



The Use in Maryland of Medically Important Antimicrobial Drugs in Cattle, Swine, and Poultry

February 2022

SUMMARY

Senate Bill 471 requires that each year the Maryland Department of Agriculture (MDA) collect data from Maryland veterinarians and publicly available sources and report to the legislature on the use in Maryland of medically important antimicrobial drugs (MIADs) in cattle, swine and poultry.

In 2021, MIAD use data was collected for the second year in a row in Maryland, for antibiotics prescribed in Maryland from January 1 through December 31, 2021, to large cattle, swine and poultry operations/farms. The data is reported through state-mandated submissions by Maryland veterinarians of Veterinary Feed Directives (VFDs) and prescriptions for water-soluble MIADs issued for these operations. The report developed from this data provides the information required by SB 471: (i) the total number of animals raised on farm operations covered by SB 471 (beef cattle and swine farms with herds over 200 head, dairy farms with herds over 300 head, and poultry farms with over 60,000 birds), categorized by species and production class; (ii) the specific antimicrobial active ingredients and classes of antimicrobial active ingredients used; (iii) the total weight of antimicrobial active ingredients used; (iv) indications for which veterinarians prescribed MIADs; and (v) patterns of use for MIADs, including duration and seasonal variation. As this is only the second year that data has been collected, and reporting compliance has increased, there are limited evaluations made regarding any trends in use.

Key observations regarding the required information are provided in this report and shown below:

Individual trends showed:

- The largest user of MIADs was poultry operations:
 - an estimated 91% was used in chickens,
 - an estimated 8% was used in swine,
 - an estimated 7% was used in cattle, and
 - an estimated 0% was used in turkeys.(See Table 1).
- The largest amount of antimicrobial used in each species was:
 - an estimated 990 kg of Penicillin G Potassium, and 518 kg of chlortetracycline was used in poultry (chickens only),
 - an estimated 130 kg of chlortetracycline was reported used in swine, and
 - an estimated 53 kg of chlortetracycline was reported used in cattle.(See Table 1)
- By antimicrobial class, penicillin represented the largest amount of antimicrobials used:
 - penicillins accounted for 47% of all MIADs reported,
 - tetracyclines accounted for 38%,
 - sulfonamides for 13%,
 - lincosamides for 1%,
 - aminoglycosides and polypeptides for less than 1%, and
 - no cephalosporins, macrolides and fluoroquinolones were reported.

(See Table 2).

No unusual disease patterns were noted in 2021. Reasons to prescribe antimicrobials were varied, as usual. Indications are shown in Table 3.

No significant changes were noted in patterns of use. Duration of use is shown in Table 3, which shows that antimicrobials are consistently prescribed within the limit of 21 days set by SB 471. Seasonal variations are illustrated in Chart A and show the typical increase in antibiotic use in poultry during the winter due to increased disease prevalence during winter months. No seasonal patterns were noted in other species.

The U.S. Food and Drug Administration (FDA) annual national data on antimicrobial sales is provided below. Outside of this report, there was no new publicly available information located regarding MIAD use specifically in Maryland in 2021.

NATIONAL DATA SUMMARY

At this point, national available reports summarize national data only. The most recent national antibiotic use data is available in the Food and Drug Administration “2020 Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals,” published December 2021, and provided as an attachment to this report. Each year, since 2010 and subsequent to federal legislation in 2008, every sponsor of an approved or conditionally approved animal drug application containing an antimicrobial active ingredient must report to the FDA the amount of each such ingredient in these drug products sold or distributed for use in food-producing animals. FDA summarizes this information and makes it available to the public in annual summary reports.

Key observations from the 2020 FDA national report are provided on Page 3 of the report and shown below:

- Domestic sales and distribution of MIADs approved for use in food-producing animals (Table 2b):
 - decreased by 3% from 2019 through 2020.
 - decreased by 38% from 2015 (the year of peak sales) through 2020.
 - decreased by 27% from 2011 through 2020.
 - Tetracyclines, which represent the largest volume of these domestic sales (3,948,745 kg in 2020), decreased by 4% from 2019 through 2020.
- The domestic sales and distribution of MIADs approved for use in food-producing animals for 2020 included:
 - An estimated 41% was intended for use in cattle, an estimated 41% intended for use in swine, an estimated 12% intended for use in turkeys, an estimated 2% intended for use in chickens, and an estimated 4% intended for use in other species/unknown (Table 4a).
 - Tetracyclines accounted for 66%, penicillins for 13%, macrolides for 7%, sulfonamides for 5%, aminoglycosides for 5%, lincosamides for 2%, cephalosporins for less than 1%, and fluoroquinolones for less than 1% (Table 2a)

- An estimated 80% of cephalosporins, 57% of sulfonamides, 54% of aminoglycosides, and 43% of tetracyclines were intended for use in cattle. An estimated 87% of lincosamides and 42% of macrolides were intended for use in swine. An estimated 64% of penicillins were intended for use in turkeys (Table 5a)

BACKGROUND

In 2009, FDA began to collect and report the annual sales and distribution of antimicrobials approved for use in food-producing animals. Along with new judicious use guidelines, the FDA enhanced drug sales data beginning in 2016, when drug sponsors were required to begin providing species-specific estimates of the sales and distribution data, which may provide additional understanding about how antimicrobials are distributed to the major food-producing species. While providing important information, a limitation of these sales and distribution data is that they reflect the total quantity of antimicrobial drug products that enters the market, but not how much or for what purpose these drugs are ultimately used in treated animals.

In 2012, the FDA initiated a strategy designed to promote judicious use of MIADs in food-producing animals. As outlined in Guidance for Industry #209 ([fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM216936.pdf](https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM216936.pdf)), this strategy has two main principles: 1) limit MIADs to uses in food-producing animals that are necessary for assuring animal health; and 2) new requirements for veterinary oversight of antibiotic use. This strategy was implemented in January 2017. Since then, the use of MIADs for growth promotion and improved feed efficiency was no longer allowed, and veterinary oversight was required for their use in animal food and water.

The National Action Plan for Combating Antibiotic Resistant Bacteria was launched in federal FY16 to address continuing concerns regarding antibiotic resistance. Detailed information on progress are provided in an integrated report produced jointly by the FDA, Centers for Disease Control and United States Department of Agriculture through National Antimicrobial Resistance Monitoring System (NARMS), found at [fda.gov/animal-veterinary/national-antimicrobial-resistance-monitoring-system/2018-narms-update-integrated-report-summary](https://www.fda.gov/animal-veterinary/national-antimicrobial-resistance-monitoring-system/2018-narms-update-integrated-report-summary). These reports, however, lack information on national use data, but do note that pilot studies are underway to evaluate pre-harvest antimicrobial use data. Some of these studies were recently published in “Special Issue: Antimicrobial Use Date and Reporting”, *Zoonoses and Public Health*, Volume 67, Supplement 1, November 2020, 1-123, which can be accessed online at onlinelibrary.wiley.com/toc/18632378/2020/67/S1. Highlights from these studies were discussed in the 2020 Annual Report, “*The Use in Maryland of Medically Important Antimicrobial Drugs in Cattle, Swine, and Poultry*”.

METHODS

Data Collection:

Maryland specific data was obtained subsequent to requirements under SB 471. To obtain Maryland MIAD use data, the department compiled data submitted from Maryland veterinarians and farmers using a data management system developed in 2019 and updated in 2021.

There are innate complications in data collection for the purposes of meeting SB 471 requirements. VFD and prescription forms are not standardized, VFD creation is a federally regulated process, and state standardization would impede commerce; therefore, in the current construct, it is not possible to force submission of complete data, or data in a form that allows direct or precise determination of total antimicrobial mass in feed, the ultimate goal. Where key information needed for calculations was missing on a submission, typically weights of animals or production class, veterinarians were contacted by phone or email to provide the missing information. Where information was unavailable, assumptions were established for calculations, such as average production weights or total feed, based on USDA or other reliable sources. Data was extracted from the submitted information into a spreadsheet, converted to common units, assumptions added where needed, calculated and manipulated using Pivot Tables for reporting.

As this is the second year that data has been collected, and collection methods and reporting compliance is evolving (nevertheless improving), there are limited evaluations made herein regarding trends in use. In addition, given the annual deadline of February 1 of each year, this short turnaround after the year's end to produce the report has inherent problems in providing applicable and accurate data. Specifically, and for example, an established method by the European Food Safety Authority of measuring antimicrobial use and trends is called Antimicrobial Consumption (AMC), which measures mgs of an antimicrobial per kilogram (kg) of total biomass of animals (milligram/kg). This is essentially a measurement of percentage use of antimicrobials in the total population of animals studied and provides a meaningful overall measurement of the use of antimicrobials in animals. A full discussion of this measurement is provided in the recent report, "Third joint inter-agency report on integrated analysis of consumption of antimicrobial agents and occurrence of antimicrobial resistance in bacteria from humans and food producing animals in the EU/EEA", JIACRA III 2016-2018 European Centre for Disease Prevention and Control, European Food Safety Authority and European Medicines Agency, available online at efsa.europa.eu/en/efsajournal/pub/6712. Changes in the total number of animals raised, or total biomass of animals, directly affects this calculation as it is the denominator. However, 2021 data on the total number of animals raised, provided by state or national sources, is not available by February 1 of the following year. Without 2021 data for the total number of animals raised, it is impossible to provide accurate data to use for trends regarding overall "Antimicrobial Consumption." Therefore, this unit of measurement is not evaluated in this report. For this reason, and the evolving nature of data collection, statistical analyses were not applied to the data received this year as it would be considered erroneous and misleading.

Adjustments to the deadline of the data collection and reporting process for this report would improve data collection, reporting and utility of data.

In addition to Maryland data reported, data from appropriate national or state agencies, organizations, trade associations or councils was reviewed for the past calendar year to provide any additional information on state use of MIADs in cattle, swine and poultry. Organizations contacted include the FDA, CDC, USDA, Delmarva Chicken Association, U.S. Poultry and Egg Association, National Chicken Council, National Cattlemen's Beef Association, and the University of Minnesota Center for Disease Research and Policy. A literature search was also done also to locate scientific papers that might provide information on antibiotic use.

Protection of Confidentiality:

This report is designed to provide useful information to the public while protecting confidential business information of animal owners and veterinarians. SB 471 provides specific reporting rules to protect confidential business information. Information is disaggregated by county, and if there are two or fewer reporting farm operations in a particular county for any of the categories, the information for that category is reported on a regional or statewide basis.

MDA believes the broad requirement to protect confidential business information means that we cannot independently report summary data that can be used together with summary data presented elsewhere in the report or data already in the public domain to indirectly derive confidential business information. In these instances, to protect the confidential business information that could be revealed by including such summary data, these categories will be reported collectively as "Other."

As a disclaimer, the data that is presented in this report was provided from third party sources submitted to MDA. Also, some of the final mass calculations include assumptions for feeding rates that can be extremely variable and uncertain. This report is not the product of a controlled research project, and data is not verified through audit. Also, as the final submission date by law is February 1, 2021, any data that is received after the due date may not be included in this report but will be included in next year's report.

STATE DATA SUMMARY

All 937 Maryland Accredited Veterinarians were notified of the requirement to report MIAD data a minimum of five times each by direct email through the Maryland State Board of Veterinary Examiners and the MDA Animal Health Program, and by phone as needed, to ensure knowledge of and cooperation with the new rule. A total of 11 veterinarians that prescribe for large cattle, swine and poultry farms responded with data (1.2%), 60 veterinarians responded that they do not prescribe or issue VFDs for MIADs for any farms that meet the criteria of the rule, and 867 veterinarians (92%) did not respond. The majority of veterinarians are small animal/companion animal veterinarians, and the lack of response implies they did not issue prescriptions or VFDs for MIADs, as they do not serve food animal operations. An effort to include a statement of non-applicability on the annual

veterinarian registration (rather than in a separate mailing) is planned to ensure awareness and compliance with SB 471.

Key observations from the state data are provided are below:

Individual trends showed:

- The largest user of MIADs was poultry operations:
 - an estimated 91% was used in chickens, (50.6 % in 2020), a total of 1,902 kg of use reported
 - an estimated 8% was used in swine, (1.7 % reported in 2020), a total of 141 kg
 - an estimated 7% was used in cattle, (47.7% in 2020), a total of 54 kg, and
 - an estimated 0% was used in turkeys.
(See Table 1).
- The largest amount of antimicrobial used in each species was:
 - an estimated 990 kg of Penicillin G Potassium, and 518 kg of chlortetracycline was used in poultry (chickens only).
 - an estimated 130 kg of chlortetracycline was reported used in swine, and
 - an estimated 53 kg of chlortetracycline was reported used in cattle.
(See Table 1)
- By antimicrobial class, penicillin represented the largest amount of antimicrobials used:
 - penicillins accounted for 992 kg of all MIADs, 47% of all MIADs reported,
 - tetracyclines accounted for 805 kg, 38% of total MIADs,
 - sulfonamides accounted for 264 kg, 13% of total MIADs,
 - lincosamides accounted for 22.4 kg, 1% of total MIADs,
 - aminoglycosides and polypeptides accounted for less than 1%, and
 - no cephalosporins, macrolides and fluoroquinolones were reported.
(See Table 2).

Table 1. Antimicrobial Use By Species, Production Class & Active Ingredient Used

Species Class	Total Active Ingredient (KG)	Percentage of Total Drugs Used
Cattle		
Cattle - Beef		
Chlortetracycline	11.776	0.56%
Sulfamethazine	0.441	0.02%
Cattle - Dairy		
Chlortetracycline	11.4	0.54%
Cattle - Feeder		
Chlortetracycline	1.1	0.05%
Cattle - Unknown		
Chlortetracycline	29.1	1.39%
Cattle Total	53.817	2.57%
Poultry		
Poultry - Broilers		
Bacitracin Methylene Disalicylate	4.096	0.20%
Chlortetracycline Hydrochloride	130.626	6.23%
Lincomycin HCl	22.4	1.07%
Oxytetracycline Hydrochloride	103.528	4.94%
Penicillin G Potassium	990.019	47.22%
Sulfadimethoxine	250.56	11.95%
Sulphadimidine	13.44	0.64%
Poultry - Layers		
Chlortetracycline	387.0875	18.46%
Poultry Total	1901.8	90.70%
Swine		
Swine		
Amoxicillin	2.1	0.10%
Chlortetracycline	130.3316	6.22%
Gentamicin Sulfate	8.78	0.42%
Trimethoprim/Sulfamethoxazole	0.0004	0.00%
Swine Total	141.2	6.73%
Grand Total	2,097	100.00%

Table 2. Antimicrobial Amount Reported Used by Class

Drug Class / Active Ingredient	Total Amount (KG)	Percentage Total
Aminoglycosides	8.8	0.42%
Gentamicin Sulfate	8.8	0.42%
Lincosamides	22.4	1.07%
Lincomycin HCl	22.4	1.07%
Penicillins	992.1	47.32%
Amoxicillin	2.1	0.10%
Penicillin G Potassium	990.0	47.22%
Polypeptides	4.1	0.20%
Bacitracin Methylene Disalicylate	4.1	0.20%
Sulfonamides	264.4	12.61%
Sulfadimethoxine	250.6	11.95%
Sulfamethazine	0.4	0.02%
Sulphadimidine	13.4	0.64%
Trimethoprim/Sulfamethoxazole	0.0	0.00%
Tetracyclines	804.9	38.39%
Chlortetracycline	570.8	27.22%
Chlortetracycline Hydrochloride	130.6	6.23%
Oxytetracycline Hydrochloride	103.5	4.94%
Grand Total	2096.8	100.00%

Summary data of antibiotic use by production operation, active ingredient, number of animals treated, duration of treatment (average and median) and for what disease indicator is provided below in Table 3, and total numbers of animals treated with MIADs on farms by county meeting the SB 471 are shown in Table 4. Table 5 shows the number of animals treated vs. the number of animals raised on farms meeting the criteria of SB 471, and Table 6 shows the total number of animals by county that meet the criteria of SB 471.

As in 2020, the large broiler industry used the largest amount of antibiotics, a total of 1,901 kgs of antibiotics for the industry to treat an estimated 8,653,406 birds. However, with a total industry of an estimated 280,089,656 total birds (based on 2020 statistics) on large operations, this equates to 3% of all broiler chickens being treated with MIADs. This is essentially the same treatment rate as reported in 2020 (2.88%). As usual, antibiotic usage was higher in winter months, consistent with normal periods of higher viral respiratory diseases and secondary bacterial infections, as shown in Chart A.

Swine as a production group had the next highest antibiotic usage in 2021, a reported total of 141 kg in a reported 28,562 swine. Maryland does not have a large swine industry. Total

estimated number of swine on farms with over 200 head is 55,353 animals. In 2021, based on reporting farms, 52% of swine were treated with MIADs. Swine population is mostly reported statewide unless otherwise noted because there are two or less farms per county raising swine to maintain confidentiality in accordance with SB 471.

There are relatively few dairy cattle in Maryland over 300 head (est. 52,654 cattle), and few cattle reported treated with MIADs (~700 animals). Percentage of total dairy cattle in large (over 300 head) herds treated with MIADs is estimated to be 1% in 2021 based on reports (note, this is using 2020 population data). This indicates a relatively low use of antimicrobials in feed or water in dairy cattle. Maryland has an estimated 6,055 beef cattle; 11% of these were reported treated with antimicrobials.

Table 3. Antimicrobial Use By Operation and Indications

Production Class / Indication	Count of Indications	Sum of Approx. # of Animals (head)	Average Duration of Use - Days	Median Duration of Use
Cattle				
Cattle - Beef				
Bacterial enteritis caused by E. coli	2	210	5	5
Bacterial pneumonia caused by Pasteurella species	1	100	21	21
Bovine Respiratory Disease (BRD)	4	360	17	16.5
Cattle - Dairy				
Bacterial enteritis caused by E. coli	3	700	5	5
Cattle - Feeder				
respiratory & neurologic disease	2	40	5	5
Cattle - Unknown				
Bacterial enteritis caused by E. coli	1	30	5	5
Bovine Respiratory Disease (BRD)	1	50	5	5
Unspecified	4	900	5	5
Poultry				
Poultry - Broilers				
An aid in prevention and control of necrotic enteritis caused by Clostridium perfringens susceptible to bacitracin methylenedisalicylate.	2	45,800	5	5
Control of bacterial septicemia	1	29,800	5	5
Control of chronic respiratory disease (CRD) and air sac infections	33	1,004,700	4	5
Control of chronic respiratory disease (CRD) and air sac infections caused by Mycoplasma gallisepticum and Escherichia coli, susceptible to oxytetracycline.	9	343,500	5	5
Control of Clostridial Dermatitis in chickens.	8	228,300	3	3
For the treatment of colibacillosis in chickens.	4	153,200	5	5
For the treatment of gangrenous dermatitis.	138	4,073,600	4	5
For the treatment of necrotic enteritis in chickens.	89	2,714,606	4	5
For treatment of bacterial septicemia	1	19,300	5	5
Lincomycin Hydrochloride Soluble Powder is indicated for the control of necrotic enteritis caused by Clostridium perfringens susceptible to lincomycin.	1	40,600	3	3
Poultry - Layers				
For the reduction of mortality due to E. coli peritonitis infections	8	1,041,000	6	5
respiratory & neurologic disease	1	22,900	10	10
Swine				
Swine				
Bacterial enteritis caused by E. coli	7	20,750	11	14
Colibacillosis	1	1,450	3	3
For control and treatment of enteric disease in swine	2	2,461	5	5
respiratory & neurologic disease	2	3,900	9	9
Grand Total	325	9,748,257	5	5

Table 4. Animals Raised on Reporting Farms Treated with Antimicrobials in Feed or Water 2021

County	Cattle - Beef	Cattle - Dairy	Cattle - Feeder	Cattle - Unknown	Poultry - Broilers	Poultry - Layers	Swine	Grand Total
Caroline					1,421,100			1,421,100
Dorchester					1,220,500			1,220,500
Frederick	480	600		330				1,410
Other	190	100	40		102,000	1,063,900	25,761	1,191,991
Queen Anne's					841,400			841,400
Somerset					1,189,800			1,189,800
Washington				650			2,800	3,450
Wicomico					2,162,806			2,162,806
Worcester					1,715,800			1,715,800
Grand Total	670	700	40	980	8,653,406	1,063,900	28,561	9,748,257

Table 5. Percentage of Reported Animals Treated vs. Total Animals Raised On Large Operations

	Cattle - Beef	Cattle - Feeders	Cattle - Unknown	Cattle - Dairy	Dairy - Calves	Poultry - Layers	Poultry - Turkeys	Poultry Broilers	Swine	Total
Total Animals on Large Operations in Maryland	6,055	9,140	-	52,654	5,518	6,098,400	60,000	280,890,656	55,353	287,177,776
Number of Animals Treated on Large Operations in MD	670	40	980	700	-	1,063,900	-	8,653,406	28,561	9,748,257
Percentage of Total Animals Treated	11%	0.44%	n/a	1%	0%	17%	0%	3%	52%	3%

Table 6. Total Animals Raised by County on Maryland Farms Regulated by SB471

(Maryland Department of Agriculture AIR Data 2020)

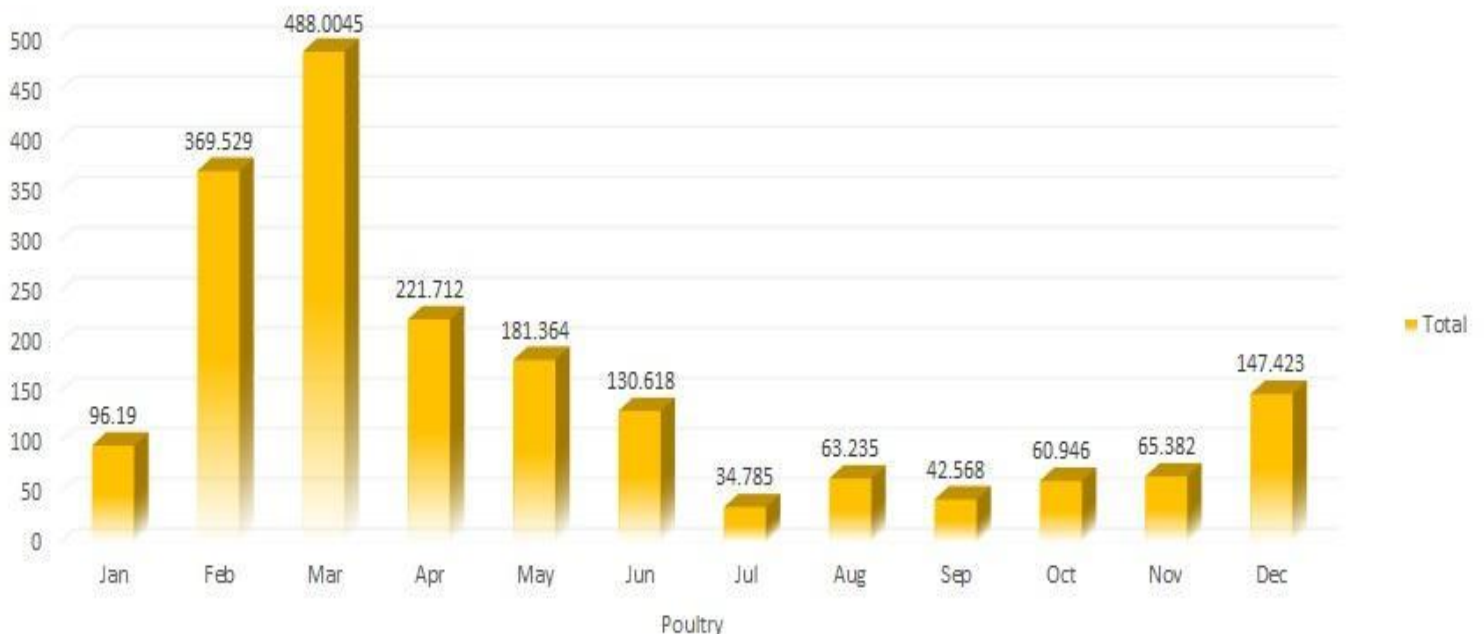
County	Cattle - Beef	Cattle - Feeders	Cattle - Dairy	Dairy - Calves	Poultry - Layers	Poultry - Turkeys	Poultry - Broilers	Swine	Grand Total
*Statewide					35,883	60,000			95,883
Anne Arundel		115	100						215
Baltimore	16	305	290	630			90,000		91,241
Caroline	60			1,200			60,000	50,479,930	50,541,190
Carroll	740	446	248	6,150			396,000		403,584
Cecil	277	194	340	1,994			3,437,000	1,854,000	5,293,805
Charles		108	95						203
Dorchester								23,771,266	23,771,266
Frederick	1,031	1,719	2,605	15,428	19,470				40,253
Garrett	272	598	1,168	1,436					3,474
Harford	463	782	1,112	2,805			40,000		45,162
Howard	50			230					280
Kent	510			5,556				4,298,400	4,304,466
Montgomery		316	242						558
Queen Anne's	243	262	286	2,292				24,518,600	24,521,683
Saint Mary's							100,000	144,000	244,000
Somerset		145	60					47,886,880	47,887,085
Talbot	67			665				4,562,600	4,563,332
Washington	1,789	1,065	2,594	13,868			74,400		93,716
Wicomico	-			400				63,104,680	63,105,080
Worcester							1,901,000	60,270,300	62,171,300
Grand Total	5,518	6,055	9,140	52,654	55,353	60,000	6,098,400	280,890,656	287,177,776

* Statewide = 2 or less farm operations per county reporting

DISCUSSION

CHART A - SEASONAL USE OF ANTIMICROBIALS IN POULTRY

2021



Data reported on MIAD use in Maryland did not show any unusual or unexpected trends. Use of antibiotics has significantly decreased in the poultry industry over years due to public and industry efforts toward judicious use of antibiotics, and the market pressure to sell and serve poultry that has not been treated with antibiotics. This industry trend appears stable, as noted by a 3% MIAD treatment rate over the past two years (2020-21). MIAD use in poultry is, according to industry representatives, only used when medically important for animal welfare. It is important to note that poultry and all food animals treated with antibiotics are subject to a withdrawal time prior to going to slaughter such that no meat that consumers eat contains antibiotics.

Changes noted in antibiotic usage data in cattle and swine between 2020 and 2021 are difficult to interpret. Caution should be taken interpreting 2021 statistics, given this is only the second year the law has been implemented. Possible lack of awareness of the reporting requirement by some veterinarians despite frequent contacts, the impact on animal sales and movement due to COVID-19 market disruptions, and the inability to access 2021 total animal population data to match up with 2021 antimicrobial use data (2020 population data was used) are all contributing factors. COVID-19 market disruptions continued throughout 2021 and may have affected animal populations and antimicrobial use. Reductions in animal sales, production or commingling such as at fairs and shows can result in reduced disease spread and therefore reduced need for antibiotic use. Conversely, reduced farmer incomes can lead to reduced ability to pay for veterinary care and antibiotic treatment needed. All to say, these confounders make it difficult to provide conclusions on the impact of the SB 471 legislation on antimicrobial use in Maryland or trends in general.

A campaign to promote the judicious use of antibiotics in food animals and companion animals is planned by MDA for CY22. Cattle, swine and poultry industries, with the help of academia and government agencies, are researching and piloting new methods of husbandry, nutrition and disease control that do not use or minimize the use of antimicrobials. Increased awareness of antimicrobial use concerns, use of alternative methods for disease control, and continued market pressures for antibiotic-free food, in combination with FDA label rules and SB 471, will likely result in continued reductions in AMC in animals. We shall see.

Attachment (1) 2020 Summary Report On Antimicrobials Sold or Distributed for Use in Food-Producing Animals, U.S. Food and Drug Administration, Center for Veterinary Medicine, December 2021



FDA

**U.S. FOOD & DRUG
ADMINISTRATION**

CENTER FOR VETERINARY MEDICINE

2020

Summary Report

On

***Antimicrobials Sold or Distributed for
Use in Food-Producing Animals***

December 2021

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Executive Summary

Each year, every sponsor of an approved or conditionally approved animal drug application containing an antimicrobial active ingredient must report to the Food and Drug Administration (FDA) the amount of each such ingredient in these drug products sold or distributed for use in food-producing animals. FDA summarizes this information and makes it available to the public in annual summary reports. This reporting requirement was enacted by Congress in 2008 to assist FDA in its continuing analysis of the interactions (including antimicrobial resistance), efficacy, and safety of antimicrobials approved for use in both humans and food-producing animals.

This summary report presents the sales and distribution data for actively marketed antimicrobial drugs approved for use in food-producing animals by drug class, medical importance,¹ route of administration, indication, and dispensing status, as well as species-specific estimates, of sales and distribution from 2011 through 2020.

Key observations from the report include:

- Domestic sales and distribution of medically important antimicrobials approved for use in food-producing animals (Table 2b):
 - decreased by 3% from 2019 through 2020.
 - decreased by 38% from 2015 (the year of peak sales) through 2020.
 - decreased by 27% from 2011 through 2020.
 - Tetracyclines, which represent the largest volume of these domestic sales (3,948,745 kg in 2020), decreased by 4% from 2019 through 2020.
- The domestic sales and distribution of medically important antimicrobials approved for use in food-producing animals for 2020 included:
 - An estimated 41% was intended for use in cattle, an estimated 41% intended for use in swine, an estimated 12% intended for use in turkeys, an estimated 2% intended for use in chickens, and an estimated 4% intended for use in other species/unknown (Table 4a).
 - Tetracyclines accounted for 66%, penicillins for 13%, macrolides for 7%, sulfonamides for 5%, aminoglycosides for 5%, lincosamides for 2%, cephalosporins for less than 1%, and fluoroquinolones for less than 1% (Table 2a).
 - An estimated 80% of cephalosporins, 57% of sulfonamides, 54% of aminoglycosides, and 43% of tetracyclines were intended for use in cattle. An estimated 87% of lincosamides and 42% of macrolides were intended for use in swine. An estimated 64% of penicillins were intended for use in turkeys (Table 5a).

¹ “Medically important antimicrobials” are those antimicrobials that have been determined to be medically important to human medicine.

I. Background

Section 105 of the Animal Drug User Fee Amendments of 2008 (ADUFA) (P.L. 110-316; 122 Stat. 3509) amended section 512 of the Federal Food, Drug, and Cosmetic Act (“the Act”) [21 U.S.C. 360b] to require that sponsors of approved and conditionally approved applications for new animal drugs containing an antimicrobial active ingredient submit an annual report to the Food and Drug Administration (FDA) on the amount of each such ingredient in the drug that is sold or distributed for use in food-producing animals, including information on any distributor-labeled product. This legislation was enacted to assist FDA in its continuing analysis of the interactions (including antimicrobial resistance), efficacy, and safety of antimicrobials approved for use in both humans and food-producing animals (see H. Rpt. 110-804).

On May 11, 2016, FDA issued a final rule codifying annual reporting requirements under section 105 of ADUFA and added a new reporting provision to obtain estimates of sales by major food-producing species (the 2016 final rule). The 2016 final rule is available at <https://www.gpo.gov/fdsys/pkg/FR-2016-05-11/pdf/2016-11082.pdf>. Sponsors must comply with the reporting requirements in the final rule when submitting their reports covering the period of calendar year 2016 and thereafter. Under 21 CFR 514.87, each report submitted to the FDA must include the following information: (1) A listing of each antimicrobial active ingredient contained in the product; (2) A description of each product sold or distributed by unit, including the container size, strength, and dosage form of such product units; (3) For each such product, a listing of the target animal species, indications, and production classes that are specified on the approved label; (4) For each such product, the number of units sold or distributed in the United States (i.e., domestic sales) for each month of the reporting year; and (5) For each such product, the number of units sold or distributed outside the United States (i.e., quantities exported) for each month of the reporting year. Each report must also provide a species-specific estimate of the percentage of each product that was sold or distributed domestically in the reporting year for use in any of the following animal species categories, but only for such species that appear on the approved label: Cattle, swine, chickens, turkeys. The total of the species-specific percentages reported for each product must account for 100 percent of its sales and distribution; therefore, a fifth category of “other species/unknown” must also be reported. Each year’s report must be submitted to FDA no later than March 31 using Form FDA 3744, “Antimicrobial Animal Drug Distribution Report,” the use of which is now mandatory as per the final rule. The form is available at <https://www.fda.gov/about-fda/reports-manuals-forms/forms>. These reports are separate from periodic drug experience reports that are required under 21 CFR 514.80(b)(4).

Under section 512(l)(3)(E) of the Act [21 U.S.C. 360b(l)(3)(E)], as codified at 21 CFR 514.87(f), FDA is directed to make annual summaries of the information reported by animal drug sponsors for each calendar year publicly available by December 31 of the following year. These annual reports must include a summary of sales and distribution data and information by antimicrobial drug class and may include additional summary data and information as determined by FDA.

Scope of Reporting

This summary report includes sales and distribution data of all antimicrobial drugs that are specifically approved for antibacterial uses or are known to have antibacterial properties, consistent with the requirements of Section 105 of ADUFA. However, as described elsewhere in this report, FDA has identified certain antimicrobial active ingredients as “medically important” based on their utility for treating disease in humans. Certain other antimicrobial drugs are not considered medically important. Ionophores, for example, lack utility in human medicine and their use in animals, primarily as coccidiostats, does not pose cross-resistance concerns; thus, they do not have the same human health risks as medically important antimicrobials and consequently they are not included in this report. Antifungal and antiviral drugs are not included in this report because, with the exception of formalin and hydrogen peroxide water immersion products, there are currently no approved drug applications actively marketed

for these purposes in food-producing animals. Antiprotozoal drugs without antibacterial properties (e.g., amprolium) are also not included.

Many antimicrobial animal drugs are approved and labeled for use in multiple species. Under section 512(l)(3)(B)(iii) of the Act [21 U.S.C. 360b(l)(3)(B)(iii)], each report submitted to the FDA must specify “a listing of the target animals... that are specified on the approved label of the product.” As stated above, the 2016 final rule includes an additional reporting requirement for species-specific sales estimates as a percentage of total domestic sales and distribution for each product, starting with calendar year 2016; therefore, this summary report includes summaries of sales and distribution estimates by certain major food-producing animal species – cattle, swine, chickens, and turkeys – but only if the species appears on the approved label for the product reported.

The total of the estimated species-specific percentages reported for each product must account for 100 percent of its sales and distribution; therefore, a fifth category of “Other Species/Unknown” must also be reported. The fifth category includes a single combined estimate of product sales and distribution for (1) other species listed on the approved label, including nonfood-producing animal species (e.g., dogs and horses) and minor food-producing species (e.g., fish and quail); (2) other species not listed on the approved label; and (3) unknown uses. For hypothetical scenarios that illustrate reporting of species-specific estimates, see the proposed rule published in the Federal Register of May 20, 2015 ([80 FR 28863 at 28866](#)).

Protecting Confidential Information

This report is designed to provide useful information to the public while, at the same time, meeting the requirement of section 512(l)(3)(E) of the Act [21 U.S.C. 360b(l)(3)(E)] to report summary data in a manner consistent with protecting both national security and confidential business information. In accordance with statutory requirements designed to protect confidential business information, and under 21 CFR 514.87(f), annual sales and distribution data are summarized by antimicrobial drug class, and only those antimicrobial drug classes and other categories with three or more distinct sponsors of approved and actively marketed animal drug products are independently reported. Antimicrobial drug classes with fewer than three distinct sponsors are reported collectively as “Not Independently Reported” (NIR).

The number of distinct sponsors in a particular antimicrobial class or other category is determined by two criteria: (1) the sponsor must be named in 21 CFR 510.600 as the holder of an approved application for an animal drug product in that particular class or category on the last day of the annual reporting period; and (2) the sponsor must have actively sold or distributed such animal drug product at some point during that annual reporting period. This same principle is utilized with the representation of any category included in this report. For example, for presentation of species-specific sales and distribution estimates, species categories (e.g., cattle) with fewer than three distinct sponsors are combined with the “Other Species/Unknown” category and reported collectively as “Not Independently Reported” (NIR).

Occasionally instances arise in which two or more individual pieces of summary data, when viewed together, can be utilized to derive other data that would reveal confidential business information (sometimes referred to as “the mosaic effect”). FDA believes the broad requirement to protect confidential business information means that we cannot independently report summary data that can be used together with summary data presented elsewhere in the report or data already in the public domain to indirectly derive confidential business information. In these instances, to protect the confidential business information that could be revealed by including such summary data, these categories will be reported collectively as “Other.”

Use of the Summary Information

The totals in this summary report represent sales and distribution data for antimicrobial drugs approved for use in food-producing animals. However, in reviewing this report it is important to keep in mind that there are certain inherent limitations on how the data provided in this report may appropriately be interpreted and used. For example, the sales and distribution data submitted by animal drug sponsors and summarized in this report are not indicative of how these antimicrobial drugs were actually used in animals (e.g., for what indications). With the exception of medicated feeds and certain drugs that are specifically prohibited from extralabel use (listed in FDA's regulations at 21 CFR 530.41), veterinarians can legally use approved animal drugs for species and therapeutic indications for which the drugs were not approved. Further, because the majority of antimicrobial drugs used in animal feed are approved for multiple indications, simply knowing that the route of administration for a drug is, for example, by oral means through animal feed cannot, by itself, be used to determine the indication for which the drug was used.

As discussed in **Description of Tables and Figures**, some of the antimicrobials included in this summary report are approved for use in both food- and nonfood-producing animals. In addition many of the applications are approved and labeled for use in multiple species, for multiple indications, and with multiple dosage regimens. These points should be carefully considered when interpreting or comparing the data presented in this summary report.

It is also important to note that animal drug sales data represent a summary of the volume of product sold or distributed through various outlets by the manufacturer intended for sale to the end user, not the volume of product ultimately purchased by the end user for administration to animals. For example, veterinarians and animal producers may purchase drugs, but never actually administer them to animals, or they may administer the drugs in later years.

Regarding the collection and reporting of species-specific data, the percentages provided by the sponsors are estimates of product sales and distribution. The data are not intended to be a substitute for actual usage data and should be used in conjunction with on-farm species-specific data on antimicrobial use. Also, there is a variety of factors that confound direct comparison of species-specific sales estimates, including differences in population size, weight, lifespan, and drug metabolism. For these reasons, caution should be applied when making direct comparisons between species-specific sales estimates.

Additionally, it should be noted that the potency of specific antimicrobials can vary substantially, which may impact the volume of drug needed to complete a course of therapy. This factor should be considered when comparing sales data for different antimicrobials.

Comparison of the information in this summary report with information published elsewhere regarding sales and distribution of antimicrobial drugs for use in humans poses many challenges. A number of differences in the circumstances in which antimicrobial drugs are used in human and veterinary medicine must be carefully considered, including:

- The number of humans in the U.S. population (approx. 331 million²) compared to the much larger number of animals in each of the many animal species (e.g., approx. 9.3 billion chickens slaughtered annually³).
- The differences in physical characteristics of humans compared to various animal species (e.g., physiology and weight: average adult human weight, 185 lb.⁴ versus adult cattle live weight, 1,373 lb.⁵).
- Duration and dosage of antibacterial drug administration may also vary by indication and, in general, between the various animal species and humans due to differences in physiology.
- As noted above, the available animal sales and distribution data are not reported to the FDA by each use indication and, thus, do not allow the FDA to distinguish between or among the different types of uses. The data, therefore, do not allow a direct comparison of the amounts of antimicrobials sold for certain animal uses with those sold for certain human uses.
- Veterinarians commonly utilize human antimicrobial drugs in their companion animal patients; therefore, amounts presented for certain human antimicrobial drugs may represent some unknown portion sold for use in companion animals.

It is, therefore, difficult to draw conclusions from any direct comparisons between the quantity of antimicrobial drugs sold for use in humans and the animal drug sales and distribution data (and species-specific estimates) for use in animals.

Description of Tables and Figures

The information presented in the following tables is based on 2020 annual sales and distribution data. Please note that the number of marketed products and associated sponsors may vary from year to year; thus, the categories presented in the tables may also vary from year to year to meet the requirements for protecting confidential business information. Any yearly variations in categories presented may make it difficult to directly compare certain tabular data between reported years. Furthermore, FDA occasionally receives updates or corrections to previously submitted 512(1)(3) data from animal drug sponsors at various times after the March 31 deadline. Therefore, minor variations in tabular data may occur over time depending on when these summary data are generated. The data included in the 2020 annual summary report differ in some cases from previously published reports. These differences may be attributed to updated sales and distribution information provided by sponsors for previous reporting years. Percent total, percent grand total, and percent change columns in the tables may sum to more than one hundred percent due to the rounding of kilogram totals. In general, the tables are formatted so that Table Xa corresponds to current-year data and Table Xb corresponds to multi-year trends, and that Figure Xa or Xb is associated with the corresponding Table Xa or Xb. Please note that the data for the multi-year trends is limited to ten years (2011 through 2020) for reasons of data representation, and which is adequate for time trend evaluation. For data before 2011, please refer to previously published reports.

² U.S. Census Bureau, “Quick Facts: United States,” available at <https://www.census.gov/quickfacts/fact/table/US/POP010220>.

³ U.S. Department of Agriculture, National Agricultural Statistics Service, “Poultry Slaughter: 2020 Summary,” February 2021, available at <https://downloads.usda.library.cornell.edu/usda-esmis/files/pg15bd88s/fl882d39g/j6731z19s/pslaan21.pdf>.

⁴ U.S. Centers for Disease Control and Prevention, National Center for Health Statistics, “Body Measurements,” available at <https://www.cdc.gov/nchs/fastats/body-measurements.htm>.

⁵ U.S. Department of Agriculture, National Agricultural Statistics Service, “Livestock Slaughter: 2020 Summary,” April 2021, available at <https://downloads.usda.library.cornell.edu/usda-esmis/files/r207tp32d/sj139x554/7w62g4561/lsan0421.pdf>.

II. Data on all marketed antimicrobial drug

Table 1

Antimicrobial drug classes and active ingredients approved for use in food-producing animals¹
Actively marketed in 2020

Aminocoumarins (NMI)²

Novobiocin

Aminoglycosides (MI)³

Dihydrostreptomycin
Gentamicin
Neomycin
Spectinomycin

Amphenicols (MI)³

Florfenicol

Cephalosporins (MI)³

Ceftiofur
Cephapirin

Diaminopyrimidines (MI)³

Ormetoprim

Fluoroquinolones (MI)³

Danofloxacin
Enrofloxacin

Glycolipids (NMI)²

Bambermycins

Ionophores (NMI)²

Laidlomycin
Lasalocid
Monensin
Narasin
Salinomycin

Lincosamides (MI)³

Lincomycin¹
Pirlimycin

Macrolides (MI)³

Gamithromycin
Tildipirosin
Tilmicosin
Tulathromycin
Tylosin
Tylvalosin

Orthosomycins (NMI)²

Avilamycin

Penicillins (MI)³

Amoxicillin
Ampicillin¹
Cloxacillin
Penicillin¹

Pleuromutilins (NMI)²

Tiamulin

Polymyxins (MI)³

Polymyxin B¹

Polypeptides (NMI)²

Bacitracin

Quinoxalines (NMI)²

Carbadox

Streptogramins (MI)³

Virginiamycin

Sulfonamides (MI)³

Sulfadimethoxine
Sulfamethazine
Sulfaquinoxaline

Tetracyclines (MI)³

Chlortetracycline¹
Oxytetracycline¹
Tetracycline

¹ Includes antimicrobial drug applications that are approved and labeled for use in both food-producing animals (e.g., cattle and swine) and nonfood-producing animals (e.g., dogs and horses).

² NMI = Not Medically Important. Refers to any antimicrobial class not listed in Appendix A of FDA's Guidance for Industry #152.

³ MI = Medically Important. Guidance for Industry #213 states that all antimicrobial drugs and their associated classes listed in Appendix A of FDA's Guidance for Industry #152 are considered "medically important" in human medical therapy.

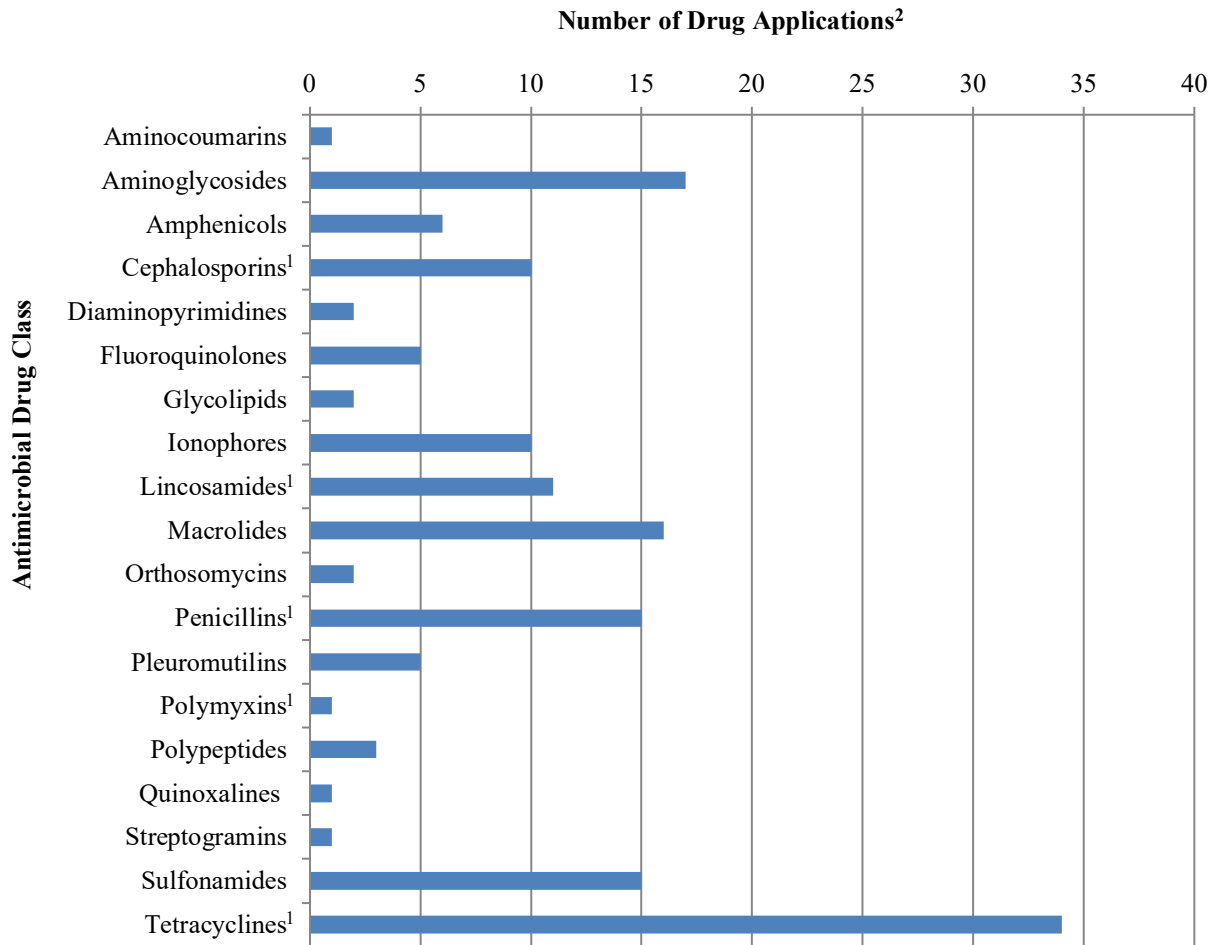
Figure 1a

Antimicrobial drug classes approved for use in food-producing animals¹

Actively marketed in 2020

Domestic sales and distribution data

Number of drug applications²



¹ Includes antimicrobial drug applications that are approved and labeled for use in both food-producing animals (e.g., cattle and swine) and nonfood-producing animals (e.g., dogs and horses).

² Some drug applications contain multiple active ingredients; therefore, drug applications containing more than one antimicrobial active ingredient may be represented more than once.

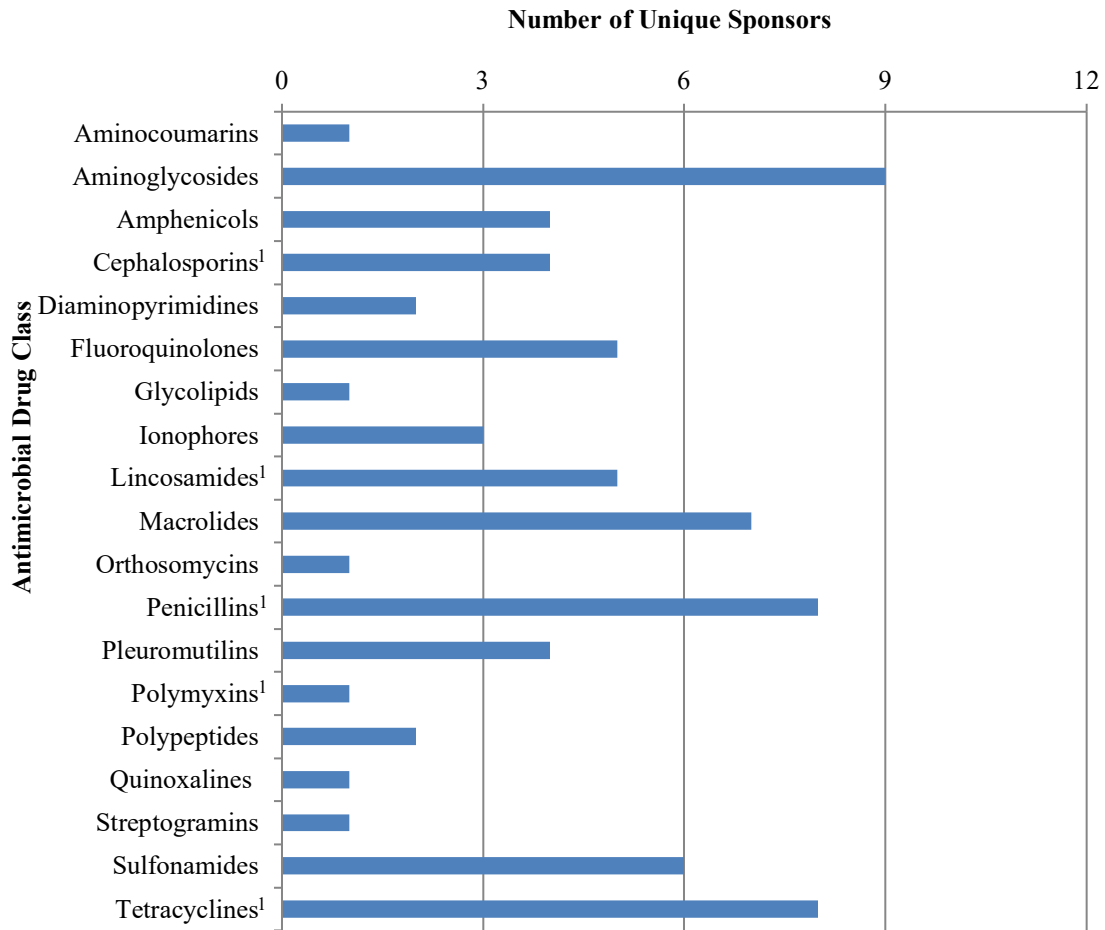
Figure 1b

Antimicrobial drug classes approved for use in food-producing animals¹

Actively marketed in 2020

Domestic sales and distribution data

Number of unique sponsors



¹ Includes antimicrobial drug applications that are approved and labeled for use in both food-producing animals (e.g., cattle and swine) and nonfood-producing animals (e.g., dogs and horses).

Table 2a

Antimicrobial drugs approved for use in food-producing animals¹
 Actively marketed in 2020
 Domestic sales and distribution data
 Reported by medical importance and drug class

	Drug Class	Annual Totals (kg)²	% Subtotal	% Grand Total
Medically Important³	<i>Aminoglycosides</i>	322,734	5%	3%
	<i>Amphenicols</i>	51,788	1%	<1%
	<i>Cephalosporins¹</i>	26,262	<1%	<1%
	<i>Fluoroquinolones</i>	24,176	<1%	<1%
	<i>Lincosamides¹</i>	147,026	2%	1%
	<i>Macrolides</i>	433,394	7%	4%
	<i>Penicillins¹</i>	762,888	13%	7%
	<i>Sulfonamides</i>	282,572	5%	3%
	<i>Tetracyclines¹</i>	3,948,745	66%	38%
	<i>NIR^{1,4}</i>	2,470	<1%	<1%
	<i>Subtotal</i>	6,002,056	100%	57%
Not Medically Important⁵	<i>Ionophores</i>	3,619,265	81%	35%
	<i>Pleuromutilins</i>	161,723	4%	2%
	<i>NIR⁶</i>	666,432	15%	6%
	<i>Subtotal</i>	4,447,420	100%	43%
	<i>Grand Total</i>	10,449,476		100%

¹ Includes antimicrobial drug applications that are approved and labeled for use in both food-producing animals (e.g., cattle and swine) and nonfood-producing animals (e.g., dogs and horses).

² kg = kilogram of active ingredient. Antimicrobial class includes drugs of different molecular weights, with some drugs labeled in different salt forms. Antimicrobials that are labeled in International Units (IU) (e.g., Penicillins) were converted to kg.

³ Guidance for Industry #213 states that all antimicrobial drugs and their associated classes listed in Appendix A of FDA's Guidance for Industry #152 are considered "medically important" in human medical therapy.

⁴ NIR = Not Independently Reported. Antimicrobial classes for which there were fewer than three distinct sponsors actively marketing products domestically are not independently reported. These classes include the following: Diaminopyrimidines, Polymyxins, and Streptogramins.

⁵ Not Medically Important refers to any antimicrobial class not listed in Appendix A of FDA's Guidance for Industry #152.

⁶ NIR = Not Independently Reported. Antimicrobial classes for which there were fewer than three distinct sponsors are not independently reported. These classes include the following: Aminocoumarins, Glycolipids, Orthosomycins, Polypeptides, and Quinoxalines.

Table 2b

Antimicrobial drugs approved for use in food-producing animals¹
 Actively marketed 2011-2020
 Domestic sales and distribution data
 Reported by medical importance and drug class

	Drug Class	2011 Annual Totals (kg) ²	2012 Annual Totals (kg) ²	2013 Annual Totals (kg) ²	2014 Annual Totals (kg) ²	2015 Annual Totals (kg) ²	2016 Annual Totals (kg) ²	2017 Annual Totals (kg) ²	2018 Annual Totals (kg) ²	2019 Annual Totals (kg) ²	2020 Annual Totals (kg) ²	% Change 2011 - 2020	% Change 2019 - 2020
Medically Important³	<i>Aminoglycosides¹</i>	214,895	277,854	267,734	304,160	344,120	319,009	259,184	289,455	307,988	322,734	50%	5%
	<i>Cephalosporins¹</i>	26,611	27,654	28,337	31,722	32,254	31,010	29,369	31,448	29,830	26,262	-1%	-12%
	<i>Fluoroquinolones</i>	*	*	15,099	17,220	20,063	18,502	22,904	23,350	24,556	24,176	**	-2%
	<i>Lincosamides¹</i>	190,101	218,140	236,450	233,681	182,543	142,458	152,497	125,514	134,962	147,026	-23%	9%
	<i>Macrolides¹</i>	582,836	616,274	563,251	621,769	627,757	554,714	468,794	473,038	488,082	433,394	-26%	-11%
	<i>Penicillins¹</i>	885,304	965,196	828,721	885,975	936,669	842,863	690,889	731,863	716,525	762,888	-14%	6%
	<i>Sulfonamides¹</i>	383,105	493,514	383,469	452,224	380,186	369,826	274,112	278,562	304,327	282,572	-26%	-7%
	<i>Tetracyclines¹</i>	5,652,855	5,954,361	6,514,779	6,604,199	6,881,530	5,861,188	3,535,701	3,974,179	4,117,031	3,948,745	-30%	-4%
	<i>NIR^{1,4}</i>	319,991	344,428	355,452	328,389	297,822	216,771	125,761	104,888	65,958	54,258	-83%	-18%
	Subtotal	8,255,697	8,897,420	9,193,293	9,479,339	9,702,943	8,356,340	5,559,212	6,032,298	6,189,260	6,002,056	-27%	-3%
Not Medically Important⁵	<i>Ionophores</i>	4,122,397	4,573,795	4,434,657	4,718,650	4,740,615	4,651,491	4,394,850	4,562,260	4,270,122	3,619,265	-12%	-15%
	<i>Pleuromutilins</i>	*	*	*	*	*	*	*	*	*	161,723	**	**
	<i>NIR⁶</i>	1,190,943	1,151,532	1,157,095	1,163,571	1,134,382	1,018,305	979,306	968,524	1,008,976	666,432	-44%	-34%
	Subtotal	5,313,340	5,725,327	5,591,752	5,882,221	5,874,997	5,669,796	5,374,156	5,530,784	5,279,098	4,447,420	-16%	-16%
Grand Total	13,569,037	14,622,747	14,785,045	15,361,560	15,577,940	14,026,136	10,933,367	11,563,081	11,468,357	10,449,476	-23%	-9%	

¹ Includes antimicrobial drug applications that are approved and labeled for use in both food-producing animals (e.g., cattle and swine) and nonfood-producing animals (e.g., dogs and horses).

² kg = kilogram of active ingredient. Antimicrobial class includes drugs of different molecular weights, with some drugs labeled in different salt forms. Antimicrobials that are labeled in International Units (IU) (e.g., Penicillins) were converted to kg.

* Not reported because there were fewer than three distinct sponsors actively marketing products domestically in 2011 and 2012.

** There were fewer than three distinct sponsors actively marketing products domestically in 2011 and 2012. Therefore, percentage change cannot be calculated.

³ Guidance for Industry #213 states that all antimicrobial drugs and their associated classes listed in Appendix A of FDA's Guidance for Industry #152 are considered "medically important" in human medical therapy.

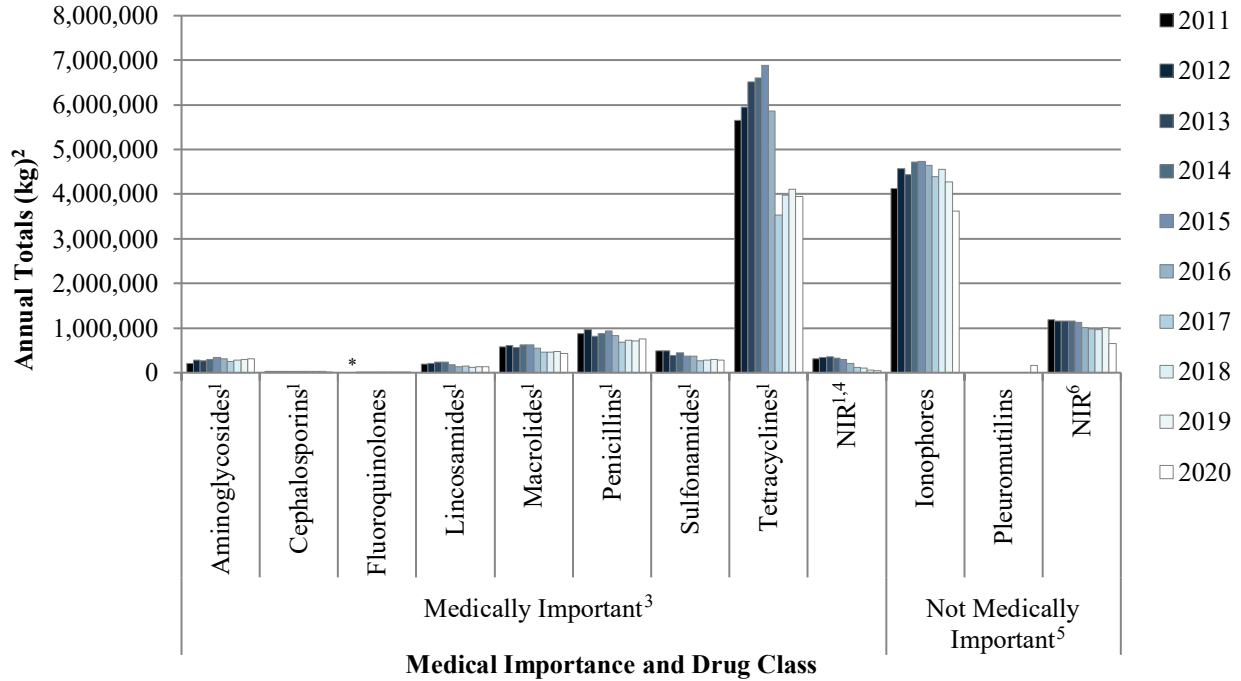
⁴ NIR = Not Independently Reported. Antimicrobial classes for which there were fewer than three distinct sponsors actively marketing products domestically are not independently reported. These classes include the following: Amphenicols, Diaminopyrimidines, Polymyxins (excluding 2012 and 2013), and Streptogramins.

⁵ Not Medically Important refers to any antimicrobial class not listed in Appendix A of FDA's Guidance for Industry #152.

⁶ NIR = Not Independently Reported. Antimicrobial classes for which there were fewer than three distinct sponsors are not independently reported. These classes include the following: Aminocoumarins, Glycolipids, Orthosomycins (excluding 2011 through 2015), Pleuromutilins (excluding 2020), Polypeptides, and Quinoxalines.

Figure 2b

Antimicrobial drugs approved for use in food-producing animals¹
 Actively marketed 2011-2020
 Domestic sales and distribution data
 Reported by medical importance and drug class



¹ Includes antimicrobial drug applications that are approved and labeled for use in both food-producing animals (e.g., cattle and swine) and nonfood-producing animals (e.g., dogs and horses).

² kg = kilogram of active ingredient. Antimicrobial class includes drugs of different molecular weights, with some drugs labeled in different salt forms. Antimicrobials that are labeled in International Units (IU) (e.g., Penicillins) were converted to kg.

* Not reported because there were fewer than three distinct sponsors actively marketing products domestically in 2011 and 2012.

³ Guidance for Industry #213 states that all antimicrobial drugs and their associated classes listed in Appendix A of FDA’s Guidance for Industry #152 are considered “medically important” in human medical therapy.

⁴ NIR = Not Independently Reported. Antimicrobial classes for which there were fewer than three distinct sponsors actively marketing products domestically are not independently reported. These classes include the following: Amphenicols, Diaminopyrimidines, Polymyxins (excluding 2012 and 2013), and Streptogramins.

⁵ Not Medically Important refers to any antimicrobial class not listed in Appendix A of FDA’s Guidance for Industry #152.

⁶ NIR = Not Independently Reported. Antimicrobial classes for which there were fewer than three distinct sponsors are not independently reported. These classes include the following: Aminocoumarins, Glycolipids, Orthosomycins (excluding 2011 through 2015), Pleuromutilins (excluding 2020), Polypeptides, and Quinoxalines.

Table 3a

Antimicrobial drugs approved for use in food-producing animals¹
Actively marketed in 2020
Domestic/export sales and distribution data

Domestic/Export	Annual Totals (kg)²	% Total
<i>Domestic¹</i>	10,449,476	100%
<i>Export^{1,3}</i>	6,433	<1%
<i>Total</i>	<i>10,455,909</i>	<i>100%</i>

¹ Includes antimicrobial drug applications that are approved and labeled for use in both food-producing animals (e.g., cattle and swine) and nonfood-producing animals (e.g., dogs and horses).

² kg = kilogram of active ingredient. Antimicrobial class includes drugs of different molecular weights, with some drugs labeled in different salt forms. Antimicrobials that are labeled in International Units (IU) (e.g., Penicillins) were converted to kg.

³ Only includes exports of FDA-approved, US-labeled antimicrobial drugs approved for use in food-producing animals.

Table 3b

Antimicrobial drugs approved for use in food-producing animals¹
 Actively marketed in 2011-2020
 Domestic/export sales and distribution data

Domestic/Export	2011 Estimated Annual Totals (kg) ²	2012 Estimated Annual Totals (kg) ²	2013 Estimated Annual Totals (kg) ²	2014 Estimated Annual Totals (kg) ²	2015 Estimated Annual Totals (kg) ²	2016 Estimated Annual Totals (kg) ²	2017 Estimated Annual Totals (kg) ²	2018 Estimated Annual Totals (kg) ²	2019 Estimated Annual Totals (kg) ²	2020 Estimated Annual Totals (kg) ²	% Change 2011 - 2020	% Change 2019 - 2020
<i>Domestic</i> ¹	13,569,037	14,622,747	14,785,045	15,361,560	15,577,940	14,026,136	10,933,367	11,563,081	11,468,357	10,449,476	-23%	-9%
<i>Export</i> ^{1,3}	202,335	139,173	74,374	30,682	20,861	6,818	10,038	8,134	5,355	6,433	-97%	20%
Total	13,771,373	14,761,919	14,859,419	15,392,242	15,598,801	14,032,953	10,943,406	11,571,216	11,473,712	10,455,909	-24%	-9%

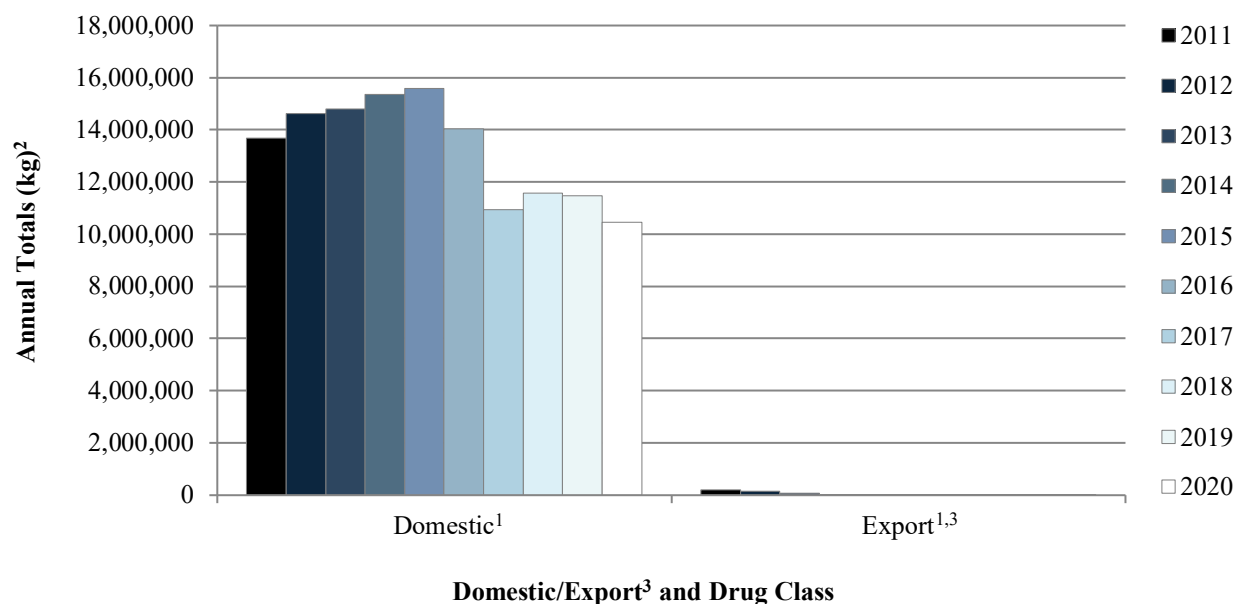
¹ Includes antimicrobial drug applications that are approved and labeled for use in both food-producing animals (e.g., cattle and swine) and nonfood-producing animals (e.g., dogs and horses).

² kg = kilogram of active ingredient. Antimicrobial class includes drugs of different molecular weights, with some drugs labeled in different salt forms. Antimicrobials that are labeled in International Units (IU) (e.g., Penicillins) were converted to kg.

³ Only includes exports of FDA-approved, US-labeled antimicrobial drugs approved for use in food-producing animals.

Figure 3b

Antimicrobial drugs approved for use in food-producing animals¹
Actively marketed 2011-2020
Domestic/export sales and distribution data



¹ Includes antimicrobial drug applications that are approved and labeled for use in both food-producing animals (e.g., cattle and swine) and nonfood-producing animals (e.g., dogs and horses).
² kg = kilogram of active ingredient. Antimicrobial class includes drugs of different molecular weights, with some drugs labeled in different salt forms. Antimicrobials that are labeled in International Units (IU) (e.g., Penicillins) were converted to kg.
³ Only includes exports of FDA-approved, US-labeled antimicrobial drugs approved for use in food-producing animals.

III. Data on medically important antimicrobial drugs

Table 4a

Medically important¹ antimicrobial drugs approved for use in food-producing animals²
Actively marketed in 2020
Domestic sales and distribution data
Reported by species-specific estimated sales

Species	Estimated Annual Totals (kg) ³	% Total
Cattle	2,449,441	41%
Swine	2,451,382	41%
Chicken	141,793	2%
Turkey	690,841	12%
Other ⁴	268,600	4%
Total	6,002,056	100%

¹ Guidance for Industry #213 states that all antimicrobial drugs and their associated classes listed in Appendix A of FDA’s Guidance for Industry #152 are considered “medically important” in human medical therapy.

² Includes antimicrobial drug applications that are approved and labeled for use in both food-producing animals (e.g., cattle and swine) and nonfood-producing animals (e.g., dogs and horses).

³ kg = kilogram of active ingredient. Antimicrobial class includes drugs of different molecular weights, with some drugs labeled in different salt forms. Antimicrobials that are labeled in International Units (IU) (e.g., Penicillins) were converted to kg.

⁴ The Other category includes estimates of product sales intended for use in (1) species listed on the approved label other than cattle, swine, chickens, and turkeys, including nonfood-producing animal species (e.g., dogs and horses) and minor food-producing species (e.g., fish); (2) other species not listed on the approved label; and (3) unknown uses.

Table 4b

Medically important¹ antimicrobial drugs approved for use in food-producing animals²
 Actively marketed in 2016-2020
 Domestic sales and distribution data
 Reported by species-specific estimated sales

Species	2016 Estimated Annual Totals (kg) ³	2017 Estimated Annual Totals (kg) ³	2018 Estimated Annual Totals (kg) ³	2019 Estimated Annual Totals (kg) ³	2020 Estimated Annual Totals (kg) ³	% Change 2016 - 2020	% Change 2019 - 2020
<i>Cattle</i>	3,605,543	2,333,839	2,517,386	2,529,281	2,449,441	-32%	-3%
<i>Swine</i>	3,133,262	2,022,932	2,374,277	2,582,399	2,451,382	-22%	-5%
<i>Chicken</i>	508,800	268,047	221,774	192,964	141,793	-72%	-27%
<i>Turkey</i>	756,620	670,831	671,108	644,921	690,841	-9%	7%
<i>Other⁴</i>	352,114	263,564	247,753	239,694	268,600	-24%	12%
Total	8,356,340	5,559,212	6,032,298	6,189,260	6,002,056	-28%	-3%

¹ Guidance for Industry #213 states that all antimicrobial drugs and their associated classes listed in Appendix A of FDA’s Guidance for Industry #152 are considered “medically important” in human medical therapy.

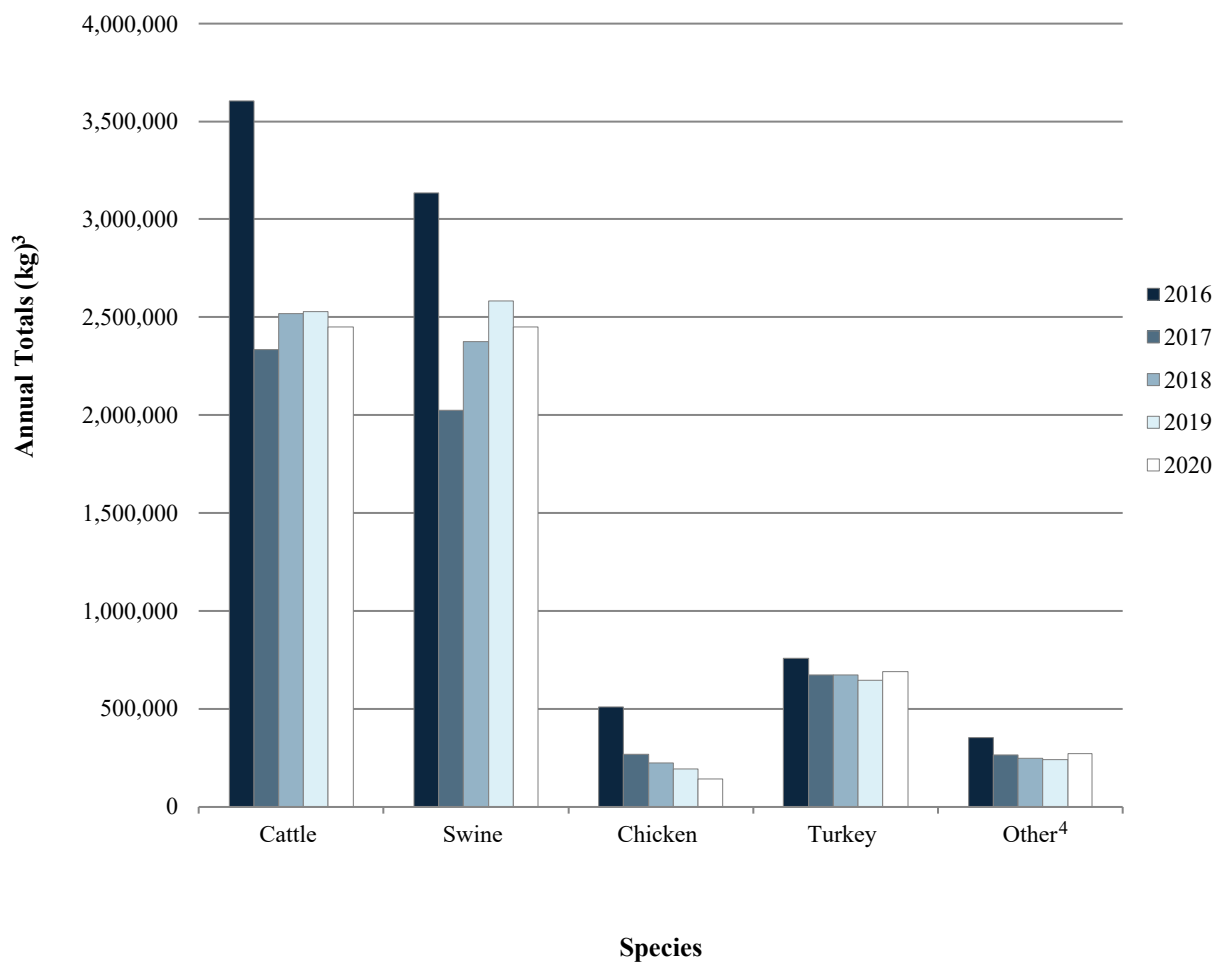
² Includes antimicrobial drug applications that are approved and labeled for use in both food-producing animals (e.g., cattle and swine) and nonfood-producing animals (e.g., dogs and horses).

³ kg = kilogram of active ingredient. Antimicrobial class includes drugs of different molecular weights, with some drugs labeled in different salt forms. Antimicrobials that are labeled in International Units (IU) (e.g., Penicillins) were converted to kg.

⁴ The Other category includes estimates of product sales intended for use in (1) species listed on the approved label other than cattle, swine, chickens, and turkeys, including nonfood-producing animal species (e.g., dogs and horses) and minor food-producing species (e.g., fish); (2) other species not listed on the approved label; and (3) unknown uses.

Figure 4b

Medically important¹ antimicrobial drugs approved for use in food-producing animals²
Actively marketed in 2016-2020
Domestic sales and distribution data
Reported by species-specific estimated sales



¹ Guidance for Industry #213 states that all antimicrobial drugs and their associated classes listed in Appendix A of FDA’s Guidance for Industry #152 are considered “medically important” in human medical therapy.

² Includes antimicrobial drug applications that are approved and labeled for use in both food-producing animals (e.g., cattle and swine) and nonfood-producing animals (e.g., dogs and horses).

³ kg = kilogram of active ingredient. Antimicrobial class includes drugs of different molecular weights, with some drugs labeled in different salt forms. Antimicrobials that are labeled in International Units (IU) (e.g., Penicillins) were converted to kg.

⁴ The Other category includes estimates of product sales intended for use in (1) species listed on the approved label other than cattle, swine, chickens, and turkeys, including nonfood-producing animal species (e.g., dogs and horses) and minor food-producing species (e.g., fish); (2) other species not listed on the approved label; and (3) unknown uses.

Table 5a

Medically important¹ antimicrobial drugs approved for use in food-producing animals²
 Actively marketed in 2020
 Domestic sales and distribution data
 Reported by drug class and species-specific estimated sales

Ingredient Class	Species	Estimated Annual Totals (kg)³	% Subtotal
Aminoglycosides	<i>Cattle</i>	174,132	54%
	<i>Swine</i>	72,659	23%
	<i>Chicken</i>	17,634	5%
	<i>Turkey</i>	25,265	8%
	<i>Other⁴</i>	33,044	10%
	Subtotal	322,734	100%
Amphenicols	<i>Cattle</i>	47,609	92%
	<i>NIR⁵</i>	4,179	8%
	Subtotal	51,788	100%
Cephalosporins²	<i>Cattle</i>	21,007	80%
	<i>Swine</i>	4,232	16%
	<i>NIR⁶</i>	1,023	4%
	Subtotal	26,262	100%
Fluoroquinolones	<i>Cattle</i>	12,446	51%
	<i>Swine</i>	11,482	47%
	<i>Other⁴</i>	248	1%
	Subtotal	24,176	100%
Lincosamides²	<i>Swine</i>	128,562	87%
	<i>Chicken</i>	7,299	5%
	<i>NIR⁷</i>	11,165	8%
	Subtotal	147,026	100%
Macrolides	<i>Cattle</i>	247,581	57%
	<i>Swine</i>	180,537	42%
	<i>Chicken</i>	2,194	1%
	<i>NIR⁴</i>	3,082	1%
	Subtotal	433,394	100%
Penicillins²	<i>Cattle</i>	82,008	11%
	<i>Turkey</i>	486,322	64%
	<i>Other</i>	177,348	23%
	<i>NIR⁸</i>	17,210	2%
	Subtotal	762,888	100%
Sulfonamides	<i>Cattle</i>	161,220	57%
	<i>Swine</i>	91,981	33%
	<i>Chicken</i>	6,230	2%
	<i>Turkey</i>	15,660	6%
	<i>Other⁴</i>	7,481	3%
	Subtotal	282,572	100%
Tetracyclines²	<i>Cattle</i>	1,703,391	43%
	<i>Swine</i>	1,943,871	49%
	<i>Chicken</i>	105,817	3%
	<i>Turkey</i>	161,909	4%
	<i>Other⁴</i>	33,757	1%
	Subtotal	3,948,745	100%
NIR^{2,9}	<i>All Species¹⁰</i>	2,470	100%
	Subtotal	2,470	100%

¹ Guidance for Industry #213 states that all antimicrobial drugs and their associated classes listed in Appendix A of FDA’s Guidance for Industry #152 are considered “medically important” in human medical therapy.

² Includes antimicrobial drug applications that are approved and labeled for use in both food-producing animals (e.g., cattle and swine) and nonfood-producing animals (e.g., dogs and horses).

³ kg = kilogram of active ingredient. Antimicrobial class includes drugs of different molecular weights, with some drugs labeled in different salt forms. Antimicrobials that are labeled in International Units (IU) (e.g., Penicillins) were converted to kg.

⁴ The Other category includes estimates of product sales intended for use in (1) species listed on the approved label other than cattle, swine, chickens, and turkeys, including nonfood-producing animal species (e.g., dogs and horses) and minor food-producing species (e.g., fish); (2) other species not listed on the approved label; and (3) unknown uses.

⁵ NIR = Not Independently Reported. Species-specific sales estimates for which there were fewer than three distinct sponsors are not independently reported. This category includes the following: Swine and Other.

⁶ NIR = Not Independently Reported. Species-specific sales estimates for which there were fewer than three distinct sponsors are not independently reported. This category includes the following: Chicken and Other.

⁷ NIR = Not Independently Reported. Species-specific sales estimates for which there were fewer than three distinct sponsors are not independently reported. This category includes the following: Cattle and Other.

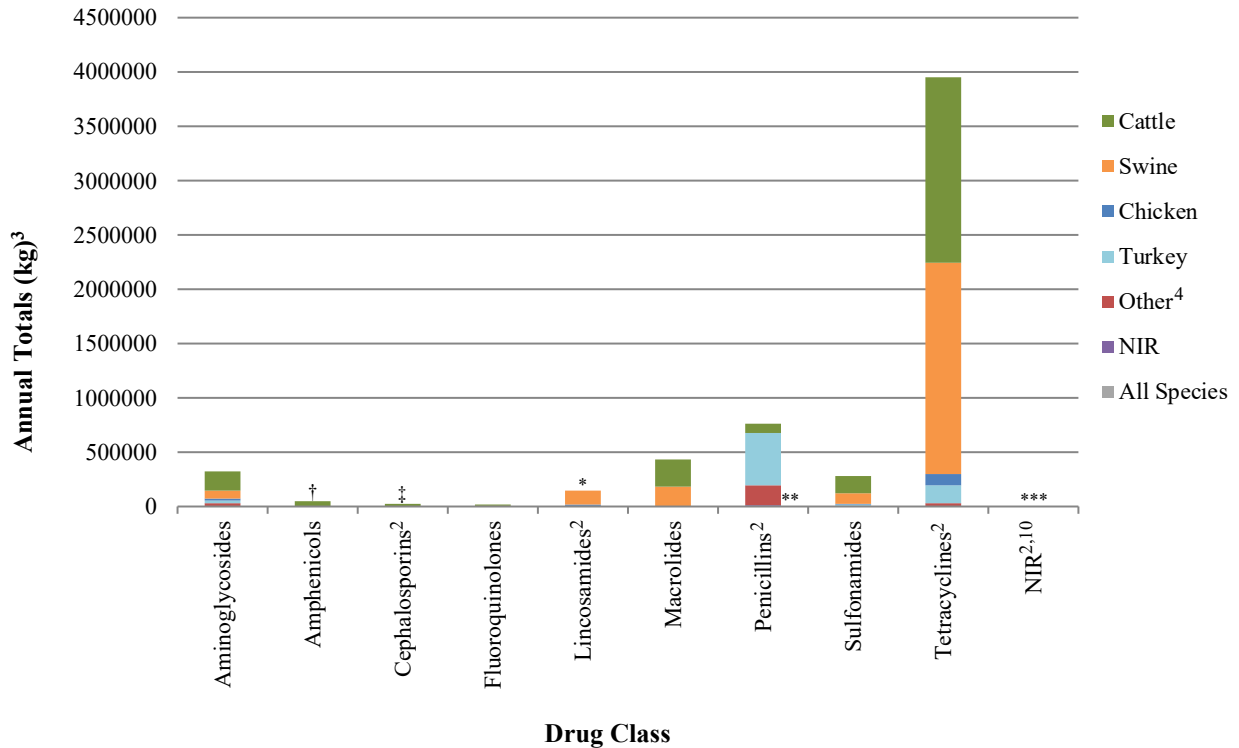
⁸ NIR = Not Independently Reported. Species-specific sales estimates for which there were fewer than three distinct sponsors are not independently reported. This category includes the following: Swine and Chicken.

⁹ NIR = Not Independently Reported. Antimicrobial classes for which there were fewer than three distinct sponsors actively marketing products domestically are not independently reported. These classes include the following: Diaminopyrimidines, Polymyxins, and Streptogramins.

¹⁰ This category includes the following: Swine, Chicken, and Other.

Figure 5a

Medically important¹ antimicrobial drugs approved for use in food-producing animals²
Actively marketed in 2020
Domestic sales and distribution data
Reported by drug class and species-specific estimated sales



¹ Guidance for Industry #213 states that all antimicrobial drugs and their associated classes listed in Appendix A of FDA’s Guidance for Industry #152 are considered “medically important” in human medical therapy.

² Includes antimicrobial drug applications that are approved and labeled for use in both food-producing animals (e.g., cattle and swine) and nonfood-producing animals (e.g., dogs and horses).

³ kg = kilogram of active ingredient. Antimicrobial class includes drugs of different molecular weights, with some drugs labeled in different salt forms. Antimicrobials that are labeled in International Units (IU) (e.g., Penicillins) were converted to kg.

⁴ The Other category includes estimates of product sales intended for use in (1) species listed on the approved label other than cattle, swine, chickens, and turkeys, including nonfood-producing animal species (e.g., dogs and horses) and minor food-producing species (e.g., fish); (2) other species not listed on the approved label; and (3) unknown uses.

[†] NIR = Not Independently Reported. Species-specific sales estimates for which there were fewer than three distinct sponsors are not independently reported. This category includes the following: Swine and Other.

[‡] NIR = Not Independently Reported. Species-specific sales estimates for which there were fewer than three distinct sponsors are not independently reported. This category includes the following: Chicken and Other.

^{*} NIR = Not Independently Reported. Species-specific sales estimates for which there were fewer than three distinct sponsors are not independently reported. This category includes the following: Cattle and Other.

^{**} This category includes the following: Swine and Other.

¹⁰ NIR = Not Independently Reported. Antimicrobial classes for which there were fewer than three distinct sponsors actively marketing products domestically are not independently reported. These classes include the following: Diaminopyrimidines, Polymyxins, and Streptogramins.

^{***} This category includes the following: Swine, Chicken, and Other.

Table 5b
Medically important¹ antimicrobial drugs approved for use in food-producing animals²
 Actively marketed 2016-2020
 Domestic sales and distribution data
 Reported by drug class and species-specific estimated sales

Ingredient Class	Species	2016 Estimated Annual Totals (kg) ³	2017 Estimated Annual Totals (kg) ³	2018 Estimated Annual Totals (kg) ³	2019 Estimated Annual Totals (kg) ³	2020 Estimated Annual Totals (kg) ³	% Change 2019 - 2020	% Change 2016 - 2020
Aminoglycosides	Cattle	161,646	124,675	133,842	139,445	174,132	8%	25%
	Swine	65,850	63,602	90,708	101,270	72,659	10%	-28%
	Chicken	24,111	20,185	13,430	16,200	17,634	-27%	9%
	Turkey	22,198	24,042	24,321	25,125	25,265	14%	1%
	Other ⁴	45,204	26,680	27,154	25,949	33,044	-27%	27%
	Subtotal	319,009	259,184	289,455	307,988	322,734	1%	5%
Amphenicols	Cattle	*	*	*	*	47,609	**	**
	NIR ⁵	*	49,321	56,056	53,212	4,179	**	-92%
	Subtotal	*	49,321	56,056	53,212	51,788	**	-3%
Cephalosporins ²	Cattle	24,677	23,512	25,337	24,158	21,007	-15%	-13%
	Swine	*	*	*	*	4,232	**	**
	NIR ⁶	6,333	5,857	6,111	5,672	1,023	-84%	-82%
	Subtotal	31,010	29,369	31,448	29,830	26,262	-15%	-12%
Fluoroquinolones	Cattle	*	*	*	12,560	12,446	**	**
	Swine	*	*	*	11,790	11,482	**	**
	Other ⁴	*	*	*	205	248	**	**
	NIR ⁷	18,502	22,904	23,350	*	*	**	**
	Subtotal	18,502	22,904	23,350	24,556	24,176	31%	-2%
Lincosamides ²	Swine	118,916	128,642	104,527	114,398	128,562	8%	12%
	Chicken	8,874	8,213	8,780	6,409	7,299	-18%	14%
	NIR ⁸	14,667	15,642	12,208	14,156	11,165	-24%	-21%
	Subtotal	142,458	152,497	125,514	134,962	147,026	3%	9%
Macrolides	Cattle	194,811	274,479	274,837	286,438	247,581	27%	-14%
	Swine	337,295	189,503	192,175	195,441	180,537	-46%	-8%
	Chicken	20,718	2,614	2,971	2,760	2,194	-89%	-20%
	Turkey	1,176	1,307	1,653	1,944	*	**	**
	Other ⁴	714	891	1,403	1,498	*	**	**
	NIR ⁹	*	*	*	*	3,082	**	**
	Subtotal	554,714	468,794	473,038	488,082	433,394	-22%	-11%
Penicillins ²	Cattle	99,935	96,936	96,591	78,887	82,008	-18%	4%
	Swine	17,958	*	*	*	*	**	**
	Turkey	529,083	423,689	463,939	471,660	486,322	-8%	3%
	Other ⁴	195,888	*	*	*	177,348	**	**
	NIR ¹⁰	*	170,263	171,333	165,978	17,210	**	-90%
	Subtotal	842,863	690,889	731,863	716,525	762,888	-9%	6%
Sulfonamides ²	Cattle	234,955	196,902	187,603	197,486	161,220	-31%	-18%
	Swine	40,215	31,024	45,581	72,126	91,981	129%	28%
	Chicken	21,115	7,319	*	5,903	6,230	-70%	**
	Turkey	41,127	28,817	30,446	14,908	15,660	-62%	5%
	Other ⁴	32,414	10,050	*	13,905	7,481	-77%	**
	NIR ¹¹	*	*	14,933	*	*	**	**
Subtotal	369,826	274,112	278,562	304,327	282,572	-24%	-7%	
Tetracyclines ²	Cattle	2,840,519	1,560,542	1,732,416	1,741,883	1,703,391	-40%	-2%
	Swine	2,520,680	1,579,145	1,902,950	2,062,275	1,943,871	-23%	-6%
	Chicken	285,513	153,621	140,561	149,295	105,817	-63%	-29%
	Turkey	156,617	192,976	150,749	131,034	161,909	3%	24%
	Other ⁴	57,859	49,416	47,502	32,545	33,757	-42%	4%
Subtotal	5,861,188	3,535,701	3,974,179	4,117,031	3,948,745	-33%	-4%	
NIR ^{2,12}	All Species ¹³	216,771	76,440	48,832	12,746	2,470	-99%	-81%
	Subtotal	216,771	76,440	48,832	12,746	2,470	-99%	-81%

¹ Guidance for Industry #213 states that all antimicrobial drugs and their associated classes listed in Appendix A of FDA's Guidance for Industry #152 are considered "medically important" in human medical therapy.

² Includes antimicrobial drug applications that are approved and labeled for use in both food-producing animals (e.g., cattle and swine) and nonfood-producing animals (e.g., dogs and horses).

³ kg = kilogram of active ingredient. Antimicrobial class includes drugs of different molecular weights, with some drugs labeled in different salt forms.

Antimicrobials that are labeled in International Units (IU) (e.g., Penicillins) were converted to kg.

⁴ The Other category includes estimates of product sales intended for use in (1) species listed on the approved label other than cattle, swine, chickens, and turkeys, including nonfood-producing animal species (e.g., dogs and horses) and minor food-producing species (e.g., fish); (2) other species not listed on the approved label; and (3) unknown uses.

* Species-specific sales estimates for which there were fewer than three distinct sponsors are not independently reported.

** Species-specific sales estimates for which there were fewer than three distinct sponsors are not independently reported. Therefore, percentage change cannot be calculated.

⁵ NIR = Not Independently Reported. Species-specific sales estimates for which there were fewer than three distinct sponsors are not independently reported. This category includes the following: Cattle (excluding 2020), Swine (excluding 2016), and Other.

⁶ NIR = Not Independently Reported. Species-specific sales estimates for which there were fewer than three distinct sponsors are not independently reported. This category includes the following: Chicken and Other.

⁷ NIR = Not Independently Reported. Species-specific sales estimates for which there were fewer than three distinct sponsors are not independently reported. This category includes the following: Cattle (excluding 2019 and 2020), Swine (excluding 2019 and 2020), and Other (excluding 2019 and 2020).

⁸ NIR = Not Independently Reported. Species-specific sales estimates for which there were fewer than three distinct sponsors are not independently reported. This category includes the following: Cattle, Turkey (excluding 2016 through 2018 and 2020), and Other.

⁹ NIR = Not Independently Reported. Species-specific sales estimates for which there were fewer than three distinct sponsors are not independently reported. This category includes the following: Turkey (excluding 2016 through 2019) and Other (excluding 2016 through 2019).

¹⁰ NIR = Not Independently Reported. Species-specific sales estimates for which there were fewer than three distinct sponsors are not independently reported. This category includes the following: Chicken (excluding 2016 through 2019), Swine (excluding 2016) and Other (excluding 2016 and 2020).

¹¹ NIR = Not Independently Reported. Species-specific sales estimates for which there were fewer than three distinct sponsors are not independently reported. This category includes the following: Chicken (excluding 2016, 2017, 2019, and 2020) and Other (excluding 2016, 2017, 2019, and 2020).

¹² NIR = Not Independently Reported. Antimicrobial classes for which there were fewer than three distinct sponsors actively marketing products domestically are not independently reported. These classes include the following: Diaminopyrimidines, Polymyxins, and Streptogramins.

¹³ This category includes the following: Cattle (excluding 2018 and 2020), Swine (excluding 2017), Chicken, Turkey (excluding 2017 through 2020), and Other.

Table 6a

Medically important¹ antimicrobial drugs approved for use in food-producing animals²
Actively marketed in 2020
Domestic sales and distribution data
Reported by route of administration

Route	Annual Totals (kg)³	% Total
<i>Feed²</i>	3,736,265	62%
<i>Injection²</i>	337,919	6%
<i>Intramammary</i>	15,645	<1%
<i>Oral^{2,4} or Topical^{2,5}</i>	82,331	1%
<i>Water⁶</i>	1,829,895	30%
<i>Total</i>	<i>6,002,056</i>	<i>100%</i>

¹ Guidance for Industry #213 states that all antimicrobial drugs and their associated classes listed in Appendix A of FDA's Guidance for Industry #152 are considered "medically important" in human medical therapy.

² Includes antimicrobial drug applications that are approved and labeled for use in both food-producing animals (e.g., cattle and swine) and nonfood-producing animals (e.g., dogs and horses).

³ kg = kilogram of active ingredient. Antimicrobial class includes drugs of different molecular weights, with some drugs labeled in different salt forms. Antimicrobials that are labeled in International Units (IU) (e.g., Penicillins) were converted to kg.

⁴ Orally administered, excluding administration by means of feed and water.

⁵ The Oral or Topical category includes Topical products marketed by less than three distinct sponsors; therefore, Topical products cannot be independently reported.

⁶ Water includes when the drug is administered either through drinking water, as a drench, through the immersion of fish, or as a syrup or dusting for honey bees.

Table 6b

Medically important¹ antimicrobial drugs approved for use in food-producing animals²
Actively marketed 2011-2020
Domestic sales and distribution data
Reported by route of administration

Route	2011 Annual Totals (kg)³	2012 Annual Totals (kg)³	2013 Annual Totals (kg)³	2014 Annual Totals (kg)³	2015 Annual Totals (kg)³	2016 Annual Totals (kg)³	2017 Annual Totals (kg)³	2018 Annual Totals (kg)³	2019 Annual Totals (kg)³	2020 Annual Totals (kg)³	% Change 2011 - 2020	% Change 2019 - 2020
<i>Feed²</i>	5,933,440	6,250,770	6,833,526	6,981,097	7,139,853	5,982,351	3,432,373	3,862,586	4,013,580	3,736,265	-37%	-7%
<i>Injection²</i>	416,775	393,422	352,693	341,790	353,197	348,239	358,534	355,994	311,562	337,919	-19%	8%
<i>Intramammary</i>	21,023	25,979	9,875	11,450	16,049	16,172	17,583	14,056	16,155	15,645	-26%	-3%
<i>Oral^{2,4} or Topical^{2,5}</i>	126,775	113,409	97,952	104,082	121,288	90,464	95,311	88,609	72,486	82,331	-35%	14%
<i>Water⁶</i>	1,757,686	2,113,840	1,899,248	2,040,920	2,072,557	1,919,115	1,655,410	1,711,053	1,775,475	1,829,895	4%	3%
Total	8,255,697	8,897,420	9,193,293	9,479,339	9,702,943	8,356,340	5,559,212	6,032,298	6,189,260	6,002,056	-27%	-3%

¹ Guidance for Industry #213 states that all antimicrobial drugs and their associated classes listed in Appendix A of FDA's Guidance for Industry #152 are considered "medically important" in human medical therapy.

² Includes antimicrobial drug applications that are approved and labeled for use in both food-producing animals (e.g., cattle and swine) and nonfood-producing animals (e.g., dogs and horses).

³ kg = kilogram of active ingredient. Antimicrobial class includes drugs of different molecular weights, with some drugs labeled in different salt forms. Antimicrobials that are labeled in International Units (IU) (e.g., Penicillins) were converted to kg.

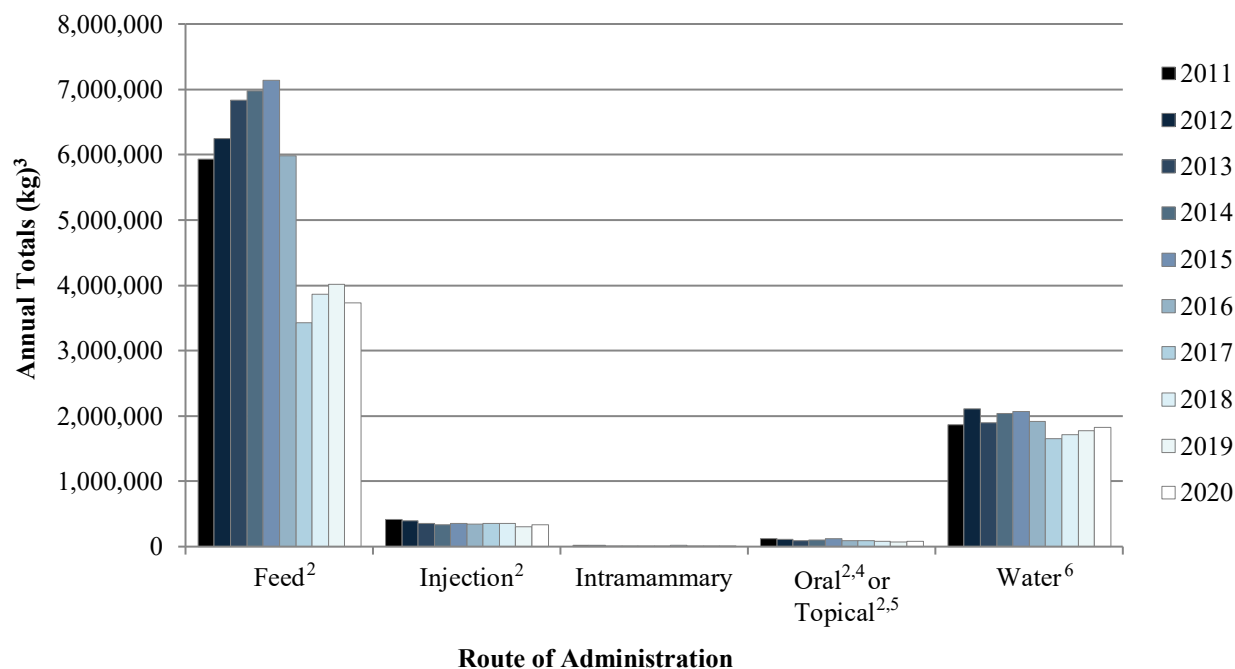
⁴ Orally administered, excludes administration by means of feed and water.

⁵ The Oral or Topical category includes Topical products marketed by less than three distinct sponsors; therefore, Topical products cannot be independently reported (excluding 2012 and 2013).

⁶ Water includes when the drug is administered either through drinking water, as a drench, through the immersion of fish, or as a syrup or dusting for honey bees.

Figure 6b

Medically important¹ antimicrobial drugs approved for use in food-producing animals²
Actively marketed 2011-2020
Domestic sales and distribution data
Reported by route of administration



¹ Guidance for Industry #213 states that all antimicrobial drugs and their associated classes listed in Appendix A of FDA’s Guidance for Industry #152 are considered “medically important” in human medical therapy.

² Includes antimicrobial drug applications that are approved and labeled for use in both food-producing animals (e.g., cattle and swine) and nonfood-producing animals (e.g., dogs and horses).

³ kg = kilogram of active ingredient. Antimicrobial class includes drugs of different molecular weights, with some drugs labeled in different salt forms. Antimicrobials that are labeled in International Units (IU) (e.g., Penicillins) were converted to kg.

⁴ Orally administered, excluding administration by means of feed and water.

⁵ The Oral or Topical category includes Topical products marketed by less than three distinct sponsors; therefore, Topical products cannot be independently reported (excluding 2012 and 2013).

⁶ Water includes when the drug is administered either through drinking water, as a drench, through the immersion of fish, or as a syrup or dusting for honey bees.

Table 7a

**Medically important¹ antimicrobial drugs approved for use in food-producing animals²
Actively marketed 2011-2020
Domestic sales and distribution data
Reported by indications**

Indications	2011 Annual Totals (kg) ³	2012 Annual Totals (kg) ³	2013 Annual Totals (kg) ³	2014 Annual Totals (kg) ³	2015 Annual Totals (kg) ³	2016 Annual Totals (kg) ³	2017 Annual Totals (kg) ³	2018 Annual Totals (kg) ³	2019 Annual Totals (kg) ³	2020 Annual Totals (kg) ³	% Change 2011 - 2020	% Change 2019 - 2020
<i>Production⁴ or Production/Therapeutic⁵ Indications^{2,6}</i>	5,770,871	6,073,485	6,664,835	6,790,996	6,917,639	5,770,655	0*	0*	0*	0*	**	**
<i>Therapeutic Indications Only^{2,5}</i>	2,484,827	2,823,935	2,528,458	2,688,343	2,785,304	2,585,685	5,559,212*	6,032,298	6,189,260	6,002,056	142%	-3%
Total	8,255,697	8,897,420	9,193,293	9,479,339	9,702,943	8,356,340	5,559,212	6,032,298	6,189,260	6,002,056	-27%	-3%

¹ Guidance for Industry #213 states that all antimicrobial drugs and their associated classes listed in Appendix A of FDA’s Guidance for Industry #152 are considered “medically important” in human medical therapy.

² Includes antimicrobial drug applications that are approved and labeled for use in both food-producing animals (e.g., cattle and swine) and nonfood-producing animals (e.g., dogs and horses).

³ kg = kilogram of active ingredient. Antimicrobial class includes drugs of different molecular weights, with some drugs labeled in different salt forms. Antimicrobials that are labeled in International Units (IU) (e.g., Penicillins) were converted to kg.

⁴ The implementation of GFI #213 was completed in January 2017; all affected medically important products had production indications removed from their labeling at that time.

⁵ Therapeutic Indications (e.g., treatment, control, or prevention of disease).

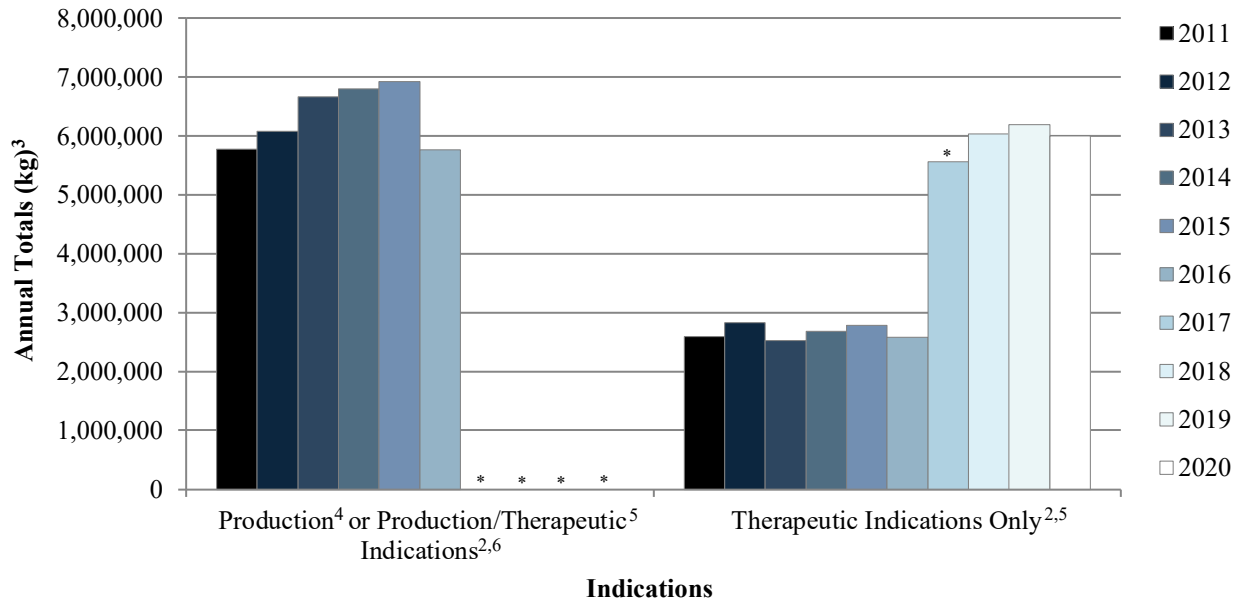
⁶ There were fewer than three distinct sponsors marketing antimicrobial animal drugs with only production indications (i.e., with no therapeutic indications). To protect confidential business information these data cannot be independently reported and are, therefore, combined with the data for drugs with both production and therapeutic (production/therapeutic) indications.

* The quantities reported in 2017 through 2020 under the production indications category dropped to zero as a result of the implementation of GFI #213. Applications that were formerly in the Production category were voluntarily withdrawn. Applications that were formerly in the Production/Therapeutic Indications category had production claims eliminated and were moved to the Therapeutic Only Indications category.

** Cannot divide by zero.

Figure 7a

Medically important¹ antimicrobial drugs approved for use in food-producing animals²
Actively marketed 2011-2020
Domestic sales and distribution data
Reported by indications



¹ Includes antimicrobial drug applications that are approved and labeled for use in both food-producing animals (e.g., cattle and swine) and nonfood-producing animals (e.g., dogs and horses).

² Includes antimicrobial drug applications that are approved and labeled for use in both food-producing animals (e.g., cattle and swine) and nonfood-producing animals (e.g., dogs and horses).

³ kg = kilogram of active ingredient. Antimicrobial class includes drugs of different molecular weights, with some drugs labeled in different salt forms. Antimicrobials that are labeled in International Units (IU) (e.g., Penicillins) were converted to kg.

⁴ The implementation of GFI #213 was completed in January 2017; all affected medically important products had production indications removed from their labeling at that time.

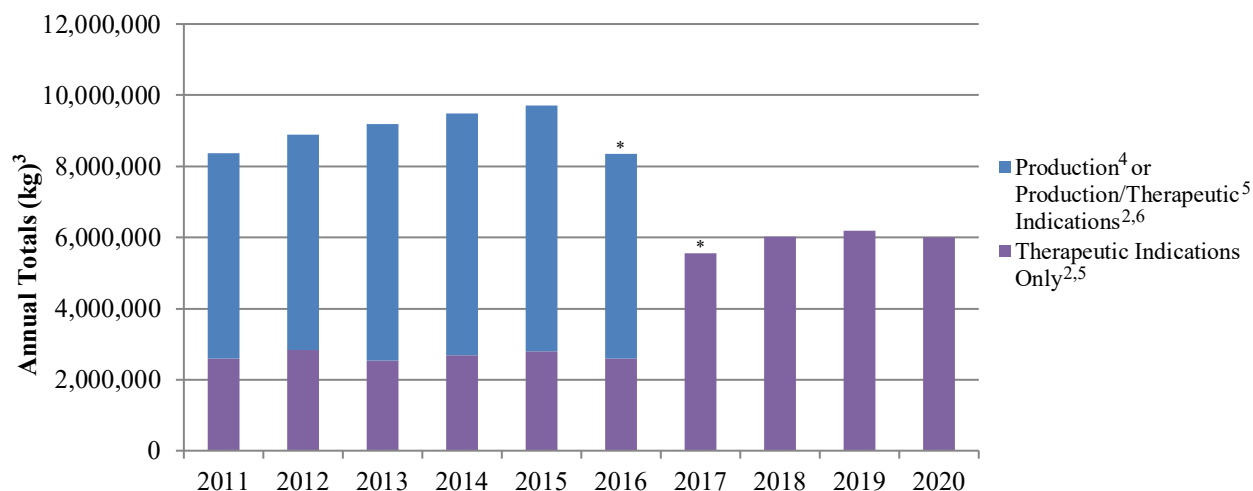
⁵ Therapeutic Indications (e.g., treatment, control, or prevention of disease).

⁶ There were fewer than three distinct sponsors (excluding 2013 through 2016 for the Not Medically Important category) marketing antimicrobial animal drugs with only production indications (i.e., with no therapeutic indications). To protect confidential business information these data cannot be independently reported and are, therefore, combined with the data for drugs with both production and therapeutic (production/therapeutic) indications.

* The quantity reported in 2017 under the production indications category dropped to zero as a result of the implementation of GFI #213. Applications that were formerly in the Production category were voluntarily withdrawn. Applications that were formerly in the Production/Therapeutic Indications category had production claims eliminated and were moved to the Therapeutic Only Indications category.

Figure 7b

Medically important¹ antimicrobial drugs approved for use in food-producing animals²
Actively marketed 2011-2020
Domestic sales and distribution data
Reported by indications (combined annual totals)



¹ Includes antimicrobial drug applications that are approved and labeled for use in both food-producing animals (e.g., cattle and swine) and nonfood-producing animals (e.g., dogs and horses).

² Includes antimicrobial drug applications that are approved and labeled for use in both food-producing animals (e.g., cattle and swine) and nonfood-producing animals (e.g., dogs and horses).

³ kg = kilogram of active ingredient. Antimicrobial class includes drugs of different molecular weights, with some drugs labeled in different salt forms. Antimicrobials that are labeled in International Units (IU) (e.g., Penicillins) were converted to kg.

⁴ The implementation of GFI #213 was completed in January 2017; all affected medically important products had production indications removed from their labeling at that time.

⁵ Therapeutic Indications (e.g., treatment, control, or prevention of disease).

⁶ There were fewer than three distinct sponsors (excluding 2013 through 2016 for the Not Medically Important category) marketing antimicrobial animal drugs with only production indications (i.e., with no therapeutic indications). To protect confidential business information these data cannot be independently reported and are, therefore, combined with the data for drugs with both production and therapeutic (production/therapeutic) indications.

* The quantity reported in 2017 under the production indications category dropped to zero as a result of the implementation of GFI 213. Applications that were formerly in the Production category were voluntarily withdrawn. Applications that were formerly in the Production/Therapeutic Indications category had production claims eliminated and were moved to the Therapeutic Only Indications category.

Table 8a

**Medically important¹ antimicrobial drugs approved for use in food-producing animals²
Actively marketed in 2020
Domestic sales and distribution data
Reported by dispensing status**

Dispensing Status	Annual Totals (kg)³	% Total
<i>OTC^{2,4,5}</i>	240,986	4%
<i>Rx^{2,6} or Rx/OTC^{2,4,7,8}</i>	2,024,805	34%
<i>VFD^{2,9}</i>	3,736,265	62%
<i>Total</i>	<i>6,002,056</i>	<i>100%</i>

¹ Guidance for Industry #213 states that all antimicrobial drugs and their associated classes listed in Appendix A of FDA's Guidance for Industry #152 are considered "medically important" in human medical therapy.

² Includes antimicrobial drug applications that are approved and labeled for use in both food-producing animals (e.g., cattle and swine) and nonfood-producing animals (e.g., dogs and horses).

³ kg = kilogram of active ingredient. Antimicrobial class includes drugs of different molecular weights, with some drugs labeled in different salt forms. Antimicrobials that are labeled in International Units (IU) (e.g., Penicillins) were converted to kg.

⁴ OTC = Over-the-Counter. Approved animal drugs that are available without a prescription or veterinary feed directive.

⁵ The implementation of GFI #213 was completed in January 2017; all affected medically important products transitioned from OTC to either Rx or VFD dispensing status at that time.

⁶ Rx = Prescription. Approved animal drugs that require a prescription from a licensed veterinarian.

⁷ Animal drugs that were approved with both a prescription and OTC dispensing status (Rx/OTC), with the approved drug being marketed with either a prescription label or an OTC label, depending upon the species and indication on the label.

⁸ There were fewer than three distinct sponsors marketing Rx/OTC antimicrobial animal drugs. To protect confidential business information these data cannot be independently reported and are, therefore, combined with the data for drugs with Rx dispensing statuses.

⁹ VFD = Veterinary Feed Directive. Approved animal drugs that are intended for use in or on animal feed and must be used under the professional supervision of a licensed veterinarian.

Table 8b

**Medically important¹ antimicrobial drugs approved for use in food-producing animals²
Actively marketed 2011-2020
Domestic sales and distribution data
Reported by dispensing status**

Dispensing Status	2011 Annual Totals (kg) ³	2012 Annual Totals (kg) ³	2013 Annual Totals (kg) ³	2014 Annual Totals (kg) ³	2015 Annual Totals (kg) ³	2016 Annual Totals (kg) ³	2017 Annual Totals (kg) ³	2018 Annual Totals (kg) ³	2019 Annual Totals (kg) ³	2020 Annual Totals (kg) ³	% Change 2011 - 2020	% Change 2019 - 2020
<i>OTC</i> ^{2,4,5}	8,139,594	8,642,153	8,964,750	9,219,892	9,422,402	8,000,326	271,280 [*]	262,678	223,753	240,986	-97%	8%
<i>Rx/OTC</i> ^{2,1,6} or <i>Rx</i> ^{1,7} or <i>VFD</i> ^{2,8,9}	226,260	255,267	228,543	259,447	280,541	356,014	1,798,290 [*]	5,769,620	5,965,506	5,761,070	2446%	-3%
Total	8,365,853	8,897,420	9,193,293	9,479,339	9,702,943	8,356,340	5,559,212	6,032,298	6,189,260	6,002,056	-28%	-3%

¹ Guidance for Industry #213 states that all antimicrobial drugs and their associated classes listed in Appendix A of FDA’s Guidance for Industry #152 are considered “medically important” in human medical therapy.

² Includes antimicrobial drug applications that are approved and labeled for use in both food-producing animals (e.g., cattle and swine) and nonfood-producing animals (e.g., dogs and horses).

³ kg = kilogram of active ingredient. Antimicrobial class includes drugs of different molecular weights, with some drugs labeled in different salt forms. Antimicrobials that are labeled in International Units (IU) (e.g., Penicillins) were converted to kg.

⁴ OTC = Over-the-Counter. Approved animal drugs that are available without a prescription or veterinary feed directive.

⁵ The implementation of GFI #213 was completed in January 2017; all affected medically important products transitioned from OTC to either Rx or VFD dispensing status at that time.

^{*} The quantity reported in 2017 under the OTC category dropped sharply as a result of the implementation of GFI #213. Applications that were formerly in the OTC category moved to the Rx or VFD category.

⁶ Animal drugs that were approved with both a prescription and OTC dispensing status (Rx/OTC), with the approved drug being marketed with either a prescription label or an OTC label, depending upon the species and indication on the label.

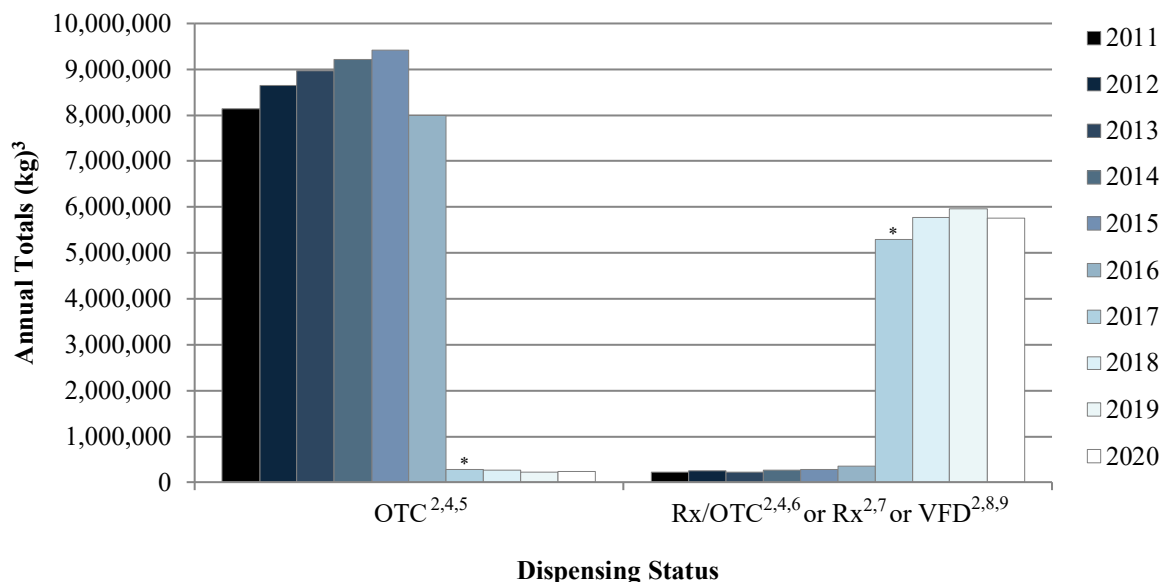
⁷ Rx = Prescription. Approved animal drugs that require a prescription from a licensed veterinarian.

⁸ VFD = Veterinary Feed Directive. Approved animal drugs that are intended for use in or on animal feed and must be used under the professional supervision of a licensed veterinarian.

⁹ There were fewer than three distinct sponsors marketing Rx/OTC antimicrobial animal drugs. To protect confidential business information these data cannot be independently reported and are, therefore, combined with the data for drugs with both Rx and VFD dispensing statuses.

Figure 8b

Medically important¹ antimicrobial drugs approved for use in food-producing animals²
 Actively marketed 2011-2020
 Domestic sales and distribution data
 Reported by dispensing status



¹ Guidance for Industry #213 states that all antimicrobial drugs and their associated classes listed in Appendix A of FDA’s Guidance for Industry #152 are considered “medically important” in human medical therapy.

² Includes antimicrobial drug applications that are approved and labeled for use in both food-producing animals (e.g., cattle and swine) and nonfood-producing animals (e.g., dogs and horses).

³ kg = kilogram of active ingredient. Antimicrobial class includes drugs of different molecular weights, with some drugs labeled in different salt forms. Antimicrobials that are labeled in International Units (IU) (e.g., Penicillins) were converted to kg.

⁴ OTC = Over-the-Counter. Approved animal drugs that are available without a prescription or veterinary feed directive.

⁵ The implementation of GFI #213 was completed in January 2017; all affected medically important products transitioned from OTC to either Rx or VFD dispensing status at that time.

* The quantity reported in 2017 under the OTC category dropped sharply as a result of the implementation of GFI #213. Applications that were formerly in the OTC category moved to the Rx or VFD category.

⁶ Animal drugs that were approved with both a prescription and OTC dispensing status (Rx/OTC), with the approved drug being marketed with either a prescription label or an OTC label, depending upon the species and indication on the label.

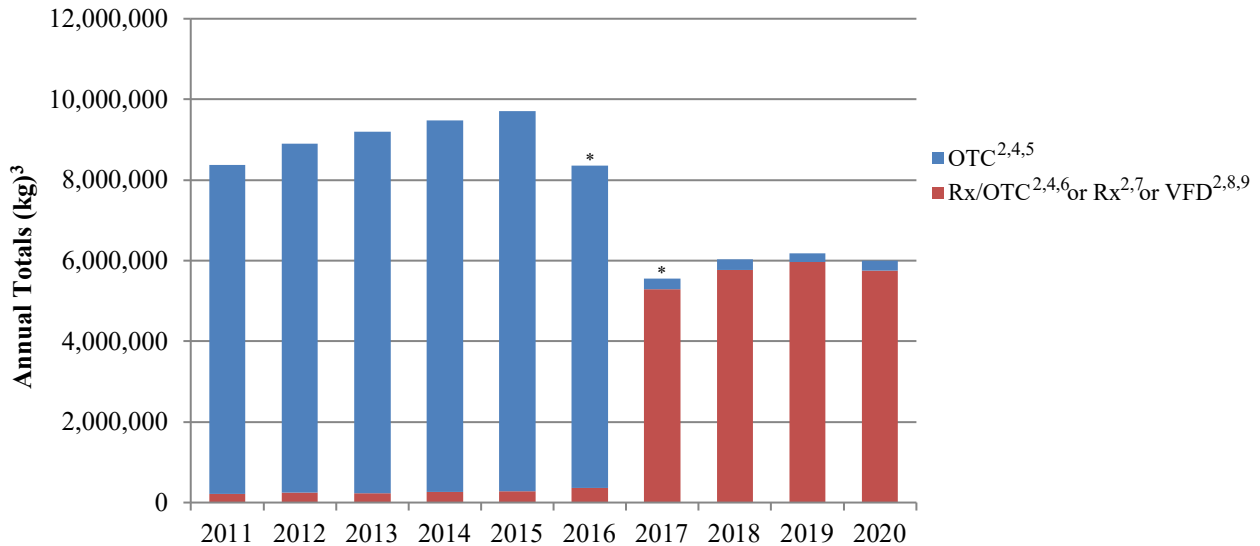
⁷ Rx = Prescription. Approved animal drugs that require a prescription from a licensed veterinarian.

⁸ VFD = Veterinary Feed Directive. Approved animal drugs that are intended for use in or on animal feed and must be used under the professional supervision of a licensed veterinarian.

⁹ There were fewer than three distinct sponsors marketing Rx/OTC antimicrobial animal drugs. To protect confidential business information these data cannot be independently reported and are, therefore, combined with the data for drugs with both Rx and VFD dispensing statuses.

Figure 8c

Medically important¹ antimicrobial drugs approved for use in food-producing animals²
Actively marketed 2011-2020
Domestic sales and distribution data
Reported by dispensing status (combined annual totals)



¹ Guidance for Industry #213 states that all antimicrobial drugs and their associated classes listed in Appendix A of FDA’s Guidance for Industry #152 are considered “medically important” in human medical therapy.

² Includes antimicrobial drug applications that are approved and labeled for use in both food-producing animals (e.g., cattle and swine) and nonfood-producing animals (e.g., dogs and horses).

³ kg = kilogram of active ingredient. Antimicrobial class includes drugs of different molecular weights, with some drugs labeled in different salt forms. Antimicrobials that are labeled in International Units (IU) (e.g., Penicillins) were converted to kg.

⁴ OTC = Over-the-Counter. Approved animal drugs that are available without a prescription or veterinary feed directive.

⁵ The implementation of GFI #213 was completed in January 2017; all affected medically important products transitioned from OTC to either Rx or VFD dispensing status at that time.

* The quantity reported in 2017 under the OTC category dropped sharply as a result of the implementation of GFI 213. Applications that were formerly in the OTC category moved to the Rx or VFD category.

⁶ Animal drugs that were approved with both a prescription and OTC dispensing status (Rx/OTC), with the approved drug being marketed with either a prescription label or an OTC label, depending upon the species and indication on the label.

⁷ Rx = Prescription. Approved animal drugs that require a prescription from a licensed veterinarian.

⁸ VFD = Veterinary Feed Directive. Approved animal drugs that are intended for use in or on animal feed and must be used under the professional supervision of a licensed veterinarian.

⁹ There were fewer than three distinct sponsors marketing Rx/OTC antimicrobial animal drugs. To protect confidential business information these data cannot be independently reported and are, therefore, combined with the data for drugs with both Rx and VFD dispensing statuses.

Table 9a

Medically important¹ antimicrobial drugs approved for use in food-producing animals²
 Actively marketed in 2020
 Domestic sales and distribution data
 Reported by route of administration and drug class

Route	Drug Class	Annual Total (kg)³	% Total
Feed	<i>Sulfonamides</i>	20,915	<1%
	<i>Tetracyclines²</i>	3,256,519	54%
	<i>Other Drugs⁴</i>	458,831	8%
Water	<i>Aminoglycosides</i>	254,448	4%
	<i>Lincosamides</i>	62,297	1%
	<i>Penicillins</i>	655,060	11%
	<i>Sulfonamides</i>	176,062	3%
	<i>Tetracyclines</i>	591,722	10%
	<i>Other Drugs⁵</i>	90,307	2%
Other Routes⁶	<i>Amphenicols</i>	48,626	1%
	<i>Cephalosporins²</i>	26,262	<1%
	<i>Tetracyclines²</i>	100,505	2%
	<i>Other Drugs^{2,7}</i>	260,502	4%
	Total	6,002,056	100%

¹ Guidance for Industry #213 states that all antimicrobial drugs and their associated classes listed in Appendix A of FDA's Guidance for Industry #152 are considered "medically important" in human medical therapy.

² Includes antimicrobial drug applications that are approved and labeled for use in both food-producing animals (e.g., cattle and swine) and nonfood-producing animals (e.g., dogs and horses).

³ kg = kilogram of active ingredient. Antimicrobial class includes drugs of different molecular weights, with some drugs labeled in different salt forms. Antimicrobials that are labeled in International Units (IU) (e.g., Penicillins) were converted to kg.

⁴ This category includes the following: Aminoglycosides, Amphenicols, Diaminopyrimidines, Lincosamides, Macrolides, and Streptogramins.

⁵ This category includes the following: Amphenicols and Macrolides.

⁶ This category includes the following: Injection, Intramammary, Oral (excluding administration by means of feed or water), and Topical.

⁷ This category includes the following: Aminoglycosides, Fluoroquinolones, Lincosamides, Macrolides, Penicillins, Polymyxins, and Sulfonamides.

Table 9b

**Medically important¹ antimicrobial drugs approved for use in food-producing animals²
Actively marketed 2011-2020
Domestic sales and distribution data
Reported by route of administration and drug class**

Route	Drug Class	2011 Annual Total (kg) ³	2012 Annual Total (kg) ³	2013 Annual Total (kg) ³	2014 Annual Total (kg) ³	2015 Annual Total (kg) ³	2016 Annual Total (kg) ³	2017 Annual Total (kg) ³	2018 Annual Total (kg) ³	2019 Annual Total (kg) ³	2020 Annual Total (kg) ³	% Change 2011 - 2020	% Change 2019 - 2020
Feed	<i>Sulfonamides</i>	105,400	90,972	90,723	103,243	98,831	77,217	21,871	28,838	34,510	20,915	-80%	-39%
	<i>Tetracyclines</i> ²	4,848,946	5,085,178	5,699,364	5,811,961	6,033,388	5,109,033	2,819,727	3,282,091	3,443,546	3,256,519	-33%	-5%
	<i>Other Drugs</i> ⁴	979,093	1,074,620	1,043,439	1,065,893	1,007,634	796,102	590,775	551,656	535,524	458,831	-53%	-14%
Water	<i>Aminoglycosides</i>	162,672	195,043	198,247	198,505	223,139	233,668	188,684	204,826	215,980	254,448	56%	18%
	<i>Lincosamides</i>	66,510	72,187	88,709	100,057	90,086	57,085	63,959	63,249	70,444	62,297	-6%	-12%
	<i>Penicillins</i>	650,220	753,510	672,131	740,929	793,018	700,779	559,589	599,409	607,741	655,060	1%	8%
	<i>Sulfonamides</i>	145,972	283,909	192,995	239,582	154,529	199,201	152,432	158,257	197,631	*	**	**
	<i>Tetracyclines</i>	710,403	782,959	719,529	712,026	762,411	663,602	625,568	609,430	598,052	591,722	-17%	-1%
	<i>Other Drugs</i> ⁵	21,909	26,233	27,637	49,822	49,374	64,780	65,179	75,881	85,627	90,307	312%	5%
Other Routes ⁶	<i>Cephalosporins</i> ²	26,611	27,654	28,337	31,722	32,254	31,010	29,369	31,448	29,830	26,262	-1%	-12%
	<i>Fluoroquinolones</i>	*	*	15,099	17,220	20,063	18,502	22,904	23,350	24,556	*	**	**
	<i>Tetracyclines</i> ²	93,506	86,224	95,887	80,211	85,732	88,553	90,406	82,657	75,433	100,505	7%	33%
	<i>Other Drugs</i> ^{2,7}	444,456	418,933	321,196	328,168	352,485	316,809	328,749	321,205	270,385	309,128	-30%	14%
	Total	8,255,697	8,897,420	9,193,293	9,479,339	9,702,943	8,356,340	5,559,212	6,032,298	6,189,260	5,825,994	-29%	-6%

¹ Guidance for Industry #213 states that all antimicrobial drugs and their associated classes listed in Appendix A of FDA’s Guidance for Industry #152 are considered “medically important” in human medical therapy.

² Includes antimicrobial drug applications that are approved and labeled for use in both food-producing animals (e.g., cattle and swine) and nonfood-producing animals (e.g., dogs and horses).

³ kg = kilogram of active ingredient. Antimicrobial class includes drugs of different molecular weights, with some drugs labeled in different salt forms. Antimicrobials that are labeled in International Units (IU) (e.g., Penicillins) were converted to kg.

⁴ This category includes the following: Aminoglycosides, Amphenicols, Diaminopyrimidines, Lincosamides, Macrolides, Penicillins (excluding 2017 through 2020), and Streptogramins.

* Not reported because there were fewer than three distinct sponsors actively marketing products domestically in 2011, 2012, and 2020.

** Not reported because there were fewer than three distinct sponsors actively marketing products domestically in 2011, 2012, and 2020. Therefore, percentage change cannot be calculated.

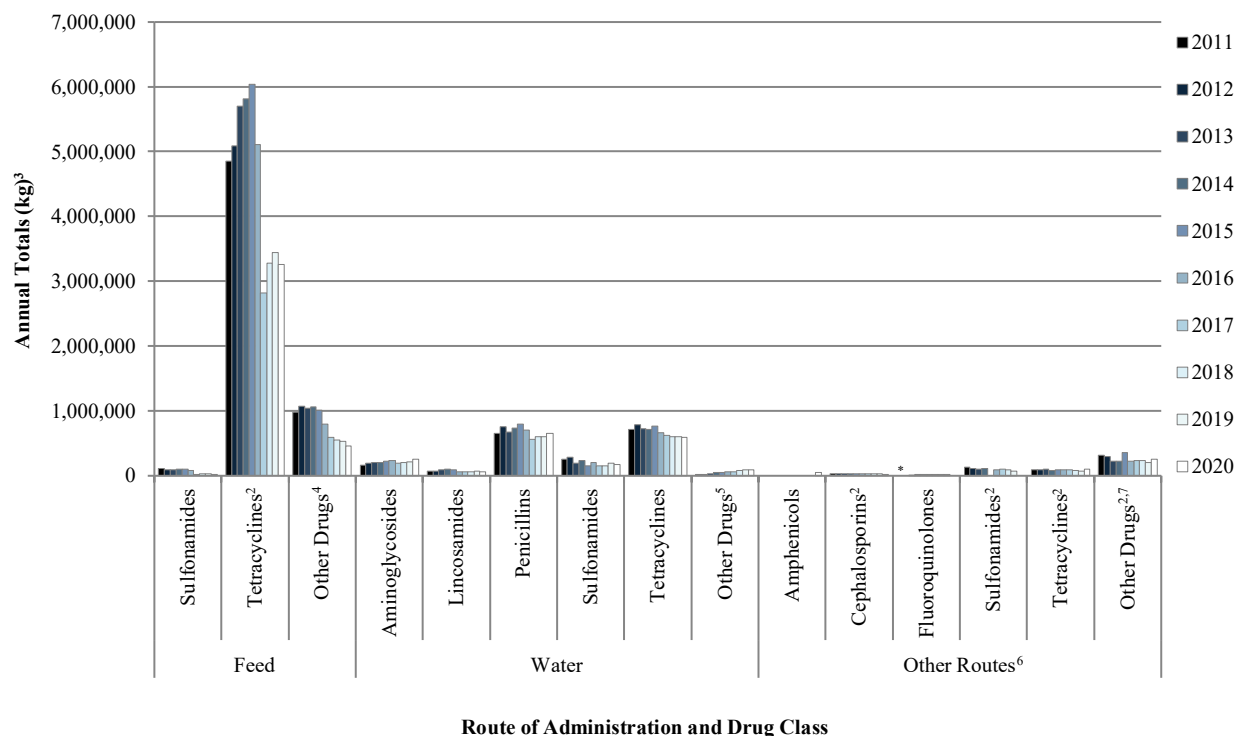
⁵ This category includes the following: Amphenicols (excluding 2013 and 2016) and Macrolides.

⁶ This category includes the following: Injection, Intramammary, Oral (excluding administration by means of feed or water), and Topical (excluding 2012 and 2013).

⁷ This category includes the following: Aminoglycosides, Amphenicols (excluding 2020), Lincosamides, Macrolides, Penicillins, Polymyxins (excluding 2012 and 2013), and Sulfonamides (excluding 2011 through 2014 and 2016 through 2019).

Figure 9b

**Medically important¹ antimicrobial drugs approved for use in food-producing animals²
Actively marketed 2011-2020
Domestic sales and distribution data
Reported by route of administration and drug class**



¹ Guidance for Industry #213 states that all antimicrobial drugs and their associated classes listed in Appendix A of FDA’s Guidance for Industry #152 are considered “medically important” in human medical therapy.

² Includes antimicrobial drug applications that are approved and labeled for use in both food-producing animals (e.g., cattle and swine) and nonfood-producing animals (e.g., dogs and horses).

³ kg = kilogram of active ingredient. Antimicrobial class includes drugs of different molecular weights, with some drugs labeled in different salt forms. Antimicrobials that are labeled in International Units (IU) (e.g., Penicillins) were converted to kg.

⁴ This category includes the following: Aminoglycosides, Amphenicols, Diaminopyrimidines, Lincosamides, Macrolides, Penicillins (excluding 2017 through 2020), and Streptogramins.

⁵ This category includes the following: Amphenicols (excluding 2013 and 2016) and Macrolides.

* Not reported because there were fewer than three distinct sponsors actively marketing products domestically.

⁶ This category includes the following: Injection, Intramammmary, Oral (excluding administration by means of feed or water), and Topical (excluding 2012 and 2013).

⁷ This category includes the following: Aminoglycosides, Amphenicols (excluding 2020), Lincosamides, Macrolides, Penicillins, Polymyxins (excluding 2012 and 2013), and Sulfonamides (excluding 2011 through 2014 and 2016 through 2019).

IV. Data on antimicrobial drugs that are not medically important

Table 10a

Not medically important¹ antimicrobial drugs approved for use in food-producing animals
Actively marketed in 2020
Domestic sales and distribution data
Reported by species-specific estimated sales

Species	Estimated Annual Totals (kg)²	% Total
<i>Cattle</i>	2,758,786	62%
<i>Swine</i>	381,212	9%
<i>Chicken</i>	1,074,451	24%
<i>Turkey</i>	230,425	5%
<i>Other³</i>	2,545	<1%
Total	4,447,420	100%

¹ Not Medically Important refers to any antimicrobial class not listed in Appendix A of FDA's Guidance for Industry #152.

² kg = kilogram of active ingredient. Antimicrobial class includes drugs of different molecular weights, with some drugs labeled in different salt forms. Antimicrobials that are labeled in International Units (IU) (e.g., Penicillins) were converted to kg.

³ The Other category includes estimates of product sales intended for use in (1) species listed on the approved label other than cattle, swine, chickens, and turkeys, including nonfood-producing animal species (e.g., dogs and horses) and minor food-producing species (e.g., fish); (2) other species not listed on the approved label; and (3) unknown uses.

Table 10b

Not medically important¹ antimicrobial drugs approved for use in food-producing animals
 Actively marketed 2016-2020
 Domestic sales and distribution data
 Reported by species-specific estimated sales

Species	2016 Estimated Annual Totals (kg)²	2017 Estimated Annual Totals (kg)²	2018 Estimated Annual Totals (kg)²	2019 Estimated Annual Totals (kg)²	2020 Estimated Annual Totals (kg)²	% Change 2016 - 2020	% Change 2019 - 2020
<i>Cattle</i>	3,164,626	3,139,331	3,376,063	3,246,667	2,758,786	-13%	-15%
<i>Swine</i>	425,568	395,994	414,170	404,343	381,212	-10%	-6%
<i>Chicken</i>	1,700,124	1,477,197	1,401,759	1,315,354	1,074,451	-37%	-18%
<i>Turkey</i>	379,478	358,774	335,826	310,426	230,425	-39%	-26%
<i>Other³</i>	0	2,860	2,965	2,308	2,545	*	10%
Total	5,669,796	5,374,156	5,530,784	5,279,098	4,447,420	-22%	-16%

¹ Not Medically Important refers to any antimicrobial class not listed in Appendix A of FDA's Guidance for Industry #152.

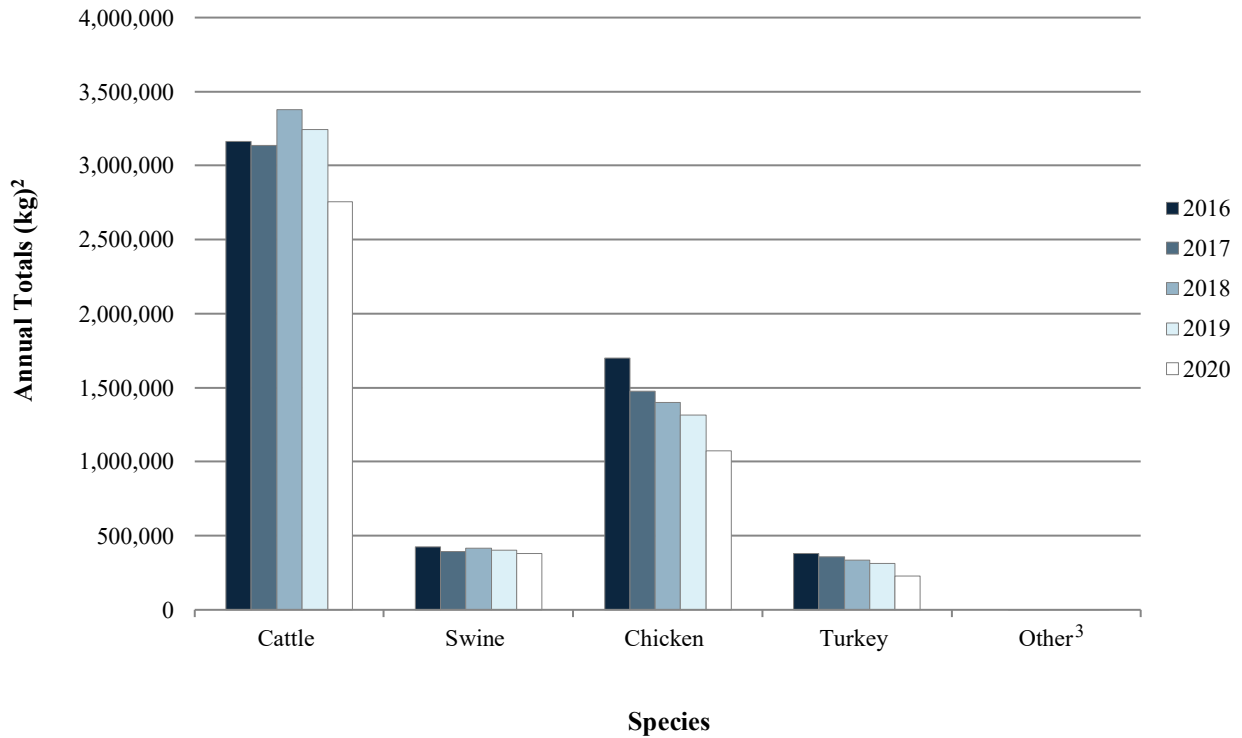
² kg = kilogram of active ingredient. Antimicrobial class includes drugs of different molecular weights, with some drugs labeled in different salt forms. Antimicrobials that are labeled in International Units (IU) (e.g., Penicillins) were converted to kg.

³ The Other category includes estimates of product sales intended for use in (1) species listed on the approved label other than cattle, swine, chickens, and turkeys, including nonfood-producing animal species (e.g., dogs and horses) and minor food-producing species (e.g., fish); (2) other species not listed on the approved label; and (3) unknown uses.

* Cannot divide by zero.

Figure 10b

Not medically important¹ antimicrobial drugs approved for use in food-producing animals
Actively marketed in 2020
Domestic sales and distribution data
Reported by species-specific estimated sales



¹ Not Medically Important refers to any antimicrobial class not listed in Appendix A of FDA’s Guidance for Industry #152.

² kg = kilogram of active ingredient. Antimicrobial class includes drugs of different molecular weights, with some drugs labeled in different salt forms. Antimicrobials that are labeled in International Units (IU) (e.g., Penicillins) were converted to kg.

³ The Other category includes estimates of product sales intended for use in (1) species listed on the approved label other than cattle, swine, chickens, and turkeys, including nonfood-producing animal species (e.g., dogs and horses) and minor food-producing species (e.g., fish); (2) other species not listed on the approved label; and (3) unknown uses.

Table 11a

Not medically important¹ antimicrobial drugs approved for use in food-producing animals
Actively marketed 2011-2020
Domestic sales and distribution data
Reported by route of administration

Route	2011 Annual Totals (kg) ²	2012 Annual Totals (kg) ²	2013 Annual Totals (kg) ²	2014 Annual Totals (kg) ²	2015 Annual Totals (kg) ²	2016 Annual Totals (kg) ²	2017 Annual Totals (kg) ²	2018 Annual Totals (kg) ²	2019 Annual Totals (kg) ²	2020 Annual Totals (kg) ²	% Change 2011 - 2020	% Change 2019 - 2020
<i>All Routes³</i>	5,313,340	5,725,327	5,591,752	5,882,221	5,874,997	5,669,796	5,374,156	5,530,784	5,279,098	4,447,420	-16%	-16%

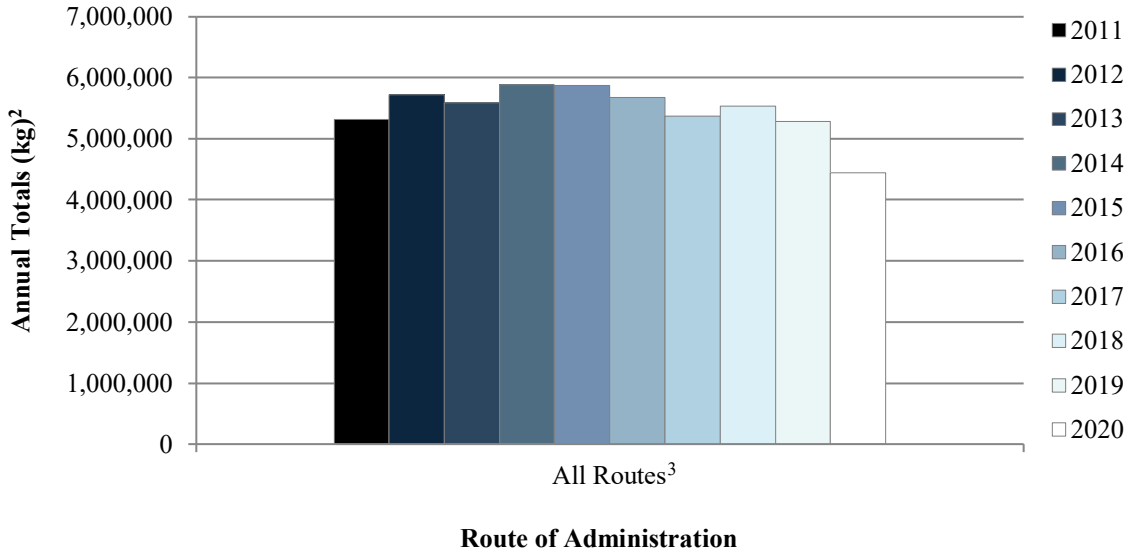
¹ Not Medically Important refers to any antimicrobial class not listed in Appendix A of FDA's Guidance for Industry #152.

² kg = kilogram of active ingredient. Antimicrobial class includes drugs of different molecular weights, with some drugs labeled in different salt forms. Antimicrobials that are labeled in International Units (IU) (e.g., Penicillins) were converted to kg.

³ This category includes the following: Feed, Intramammary, and Water. To protect confidential business information, the routes of administration for the Not Medically Important antimicrobial drugs are not separately presented.

Figure 11a

Not medically important¹ antimicrobial drugs approved for use in food-producing animals
Actively marketed 2011-2020
Domestic sales and distribution data
Reported by route of administration



¹ Not Medically Important refers to any antimicrobial class not listed in Appendix A of FDA's Guidance for Industry #152.

² kg = kilogram of active ingredient. Antimicrobials that were reported in International Units (IU) (e.g., Penicillins) were converted to kg. Antimicrobial class includes drugs of different molecular weights, with some drugs reported in different salt forms.

³ This category includes the following: Feed, Intramammary, and Water. To protect confidential business information, the routes of administration for the Not Medically Important antimicrobial drugs are not separately presented.

Table 12a

Not medically important¹ antimicrobial drugs approved for use in food-producing animals
Actively marketed in 2020
Domestic sales and distribution data
Reported by indications

Indications	Annual Totals (kg)²	% Total
<i>Production Indications Only³</i>	78,665	2%
<i>Production/Therapeutic⁴ Indications</i>	3,512,488	79%
<i>Therapeutic Indications Only⁴</i>	856,267	19%
Total	4,447,420	100%

¹ Not Medically Important refers to any antimicrobial class not listed in Appendix A of FDA's Guidance for Industry #152.

² kg = kilogram of active ingredient. Antimicrobial class includes drugs of different molecular weights, with some drugs labeled in different salt forms. Antimicrobials that are labeled in International Units (IU) (e.g., Penicillins) were converted to kg.

³ Production Indications (e.g., increased rate of weight gain or improved feed efficiency).

⁴ Therapeutic Indications (e.g., treatment, control, or prevention of disease).

Table 12b

**Not medically important¹ antimicrobial drugs approved for use in food-producing animals
Actively marketed 2011-2020
Domestic sales and distribution data
Reported by indications**

Indications	2011 Annual Totals (kg) ²	2012 Annual Totals (kg) ²	2013 Annual Totals (kg) ²	2014 Annual Totals (kg) ²	2015 Annual Totals (kg) ²	2016 Annual Totals (kg) ²	2017 Annual Totals (kg) ²	2018 Annual Totals (kg) ²	2019 Annual Totals (kg) ²	2020 Annual Totals (kg) ²	% Change 2011 - 2020	% Change 2019 - 2020
<i>Production³ or Production/Therapeutic⁴ Indications⁵</i>	3,790,628	3,972,057	3,900,298	4,259,148	4,329,598	4,350,075	4,229,651	4,453,964	4,262,766	3,591,153	-5%	-16%
<i>Therapeutic Indications Only¹</i>	1,522,712	1,753,270	1,691,454	1,623,073	1,545,399	1,319,721	1,144,504	1,076,819	1,016,332	856,267	-44%	-16%
Total	5,313,340	5,725,327	5,591,752	5,882,221	5,874,997	5,669,796	5,374,156	5,530,784	5,279,098	4,447,420	-16%	-16%

¹ Not Medically Important refers to any antimicrobial class not listed in Appendix A of FDA's Guidance for Industry #152.

² kg = kilogram of active ingredient. Antimicrobial class includes drugs of different molecular weights, with some drugs labeled in different salt forms. Antimicrobials that are labeled in International Units (IU) (e.g., Penicillins) were converted to kg.

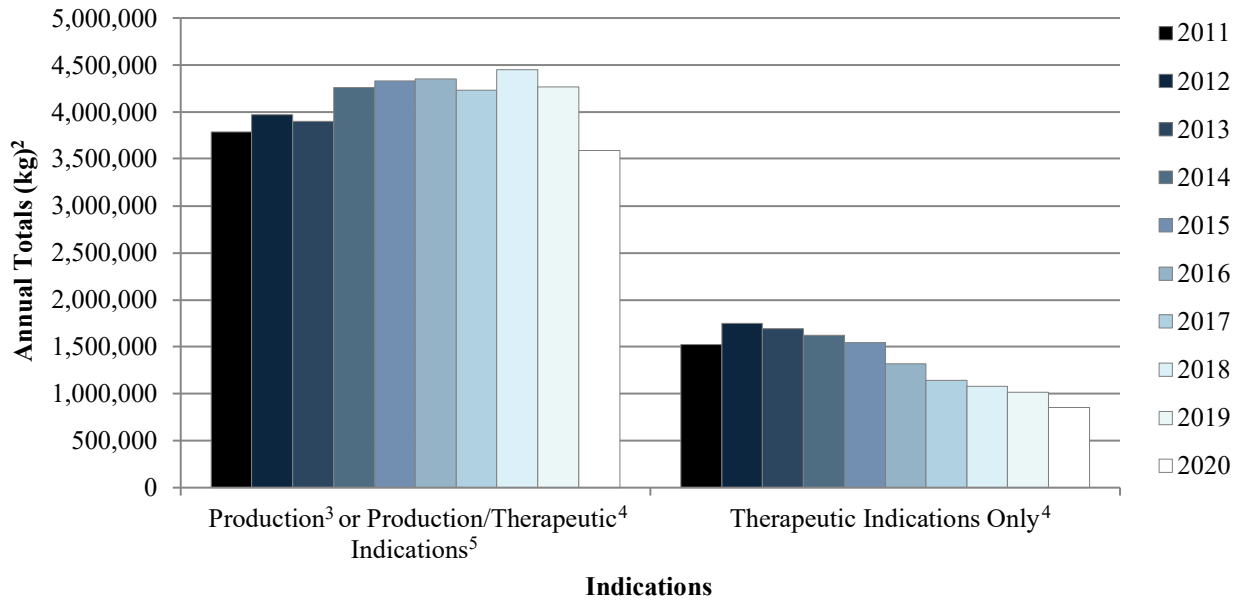
³ Production Indications (e.g., increased rate of weight gain or improved feed efficiency).

⁴ Therapeutic Indications (e.g., treatment, control, or prevention of disease).

⁵ There were fewer than three distinct sponsors (excluding 2012 through 2020 for the Not Medically Important category) marketing antimicrobial animal drugs with only production indications (i.e., with no therapeutic indications). To protect confidential business information these data cannot be independently reported and are, therefore, combined with the data for drugs with both production and therapeutic (production/therapeutic) indications.

Figure 12b

Not medically important¹ antimicrobial drugs approved for use in food-producing animals
Actively marketed 2011-2020
Domestic sales and distribution data
Reported by indications



¹ Not Medically Important refers to any antimicrobial class not listed in Appendix A of FDA’s Guidance for Industry #152.

² kg = kilogram of active ingredient. Antimicrobial class includes drugs of different molecular weights, with some drugs labeled in different salt forms. Antimicrobials that are labeled in International Units (IU) (e.g., Penicillins) were converted to kg.

³ Production Indications (e.g., increased rate of weight gain or improved feed efficiency).

⁴ Therapeutic Indications (e.g., treatment, control, or prevention of disease).

⁵ There were fewer than three distinct sponsors (excluding 2012 through 2020 for the Not Medically Important category) marketing antimicrobial animal drugs with only production indications (i.e., with no therapeutic indications). To protect confidential business information these data cannot be independently reported and are, therefore, combined with the data for drugs with both production and therapeutic (production/therapeutic) indications.

Table 13a

Not medically important¹ antimicrobial drugs approved for use in food-producing animals
 Actively marketed 2011-2020
 Domestic sales and distribution data
 Reported by dispensing status

Dispensing Status	2011 Annual Totals (kg) ²	2012 Annual Totals (kg) ²	2013 Annual Totals (kg) ²	2014 Annual Totals (kg) ²	2015 Annual Totals (kg) ²	2016 Annual Totals (kg) ²	2017 Annual Totals (kg) ²	2018 Annual Totals (kg) ²	2019 Annual Totals (kg) ²	2020 Annual Totals (kg) ²	% Change 2011 - 2020	% Change 2019 - 2020
<i>All Dispensing Statuses³</i>	5,313,340	5,725,327	5,591,752	5,882,221	5,874,997	5,669,796	5,374,156	5,530,784	5,279,098	4,447,420	-16%	-16%

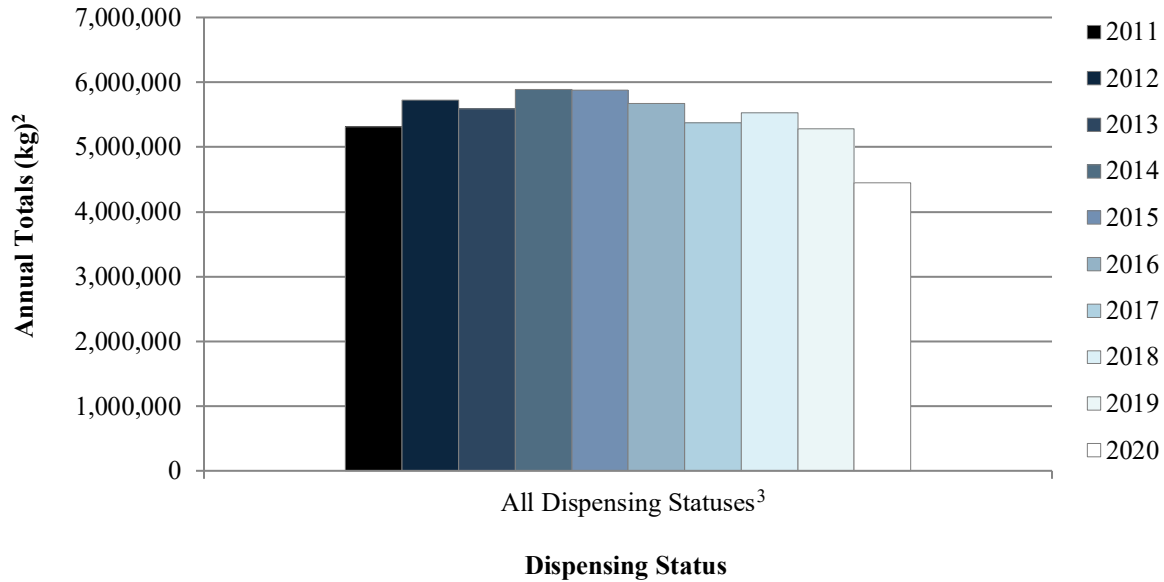
¹ Not Medically Important refers to any antimicrobial class not listed in Appendix A of FDA's Guidance for Industry #152.

² kg = kilogram of active ingredient. Antimicrobial class includes drugs of different molecular weights, with some drugs labeled in different salt forms. Antimicrobials that are labeled in International Units (IU) (e.g., Penicillins) were converted to kg.

³ The All Dispensing Statuses category includes the following: OTC, Rx/OTC (excluding 2011 through 2015 and 2019 through 2020), and VFD (excluding 2011 through 2015). There were fewer than three distinct sponsors marketing antimicrobial animal drugs in these categories. To protect confidential business information these data cannot be independently reported and are, therefore, combined into the All Dispensing Statuses category.

Figure 13a

Not medically important¹ antimicrobial drugs approved for use in food-producing animals
Actively marketed 2011-2020
Domestic sales and distribution data
Reported by dispensing status



¹ Not Medically Important refers to any antimicrobial class not listed in Appendix A of FDA's Guidance for Industry #152.

² kg = kilogram of active ingredient. Antimicrobials that were reported in International Units (IU) (e.g., Penicillins) were converted to kg. Antimicrobial class includes drugs of different molecular weights, with some drugs reported in different salt forms.

³ The All Dispensing Statuses category includes the following: OTC, Rx/OTC (excluding 2011 through 2015 and 2019 through 2020), and VFD (excluding 2011 through 2015). There were fewer than three distinct sponsors marketing antimicrobial animal drugs in these categories. To protect confidential business information these data cannot be independently reported and are, therefore, combined into the All Dispensing Statuses category.

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