ca.gov/ahfss/AUS/docs/Guidelines_Judicious_Use_of_Antimicrobials_Livestock.pdf)

AUS Legislature Report -

[https://www.cdfa.ca.gov/ahfss/AUS/docs/CDFA\\_AUS\\_Report\\_2019.pdf](https://www.cdfa.ca.gov/ahfss/AUS/docs/CDFA_AUS_Report_2019.pdf)

AUS Principles of Antimicrobial Stewardship -

[https://www.cdfa.ca.gov/ahfss/AUS/docs/Antimicrobial\\_Stewardship\\_Principles.pdf](https://www.cdfa.ca.gov/ahfss/AUS/docs/Antimicrobial_Stewardship_Principles.pdf)

AUS Veterinarians Judicious Use of Antimicrobials -

[https://www.cdfa.ca.gov/ahfss/AUS/docs/Guidelines\\_Veterinarians\\_Judicious\\_Use\\_of\\_Antimicrobials\\_Livestock.pdf](https://www.cdfa.ca.gov/ahfss/AUS/docs/Guidelines_Veterinarians_Judicious_Use_of_Antimicrobials_Livestock.pdf)

AUS Website - <https://www.cdfa.ca.gov/ahfss/AUS/Stewardship.html>

CDFA Commercial Feed Regulatory Program -

<https://www.cdfa.ca.gov/is/ffldrs/CommercialFeedReg.html>

CDFA Inspection Services - <https://www.cdfa.ca.gov/is/>

CDFA Livestock Drug Program - <https://www.cdfa.ca.gov/is/ffldrs/LivestockDrug.html>

CDFA – Safe Animal Feed Education Program -

<https://www.cdfa.ca.gov/is/ffldrs/safe.html>

CDFA VFD Page - <https://www.cdfa.ca.gov/is/ffldrs/VeterinaryFeedDirective.html>

CDFA Website - <https://www.cdfa.ca.gov/>

CPG 615.115 - <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-615115-extralebel-use-medicated-feeds-minor-species>

eCFR Part 558 New Animal Drugs for Use in Animal Feeds - <https://www.ecfr.gov/cgi-bin/text->

[idx?SID=b8e74620d2b65cd5c35fb00efa6dbcd9&mc=true&node=pt21.6.558&rqn=dv5#se21.6.558\\_14](https://www.ecfr.gov/cgi-bin/text-idx?SID=b8e74620d2b65cd5c35fb00efa6dbcd9&mc=true&node=pt21.6.558&rqn=dv5#se21.6.558_14)

FDA 2017 Summary Report - <https://www.fda.gov/media/119332/download>

FDA GFI #120 - <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-120-veterinary-feed-directive-regulation-questions-and-answers>

FDA GFI #209 - <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-209-judicious-use-medically-important-antimicrobial-drugs-food-producing-animals>

FDA GFI 233 - <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-233-veterinary-feed-directive-common-format-questions-and-answers>

FDA VFD Final Rule - <https://www.govinfo.gov/content/pkg/FR-2015-06-03/pdf/2015-13393.pdf>

FDA VFD Final Rule homepage: <https://www.fda.gov/animal-veterinary/development-approval-process/veterinary-feed-directive-vfd>