

2022 Veterinary Feed Directive Summary Report



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Executive Summary

Veterinary feed directives (VFDs) are written orders that establish veterinary oversight for the administration of certain drugs in animal feed to food-producing animals. The VFD rule requires livestock producers to have their animals evaluated and diagnosed by a veterinarian who can issue a VFD order to the livestock producer for the lawful use of feed containing a VFD drug. In 2015, the United States Food and Drug Administration (FDA) introduced legislation that extended the list of drugs requiring VFD orders to include medically important antimicrobial drugs (MIADs) that had previously been available over the counter. This expansion of federal oversight was intended to help mitigate the development of antimicrobial resistance in food producing livestock.

California Senate Bill 27 (Hill, 2015), chaptered as Food and Agricultural Code (FAC) Sections 14400-14408, placed additional restrictions on MIADs used in livestock production and mandated the California Department of Food and Agriculture (CDFA) to gather information on sales within the state.

In 2017, CDFA introduced the Antimicrobial Use and Stewardship (AUS) Program that mirrored and expanded upon FDA's antimicrobial resistance mitigation goals. AUS is the first program to overlap two CDFA divisions: the Inspection Services Division, which handles regulation, inspection, compliance, and enforcement; and the Animal Health and Food Safety Services Division, which focuses on stewardship, surveys and studies, judicious use, and best on-farm practices. The divisions work cooperatively to promote public health and welfare via a safe and stable food supply for California.

General Information

This report comprises four main sections:

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

The data being reported encompasses a span of five years. For information specific to data reported prior to the five years in this report, the background and definitions of VFDs, manufacturing and distributing VFD feed, or CDFA's data collection methods, please reference previous years' VFD Summary Reports at the links below:

- 2020 2021 Veterinary Feed Directive Summary Report https://www.cdfa.ca.gov/is/ffldrs/pdfs/aus_vfd_summary_report_20-21.pdf
- 2019 VFD Summary Report <u>https://www.cdfa.ca.gov/is/ffldrs/pdfs/AUS_VFD_Summary_Report_2019.pdf</u>.
- 2017 2019 Quarter 1 VFD Summary Report <u>https://www.cdfa.ca.gov/is/ffldrs/pdfs/AUS_VFD_Summary_Report_2017-19.pdf</u>

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Scope of Reporting

This report summarizes manufacturing and distribution data from the last five years for medicated feed containing a VFD drug or combination of VFD drugs in California. See the previous VFD summary report links in the "General Information" section for any data reported prior to the last five years.

The reporting period for each VFD order is determined by the issue date expressed on a VFD order. However, because the extent of time between issue and expiration date varies by VFD drug or combination of VFD drugs, AUS will periodically receive VFD orders outside of the requested reporting periods causing slight variations in the data shown in previous years. The data reported is categorized by:

- the MIADs used to manufacture VFD medicated feed,
- the species the feed is intended for,
- and the indication for use as it falls into the category of "respiratory disease," "gastrointestinal disease," "both," or "other"

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% 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 the 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 identified based on rare or unique characteristics, such as when a VFD drug is used for only one species.

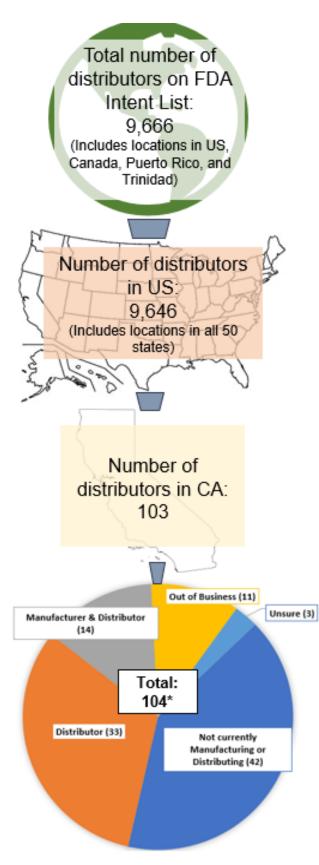
For reference to the number of livestock animals in California by year, refer to United States Department of Agriculture's (USDA) National Agricultural Statistics Service (NASS) database at https://www.nass.usda.gov/Statistics_by_State/California/index.php.

Protecting Confidential Information

To provide the public a summary of information collected under Food and Agricultural Code (FAC) Division 7 Chapter 4.5, this information is being reported in a manner consistent with maintaining confidentiality of a business or an 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



*1 distributor is not on FDA's Intent List; firm has been notified to submit VFD Intent Letter under FAC 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 disclosed to any person or government agency, except to the Veterinary Medical Board (VMB), as appropriate.

Description of Tables and Figures

The information presented in the tables and figures is based on quarterly collections of VFD orders and other manufacturer or distributor VFD information from the last five years. Whether data is reported independently or not independently will vary each year depending on factors that could lead to revealing personally identifying information (PII) of a business or producer. Some factors may include, but are not limited to:

- disease outbreaks
- environmental factors
- different drugs being approved or used
- firm location changes

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. Some figures may have the following abbreviations for VFD drugs:

- Chlortetracycline (CTC)
- Neomycin (Neo)
- Oxytetracycline (Oxy)

For a list of drugs approved by FDA for use in medicated animal feed, including VFD drugs, approved combinations with VFD drugs and additional information, please review the Code of Federal Regulations at:

https://ecfr.federalregister.gov/current/title-21/chapterl/subchapter-E/part-558.

Veterinary Feed Directive Data Tables

The data shown in the following tables encompasses five years and is subject to fluctuations based on factors that include timeliness of industry reporting and the date the summary report was published. Numbers are likely to update in future summary reports.

Veterinary feed directive order summary

Reported for 2018 – 2022 Veterinary feed directive order data

	2018	2019	2020	2021	2022*	
Total Number of VFD Orders ¹	634	714	649	595	629	
Number of VFD Collection Locations ²	36	36	39	27	31	
Total Number of Locations VFD Orders Were Issued to ³	287	337	338	302	307	
Total Number of Veterinarians Who Issued VFD Orders⁴	112	111	101	100	94	

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- ^{1.} 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.
- ² Number of VFD collection locations is inclusive of all manufacturers and distributors in CA that received VFD orders.
- ^{3.} Total number of locations to which VFD orders were issued represents the locations where the animals were housed.
- ^{4.} Total number of veterinarians who issued VFD orders are licensed veterinarians who deemed that VFD feed should be used for treatment.
- * Total number of VFD orders received from manufacturers and distributors located in CA in the year 2022 will likely show fluctuations due to timeliness of reporting. Reporting periods are determined by the VFD issue date and is not a guarantee of when the VFD will be received by the manufacturer, or distributor, or submitted for collection to CDFA.

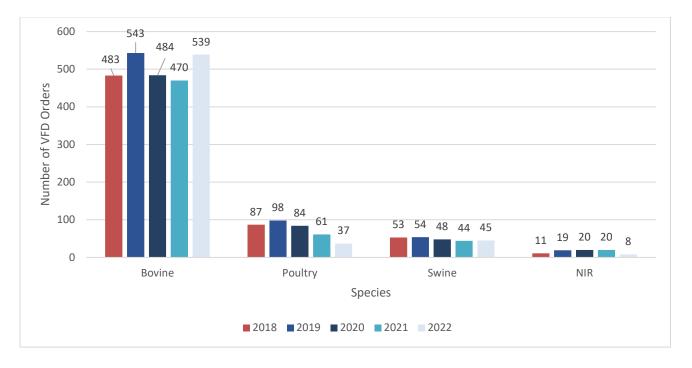
Number of VFD orders represented by intended species

Reported for 2018 – 2022 Veterinary feed directive order data

Table 2a

Species	2018	2019	2020	2021	2022*
Bovine	483	543	484	470	539
Poultry	87	98	84	61	37
Swine	53	54	48	44	45
NIR ¹	11	19	20	20	8
Total	634	714	636	595	629

Figure 2a



- Total number of VFD orders received from manufacturers and distributors located in CA in the year 2022 will likely show fluctuations due to timeliness of reporting.
- ¹ NIR = Not Independently Reported. This category includes Aquaculture, Caprine, and Ovine. These species independently represent less than 5% of the total VFD orders.

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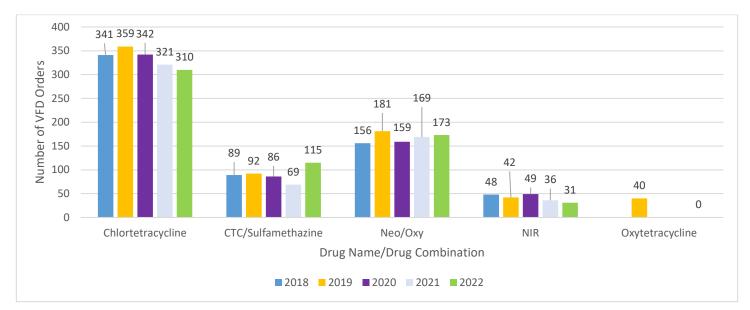
Number of VFD orders represented by drug name

Reported for 2018 – 2022 Veterinary feed directive order data

Table 3a

Drug Name/Drug Combination Indicated on VFD Order	2018	2019	2020	2021	2022*
Chlortetracycline	341	359	342	321	310
CTC/Sulfamethazine	89	92	86	69	115
Neo/Oxy	156	181	159	169	173
NIR ¹	48	42	49	36	31
Oxytetracycline ²	-	40	-	-	-
Total	634	714	636	595	629





- * Total number of VFD orders received from manufacturers and distributors located in CA in the year 2022 will likely show fluctuations due to timeliness of reporting.
- ^{1.} NIR = Not Independently Reported. This category includes Chlortetracycline/Tiamulin, Florfenicol, Lincomycin, Oxytetracycline, Neomycin, Tiamulin, Tilmicosin, Tylosin, and Virginiamycin (only represented in 2017). These drugs/combinations independently represent less than 5% of the total VFD orders collected.
- ^{2.} Oxytetracycline is represented in 2019 due to higher number of VFD orders for specific non-combination drug and not in NIR.

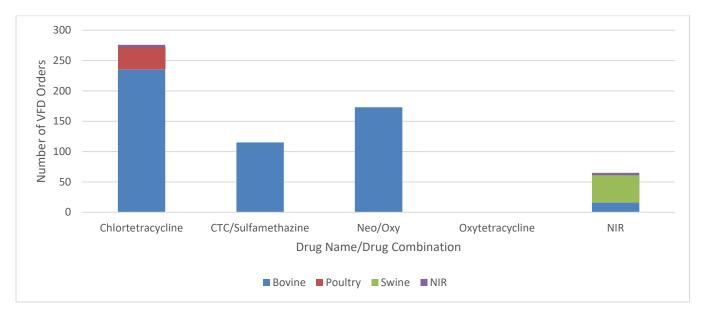
Number of VFD orders by drug and intended species

Reported for 2022 Veterinary feed directive order data

Table 4a

	2022				
Drug Name/Drug Combination Indicated on VFD Order	Bovine	Poultry	Swine	NIR ¹	Total
Chlortetracycline	235	37	-	4	276
CTC/Sulfamethazine	115	-	-	-	115
Neo/Oxy	173	-	-	-	173
Oxytetracycline	-	-	-	-	-
NIR ²	16	-	45	4	65
Total	539	37	45	8	629





- ^{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.} NIR = Not Independently Reported. This category for drug name/drug combination independently represents Chlortetracycline/Tiamulin, Florfenicol, Lincomycin, Neomycin, Oxytetracycline, Tiamulin, Tilmicosin, and Tylosin.

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Number of VFD orders by indication type

Reported for 2018 – 2022 Veterinary feed directive order data

Table 5a

Indication Type	2018	2019	2020	2021	2022*
Gastrointestinal Disease ¹	149	169	116	108	106
Respiratory Disease ²	138	179	144	102	136
Both ³	304	313	284	303	335
Other⁴	43	53	92	82	52
Total	634	714	636	595	629

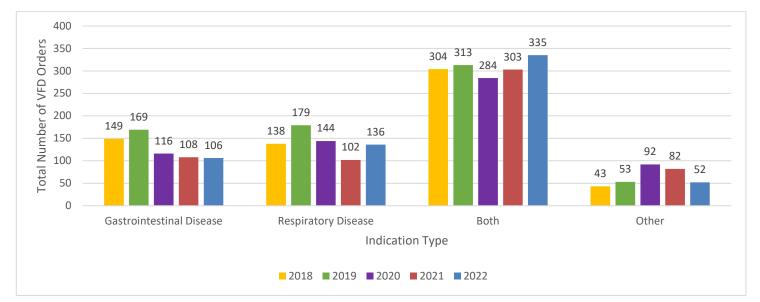


Figure 5a

- Total number of VFD orders received from manufacturers and distributors located in CA in the year 2022 will likely show fluctuations due to timeliness of reporting.
- 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 include 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, bacterial hemorrhagic septicemia, columnaris disease, fowl cholera, infectious synovitis, jowl abscesses, leptospirosis, liver abscesses, and vibrionic abortions.

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Data on 2022 Manufacturing and Distribution

Amount of VFD feed sold by distributors

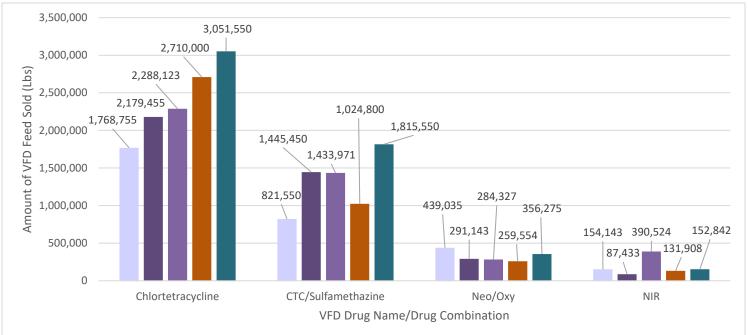
Reported for 2018 – 2022

Distributor report for amount of VFD feed sold data

Total pounds (lbs) of VFD feed sold							
Drug Name/Drug Combination Used in VFD Feed	2018	2019	2020	2021	2022		
Chlortetracycline	1,768,755	2,179,455	2,288,123	2,710,000	3,051,550		
CTC/Sulfamethazine	821,550	1,445,450	1,433,971	1,024,800	1,815,550		
Neo/Oxy	439,035	291,143	284,327	259,554	356,275		
NIR ¹	154,143	87,433	390,524	131,908	152,842		
Total	3,183,483	4,003,481	4,396,945	4,126,262	5,376,217†		

Table 6a





 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.

[†] CDFA's examination of the data included in this report indicates an increase in VFD feed containing CTC distributed following a period of intense heat.

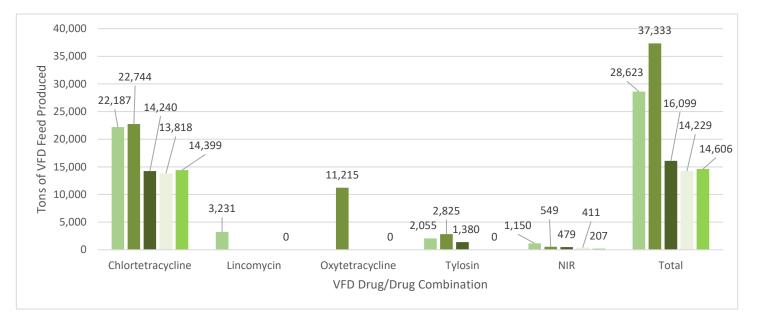
Tons of VFD feed produced by manufacturers

Reported for 2018 – 2022 Manufacturer report for tons of VFD feed produced data

Tons of VFD Feed Produced								
Drug Name/Drug								
Combination Used in	2018	2019	2020	2021	2022			
VFD Feed								
Chlortetracycline	22,187	22,744	14,240	13,818	14,399			
Lincomycin	3,231	-	-	-	-			
Oxytetracycline	-	11,215	-	-	-			
Tylosin	2,055	2,825	1,380	-	-			
NIR ¹	1,150	549	479	411	207			
Total	28,623	37,333	16,099	14,229	14,606			

Table 7a

Figure 7a



^{1.} 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.

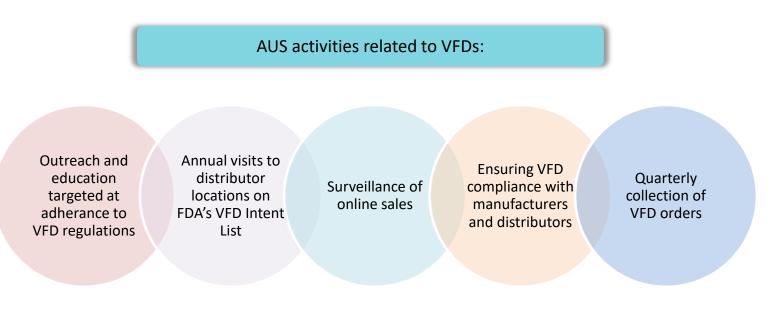
Conclusion

This report is the illustration of efforts outlining the AUS Program's commitment to collecting and utilizing aggregated information to make analytical, science-based decisions, maintain transparency in reporting; and focus on human and animal health. It is the intent of AUS to collect, review, and present VFD data transparently to the public while maintaining data confidentiality in accordance with FAC Section 14407. The intent of this report is to help the public gain a better understanding of the issuing, manufacture, and distribution of medicated feed containing VFD drugs.

In 2022, the AUS Program continued to work towards implementing the mandates of the AUS law and successfully partnered with Food Animal Residue Avoidance Databank (FARAD) to collaborate and develop a thorough VFD curriculum, offered as an online training targeted at distributors of VFD feeds, to educate their staff on better understanding the elements of a complete VFD order and how to reach out to the producer or issuing veterinarian when more information is needed.

AUS also continues to cooperatively develop outreach and education materials targeted at veterinary adherence to VFD regulations by assisting the Animal Health Food Safety Services AUS staff in reviewing informational packets to veterinarians who require additional education on completing a VFD. More information on this outreach effort can be found on their website, https://www.cdfa.ca.gov/ahfss/aus/vfdresources/.

Moving forward, the AUS Program will continue work with VFD feed manufacturers, distributors, and veterinarians to ensure continued compliance with these mandates through direct outreach, audits, VFD data collection, and enforcement, as needed.



References

Links

- AUS Guidelines for Judicious Use -<u>https://www.cdfa.ca.gov/ahfss/AUS/docs/Guidelines_Judicious_Use_of_Antimicrobia</u> Is Livestock.pdf
- AUS Report to the Legislature 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
- AUS Veterinarians' Guidelines for Judicious Use of Antimicrobials -<u>https://www.cdfa.ca.gov/ahfss/AUS/docs/Guidelines_Veterinarians_Judicious_Use_of_Antimicrobials_Livestock.pdf</u>
- AUS Website https://www.cdfa.ca.gov/ahfss/AUS/Stewardship.html
- CDFA Commercial Feed Regulatory Program <u>https://www.cdfa.ca.gov/is/ffldrs/CommercialFeedReg.html</u>
- 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 Sec 615.115 Extralabel Use of Medicated Feeds for Minor Species https://www.fda.gov/regulatory-information/search-fda-guidancedocuments/cpg-sec-615115-extralabel-use-medicated-feeds-minor-species
- eCFR Part 558 New Animal Drugs for Use in Animal Feeds -<u>https://www.ecfr.gov/current/title-21/chapter-I/subchapter-E/part-558/subpart-</u><u>A/section-558.4</u>

FARAD

http://www.farad.org/

FDA 2017 Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals - <u>https://www.fda.gov/media/119332/download</u>

FDA CVM GFI #120 Veterinary Feed Directive Regulation Questions and Answers - <u>https://www.fda.gov/regulatory-information/search-fda-guidance- documents/cvm-gfi-120-veterinary-feed-directive-regulation-questions-and-answers</u>

- FDA CVM GFI #209 The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals - <u>https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-209-judicious-use-medically-important-antimicrobial-drugs-food-producing-animals</u>
- FDA CVM GFI #233 Veterinary Feed Directive Common Format Questions and Answers - <u>https://www.fda.gov/regulatory-information/search-fda-guidance-</u> <u>documents/cvm-gfi-233-veterinary-feed-directive-common-format-questions-and-</u> <u>answers</u>
- FDA VFD Final Rule <u>https://www.govinfo.gov/content/pkg/FR-2015-06-03/pdf/2015-13393.pdf</u>
- FDA VFD Final Rule Homepage: <u>https://www.fda.gov/animal-</u> <u>veterinary/development-</u> <u>approval-process/veterinary-feed-directive-vfd</u>

Veterinary Feed Directive Online Training registration link <u>https://na.eventscloud.com/ereg/newreg.php?eventid=634458&t=9b1f964a98855</u> <u>e97447e85a1fe87a073</u>