



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

4th Annual Report February 2023

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SUMMARY

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

Maryland specific data was obtained after requirements under SB471. To obtain Maryland MIAD use data, the department compiled data submitted from Maryland veterinarians and farmers using a data management system developed in 2019. The report developed from this data provides the information required by SB471: (i) the total number of animals raised on farm operations covered by SB471 (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 a disclaimer, the data that is presented in this report was provided from third party sources submitted to the Maryland Department of Agriculture. It is not the product of a controlled research project, and data is not verified through Department audit. Also, as the final submission date by law is February 1, 2023, 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.

NATIONAL DATA SUMMARY

The nationally available reports summarize national data only. National antibiotic use data is available in the FDA "2021 Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing animals," published December 2022, and provided as an attachment to this report. Each year, since 2010, after federal legislation in 2008, 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 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 2012 through 2021.

Key observations from the FDA report include:

- Domestic sales and distribution of medically important antimicrobials approved for use in food-producing animals (Table 2b):
 - decreased by less than 1% from 2020 through 2021.
 - decreased by 38% from 2015 (the year of peak sales) through 2021.
 - decreased by 33% from 2012 through 2021.
 - Tetracyclines, which represent the largest volume of these domestic sales (3,916,864 kg in 2021), decreased by 1% from 2020 through 2021. Penicillin decreased by 19%, macrolides and Lincosamides each increased by 21%.
- The domestic sales and distribution of medically important antimicrobials approved for use in food-producing animals for 2021 included:
 - An estimated 41% was intended for use in cattle, an estimated 42% intended for use in swine, an estimated 11% intended for use in turkeys, an estimated 3% intended for use in chickens, and an estimated 3% intended for use in other species/unknown (Table 4a).
 - Tetracyclines accounted for 65%, penicillin for 10%, macrolides for 9%, sulfonamides for 5%, aminoglycosides for 6%, Lincosamides for 3%, cephalosporins for less than 1%, and fluoroquinolones for less than 1% (Table 2a).
 - An estimated 79% of cephalosporins, 45% of sulfonamides, 52% of aminoglycosides, and 43% of tetracyclines were intended for use in cattle. An estimated 89% of Lincosamides and 41% of macrolides were intended for use in swine. An estimated 72% of penicillin 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 #209fda.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 Fiscal Year 2016 to address continuing concerns regarding antibiotic resistance. Detailed information on progress are provided in an integrated report produced jointly by the FDA, CDC and USDA through *National Antimicrobial Resistance Monitoring System* (NARMS), found at <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 does 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 Data and Reporting”, *Zoonoses and Public Health*, Volume 67, Supplement 1, November 2020, 1-123, which can be accessed online at <https://onlinelibrary.wiley.com/toc/18632378/2020/67/S1>. Highlights from these studies pertinent to Maryland industry are provided below.

In “Estimates of On Farm Antimicrobial Usage in broiler chicken production in the United States 2013-2017” by Singer et al, significant decreases in antibiotic use of all types are documented. Data was voluntarily submitted representing 81% (2013) to 87% (2017). In summarizing the data, the authors state “the use of antimicrobials in the hatchery decreased substantially between 2013 and 2017; the approximate percentage of broiler chicks placed that received hatchery antimicrobials decreased from 93% in 2013 to 17% in 2017. Medically important in-feed antimicrobial use decreased substantially. For example, in-feed tetracycline use decreased approximately 95% between 2013 and 2017. Medically important water-soluble antimicrobial use decreased substantially for most antimicrobials. Between 2013 and 2017, water-soluble penicillin use decreased approximately 21%, water-soluble tetracycline use decreased approximately 47%, and water-soluble lincomycin use decreased approximately 28%.” This study supports a positive trend in controlling overuse of antibiotics that might lead to antibiotic resistance; however, the authors note, “While a reduction in antimicrobial amounts used may be an important indicator of improved stewardship, reducing the need for antimicrobials through improved disease prevention should be considered a more important objective and a better indicator of overall flock health and optimal antimicrobial use.”

Regarding antibiotic usage in cattle, information is much more limited and difficult to interpret, but some generalizations could be made using established protocols to measure antibiotic use in “standardized regimens per cow year” and “grams per cow year”. In a study of 29 dairies in the United States, the authors concluded that, that “mastitis is the disease syndrome with the greatest contribution to overall antimicrobial use”, and the “metritis, lameness and unknown disease syndromes are also significant contributors.” They also found that their studies “.... indicate the greatest magnitude of use is the cephalosporin class. However, when measures are stratified by drug” (within a class), “use within the penicillin class contributes more than any other single class. These differences highlight the need for a more complete understanding of the relationship between antimicrobial use measures and their relationship to antimicrobial resistance selection pressure.”

STATE DATA SUMMARY

1,067 Maryland Accredited Veterinarians were notified of the requirement to report MIAD data a minimum of 5 times each by direct email through the Maryland State Board of Veterinary Examiners and the Maryland Department of Agriculture Animal Health Program. A total of 7 veterinarians that prescribe for large cattle, swine and poultry farms responded with data (1 %),

Protecting Confidential Information

If there were 2 or fewer operations reporting in a county, summary data is provided on a regional or statewide basis, in a manner consistent with SB471 requirements.

Key observations from the State data are provided are below:

Table 1. Antibiotic Use by Species Reported

	Reported Animals Treated	Total ABX Per Species (In kg)	Percentage of ABX Per Species
Cattle	1,100	2,948	80.01%
Poultry	2,500,000	639	17.34%
Swine	31,031	98	2.65%
Grand Total	2,532,131	3,685	100.00%

Table 2. Total Reported Antibiotic Prescribed

	Total Reported ABX Prescribed (kg)	% Of Total
Aminoglycosides		
Neomycin Sulfate USP	30.025	0.81%
Lincosamides		
Lincomycin HCl	180.484	4.90%
Penicillin		
Amoxicillin Trihydrate	0.48	0.01%
Polypeptides		
Bacitracin	0.018944	0.005%
Tetracyclines		
Chlortetracycline	3036.718405	82.40%
Tylvalosin Tartrate		
Tylvalosin	8.96	0.24%
Grand Total	3685.183349	100.00%

Summary data of antibiotic use by production operation, active ingredient, number of animals treated and for what disease indicator is provided below in Table 3, and total numbers of animals on farms meeting the SB471 criteria are shown in Tables 4 & 5.

Table 3. Indication Report by Species/Active Ingredient Prescribed

	Total Animals Treated	Total Weight of Animals	Total ABX (kg)
Cattle			
Bacterial enteritis caused by E. coli			
Chlortetracycline	660	344,000	1,950
For treatment of necrotic enteritis caused by Clostridium spp.			
Chlortetracycline	340	116,000	862
treatment of respiratory and neurologic disease in swine			
Chlortetracycline	100	20,000	136
Poultry			
Bacterial enteritis caused by E. coli			
Neomycin Sulfate USP	200,000	1,000,000	25
For treatment of necrotic enteritis caused by Clostridium spp.			
Bacitracin	80,000	400,000	.02
Lincomycin HCl	780,000	3,900,000	180
Neomycin Sulfate USP	20,000	100,000	5
Penicillin	1,420,000	7,100,000	428
Swine			
Bacterial enteritis caused by E. coli			
Chlortetracycline	23,400	732,000	88
treatment of respiratory and neurologic disease in swine			
Amoxicillin Trihydrate	1,331	19,965	.48
Tylvalosin	6,300	441,000	9
Grand Total	2,532,131	14,172,965	3,685

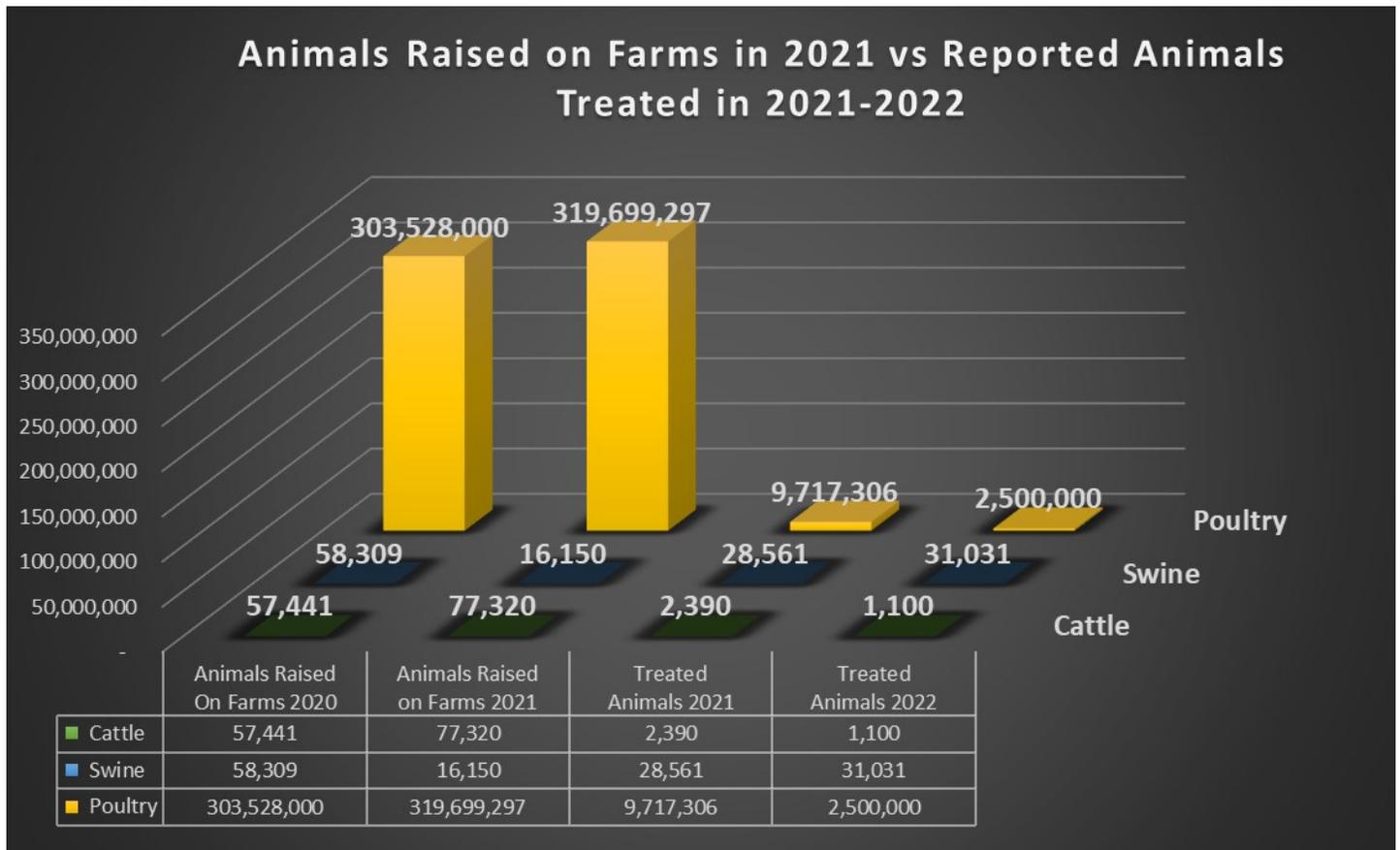
Total Cattle & Swine Raised on Farms in 2021

	Total Dairy Cattle	Total Beef Cattle	Total Swine
Baltimore	2,042	620	
Carroll	7,084	3,179	
Cecil	2,026	320	
Frederick	15,625	4,946	3,410
Garrett	1,751	1,315	
Harford	2,189	1,897	
Kent	7,047		
Montgomery		556	
Queen Anne's	1,595	310	2,050
Washington	14,948	4,698	
Other Counties (When 2 Per county is reported, county is redacted for confidentiality and only totals will be reported.)	1,672	3,776	10,690
Grand Total	55,979	21,617	16,150

Table 5. Poultry Raised on Maryland Farms 2021

	Sum of Total Broiler /Roasters	Sum of Total Pullets	Sum of Total Layers
Caroline	50,479,930		
Cecil	1,854,000		2,135,000
Dorchester	23,771,266		
Kent	4,298,400		
Queen Anne's	24,518,600		
Somerset	47,886,880		
Talbot	4,473		
Wicomico	4,562,600		
Worcester	63,104,680		
Other Counties (When 2 Per county is reported, county is redacted for confidentiality and only totals will be reported.)	60,270,300	2,666,000	1,297,400
Grand Total	280,751,129	2,666,000	3,432,400

DISCUSSION



Here are a few items to consider when you are reviewing these figures.

- The report is the previous year’s data for “Animals Raised on Farms”. The data for the current year is not received until May or June.
- Maryland only reports the information received .3rd party vendors for VFDs are not reported,
- The decrease in total count of Poultry can be attributed to
 - Covid
 - and the 2022, HPAI outbreak where more than 1.5 million birds were affected.
- Incorrect numbers from the previous year were adjusted. The adjusted totals will appear in the next report.

Attachment (1) U.S. Food and Drug Administration, Center for Veterinary Medicine, 2022 Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals, December 2021.



FDA

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

CENTER FOR VETERINARY MEDICINE

2021

Summary Report

On

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

December 2022

Table of Contents

Executive Summary	3
I. Background	4
a. Scope of Reporting	4
b. Protecting Confidential Information	5
c. Use of the Summary Information	6
d. Description of Tables and Figures	7
II. Data on all marketed antimicrobial drugs	8
a. Drug classes and active ingredients	9
b. Number of applications and sponsors	10
c. Total sales by drug class	12
d. Export data	15
III. Data on medically important antimicrobial drugs	18
a. Estimate of sales by animal species	19
b. Sales by route of administration	25
c. Sales by indication of use	28
d. Sales by dispensing status	31
e. Sales by route of administration and drug class	35
IV. Data on antimicrobial drugs that are not medically important	38
a. Estimate of sales by animal species	39
b. Sales by route of administration	42
c. Sales by indication of use	44
d. Sales by dispensing status	47
References	49

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 2012 through 2021.

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 less than 1% from 2020 through 2021.
 - decreased by 38% from 2015 (the year of peak sales) through 2021.
 - decreased by 33% from 2012 through 2021.
 - Tetracyclines, which represent the largest volume of these domestic sales (3,916,864 kg in 2021), decreased by 1% from 2020 through 2021. Penicillins decreased by 19%, macrolides and lincosamides each increased by 21%.
- The domestic sales and distribution of medically important antimicrobials approved for use in food-producing animals for 2021 included:
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 - Tetracyclines accounted for 65%, penicillins for 10%, macrolides for 9%, sulfonamides for 5%, aminoglycosides for 6%, lincosamides for 3%, cephalosporins for less than 1%, and fluoroquinolones for less than 1% (Table 2a).
 - An estimated 79% of cephalosporins, 45% of sulfonamides, 52% of aminoglycosides, and 43% of tetracyclines were intended for use in cattle. An estimated 89% of lincosamides and 41% of macrolides were intended for use in swine. An estimated 72% 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 found under the Not Medically Important section 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, 1,371 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 2021 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 2021 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 (2012 through 2021) for reasons of data representation, and which is adequate for time trend evaluation. For data before 2012, 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/fl882p86h/fq978x92g/pslaan22.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 drugs

Table 1

Antimicrobial drug classes and active ingredients approved for use in food-producing animals¹
Actively marketed in 2021

Aminocoumarins (NMI)²

Novobiocin

Aminoglycosides (MI)³

Dihydrostreptomycin
Gentamicin
Neomycin
Spectinomycin

Amphenicols (MI)³

Florfenicol

Cephalosporins (MI)³

Ceftiofur¹
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.

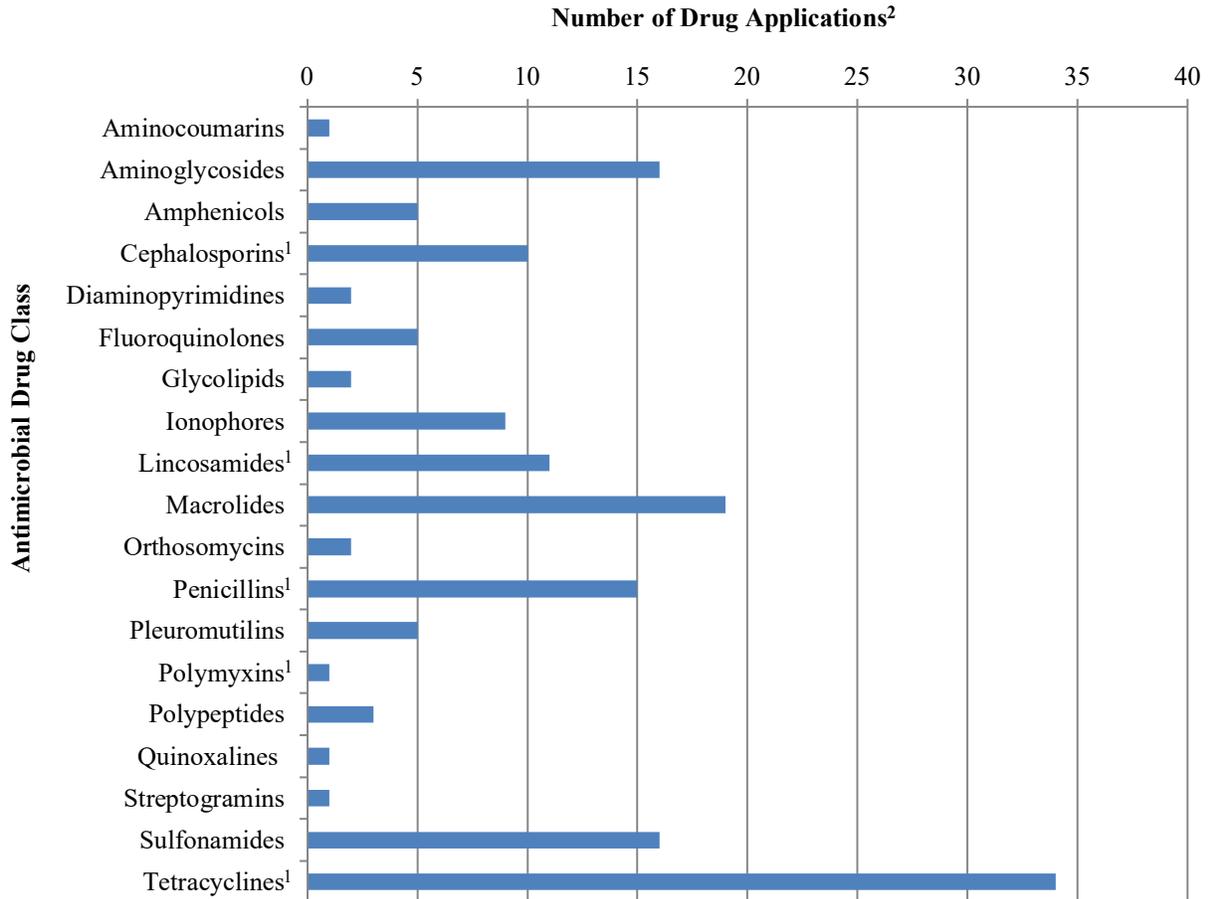
Figure 1a

Antimicrobial drug classes approved for use in food-producing animals¹

Actively marketed in 2021

Domestic sales and distribution data

Number of drug applications²

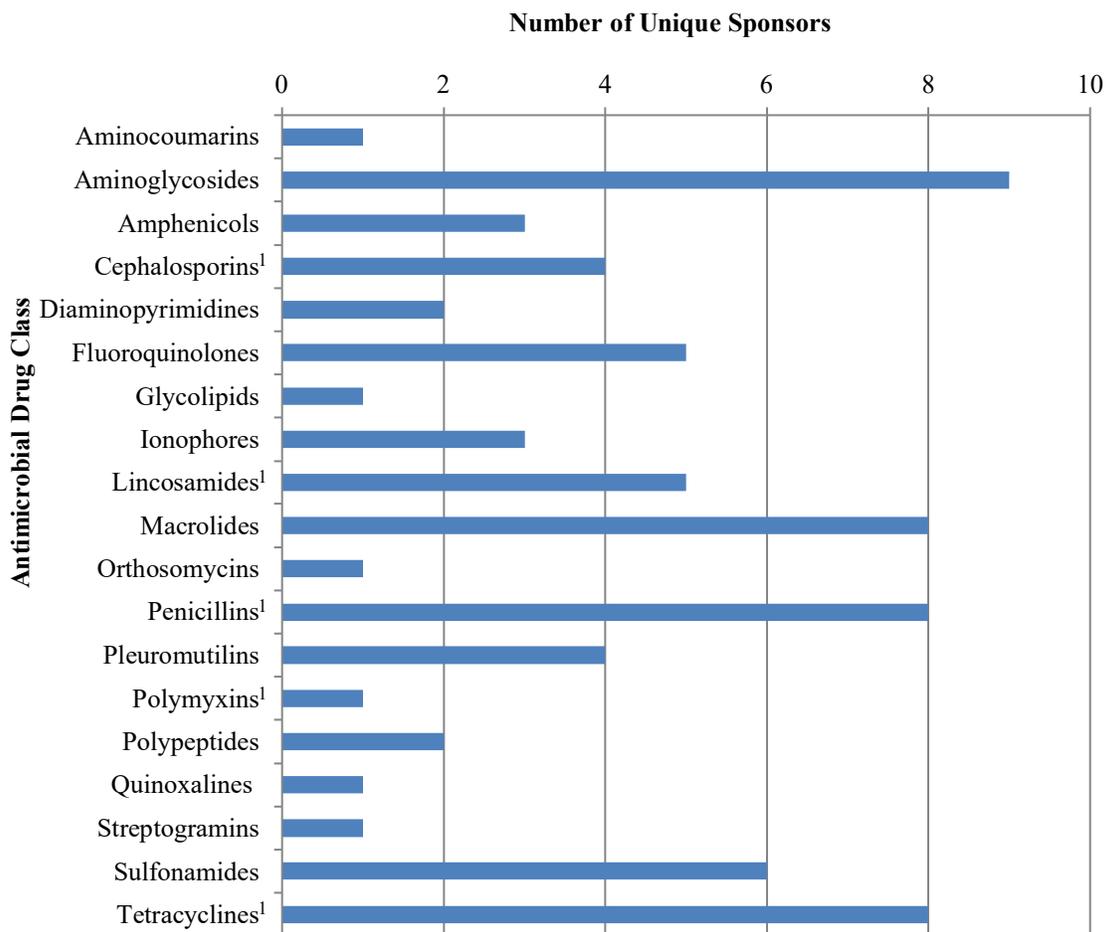


¹ Includes antimicrobial drug applications that are approved and labeled for use in both food-producing animals (e.g., cattle and swine) and nonfood-producing animals (e.g., dogs and horses).

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 2021
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 2021
 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>	339,109	6%	3%
	<i>Amphenicols</i>	52,976	1%	<1%
	<i>Cephalosporins¹</i>	26,999	<1%	<1%
	<i>Fluoroquinolones</i>	24,383	<1%	<1%
	<i>Lincosamides¹</i>	177,700	3%	2%
	<i>Macrolides</i>	524,188	9%	5%
	<i>Penicillins¹</i>	619,840	10%	6%
	<i>Sulfonamides</i>	301,691	5%	3%
	<i>Tetracyclines¹</i>	3,916,864	65%	35%
	<i>NIR⁴</i>	5,973	<1%	<1%
	<i>Subtotal</i>	<i>5,989,721</i>	<i>100%</i>	<i>54%</i>
Not Medically Important⁵	<i>Ionophores</i>	4,199,253	82%	38%
	<i>Pleuromutilins</i>	328,940	6%	3%
	<i>NIR⁶</i>	586,917	11%	5%
	<i>Subtotal</i>	<i>5,115,111</i>	<i>100%</i>	<i>46%</i>
	<i>Grand Total</i>	<i>11,104,832</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 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 2012-2021
 Domestic sales and distribution data
 Reported by medical importance and drug class

	Drug Class	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	2021 Annual Totals (kg) ²	% Change 2012 - 2021	% Change 2020 - 2021
Medically Important ³	<i>Aminoglycosides</i> ¹	277,854	267,734	304,160	344,120	319,009	259,184	289,455	307,988	322,734	339,109	22%	5%
	<i>Cephalosporins</i> ¹	27,654	28,337	31,722	32,254	31,010	29,369	31,448	29,830	26,262	26,999	-2%	3%
	<i>Fluoroquinolones</i>	*	15,099	17,220	20,063	18,502	22,904	23,350	24,556	24,176	24,383	**	1%
	<i>Lincosamides</i> ¹	218,140	236,450	233,681	182,543	142,458	152,497	125,514	134,962	147,026	177,700	-19%	21%
	<i>Macrolides</i> ¹	616,274	563,251	621,769	627,757	554,714	468,794	473,038	488,082	433,394	524,188	-15%	21%
	<i>Penicillins</i> ¹	965,196	828,721	885,975	936,669	842,863	690,889	731,863	716,525	762,888	619,840	-36%	-19%
	<i>Sulfonamides</i> ¹	493,514	383,469	452,224	380,186	369,826	274,112	278,562	304,327	282,572	301,691	-39%	7%
	<i>Tetracyclines</i> ¹	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	3,916,864	-34%	-1%
	<i>NIR</i> ^{1,4}	344,428	355,452	328,389	297,822	216,771	125,761	104,888	65,958	54,258	58,949	-83%	9%
	Subtotal	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	5,989,721	-33%	<1%
Not Medically Important ⁵	<i>Ionophores</i>	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	4,199,253	-8%	16%
	<i>Pleuromutilins</i>	*	*	*	*	*	*	*	*	161,723	328,940	**	103%
	<i>NIR</i> ⁶	1,151,532	1,157,095	1,163,571	1,134,382	1,018,305	979,306	968,524	1,008,976	666,432	586,917	-49%	-12%
	Subtotal	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	5,115,111	-11%	15%
Grand Total	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	11,104,832	-24%	6%	

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 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.

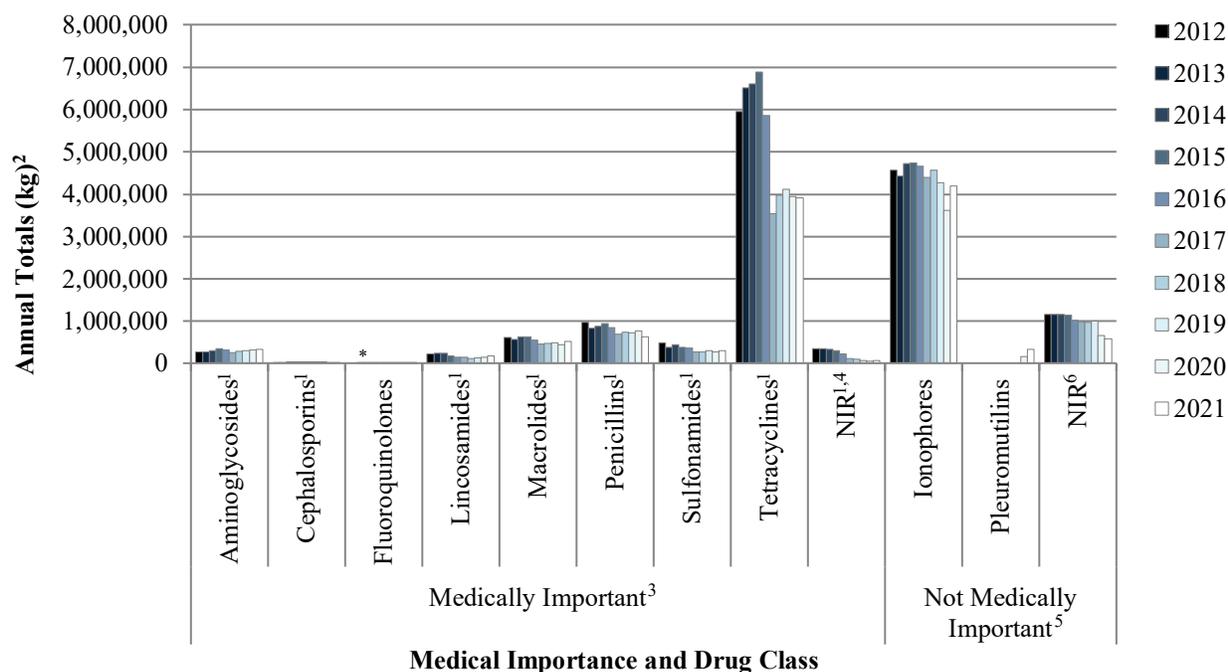
⁴ NIR = Not Independently Reported. Antimicrobial classes for which there were fewer than three distinct sponsors actively marketing products domestically are not independently reported. These classes include the following: Amphenicols, Diaminopyrimidines, Polymyxins (excluding 2012 and 2013), and Streptogramins.

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 2012 through 2015), Pleuromutilins (excluding 2020 and 2021), Polypeptides, and Quinoxalines.

Figure 2b

Antimicrobial drugs approved for use in food-producing animals¹
 Actively marketed 2012-2021
 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 2012 through 2015), Pleuromutilins (excluding 2020 and 2021), Polypeptides, and Quinoxalines.

Table 3a

Antimicrobial drugs approved for use in food-producing animals¹
Actively marketed in 2021
Domestic/export sales and distribution data

Domestic/Export	Annual Totals (kg)²	% Total
<i>Domestic¹</i>	11,104,832	100%
<i>Export^{1,3}</i>	5,535	<1%
<i>Total</i>	<i>11,110,367</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 2012-2021
 Domestic/export sales and distribution data

Domestic/Export	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	2021 Estimated Annual Totals (kg) ²	% Change 2012 - 2021	% Change 2020 - 2021
<i>Domestic</i> ¹	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	11,104,832	-24%	6%
<i>Export</i> ^{1,3}	139,173	74,374	30,682	20,861	6,818	10,038	8,134	5,355	6,433	5,535	-96%	-14%
Total	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	11,110,367	-25%	6%

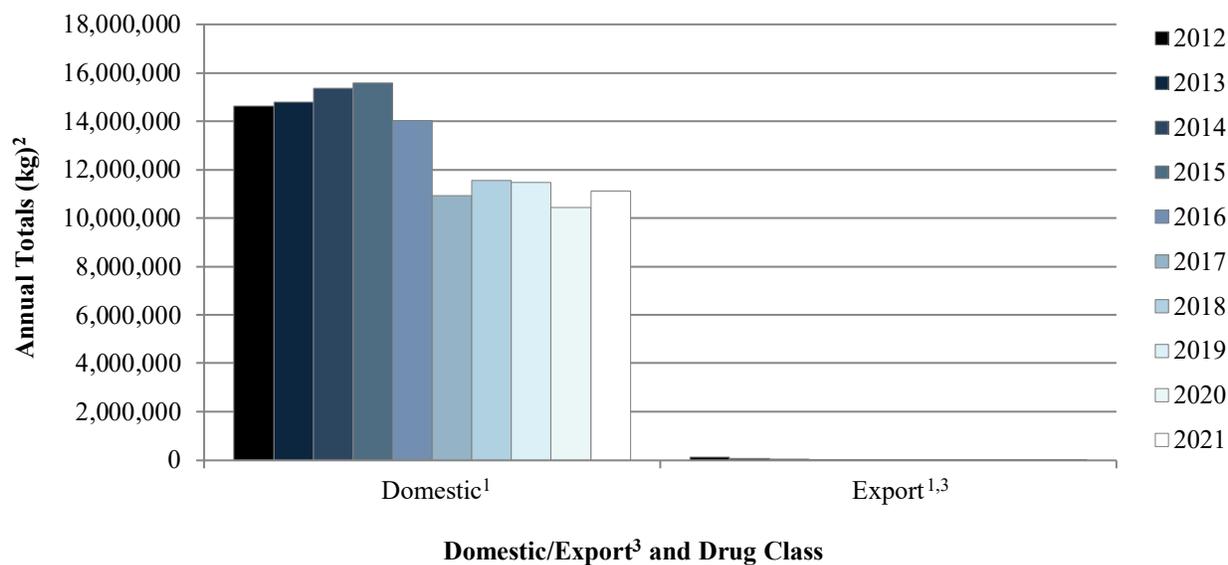
¹ Includes antimicrobial drug applications that are approved and labeled for use in both food-producing animals (e.g., cattle and swine) and nonfood-producing animals (e.g., dogs and horses).

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 2012-2021
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 2021
Domestic sales and distribution data
Reported by species-specific estimated sales

Species	Estimated Annual Totals (kg) ³	% Total
Cattle	2,460,766	41%
Swine	2,529,800	42%
Chicken	158,342	3%
Turkey	659,431	11%
Other ⁴	181,383	3%
Total	5,989,721	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 2016-2021
 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	2021 Estimated Annual Totals (kg) ³	% Change 2016 - 2021	% Change 2020 - 2021
<i>Cattle</i>	3,605,543	2,333,839	2,517,386	2,529,281	2,449,441	2,460,766	-32%	<1%
<i>Swine</i>	3,133,262	2,022,932	2,374,277	2,582,399	2,451,382	2,529,800	-19%	3%
<i>Chicken</i>	508,800	268,047	221,774	192,964	141,793	158,342	-69%	12%
<i>Turkey</i>	756,620	670,831	671,108	644,921	690,841	659,431	-13%	-5%
<i>Other⁴</i>	352,114	263,564	247,753	239,694	268,600	181,383	-48%	-32%
Total	8,356,340	5,559,212	6,032,298	6,189,260	6,002,056	5,989,721	-28%	<1%

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.

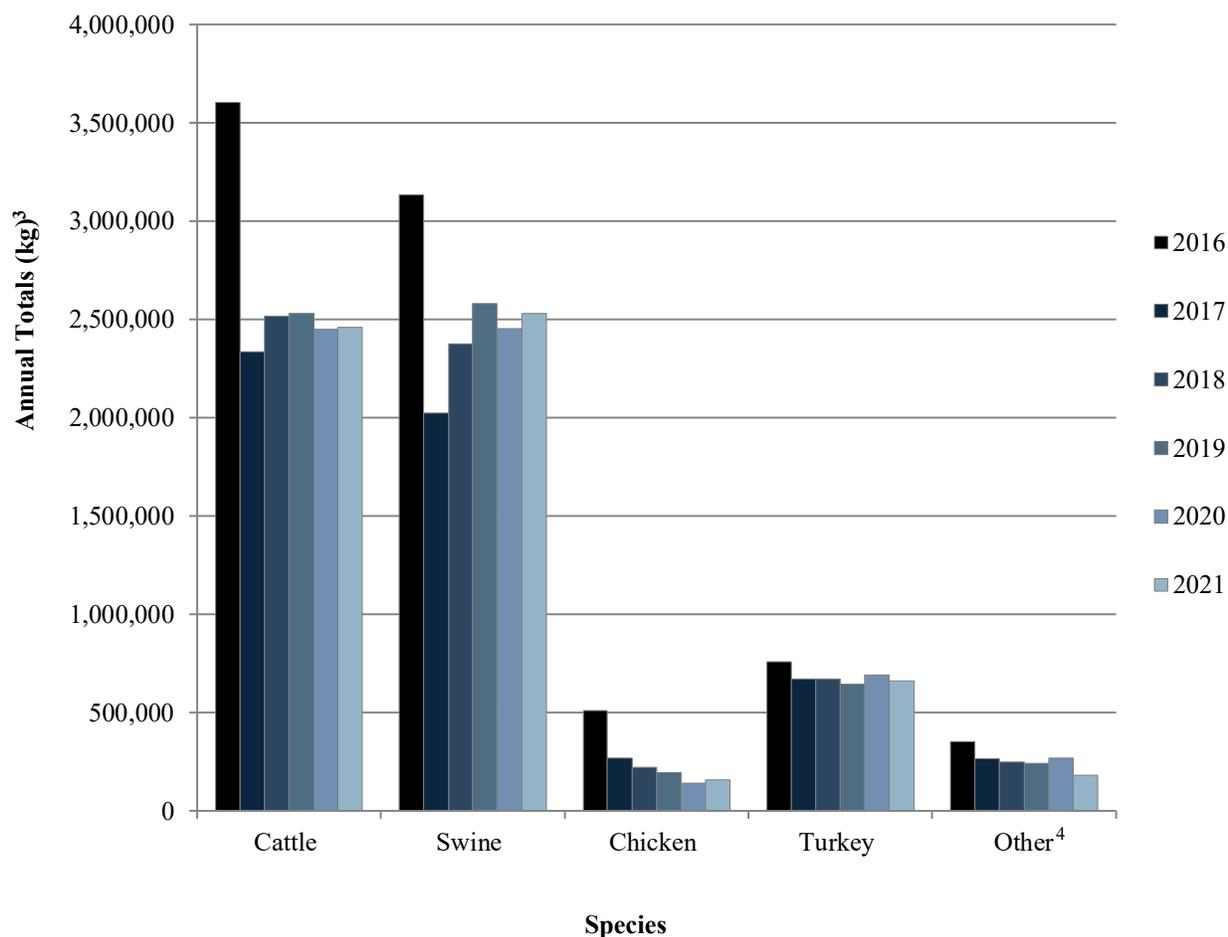
² Includes antimicrobial drug applications that are approved and labeled for use in both food-producing animals (e.g., cattle and swine) and nonfood-producing animals (e.g., dogs and horses).

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 2016-2021
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 2021
 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>	177,173	52%
	<i>Swine</i>	82,329	24%
	<i>Chicken</i>	19,588	6%
	<i>Turkey</i>	27,904	8%
	<i>Other⁴</i>	32,115	9%
	Subtotal	339,109	100%
Amphenicols	<i>Cattle</i>	50,732	96%
	<i>Other⁴</i>	2,244	4%
	Subtotal	52,976	100%
Cephalosporins²	<i>Cattle</i>	21,197	79%
	<i>Swine</i>	4,671	17%
	<i>NIR⁵</i>	1,131	4%
	Subtotal	26,999	100%
Fluoroquinolones	<i>Cattle</i>	12,086	50%
	<i>Swine</i>	11,930	49%
	<i>Other⁴</i>	367	2%
	Subtotal	24,383	100%
Lincosamides²	<i>Swine</i>	158,036	89%
	<i>Chicken</i>	7,721	4%
	<i>NIR⁶</i>	11,943	7%
	Subtotal	177,700	100%
Macrolides	<i>Cattle</i>	303,371	58%
	<i>Swine</i>	213,027	41%
	<i>Chicken</i>	2,346	0%
	<i>NIR⁷</i>	5,445	1%
	Subtotal	524,188	100%
Penicillins²	<i>Cattle</i>	66,347	11%
	<i>Turkey</i>	447,073	72%
	<i>NIR⁸</i>	106,419	17%
	Subtotal	619,840	100%
Sulfonamides	<i>Cattle</i>	136,147	45%
	<i>Swine</i>	126,771	42%
	<i>Chicken</i>	7,088	2%
	<i>Turkey</i>	26,478	9%
	<i>Other⁴</i>	5,207	2%
	Subtotal	301,691	100%
Tetracyclines²	<i>Cattle</i>	1,693,680	43%
	<i>Swine</i>	1,924,177	49%
	<i>Chicken</i>	115,887	3%
	<i>Turkey</i>	156,338	4%
	<i>Other⁴</i>	26,783	1%
	Subtotal	3,916,864	100%
NIR^{2,9}	<i>All Species¹⁰</i>	5,973	100%
	Subtotal	5,973	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 sales estimates for which there were fewer than three distinct sponsors are not independently reported. 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: Chicken 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: Cattle 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: Turkey and Other.

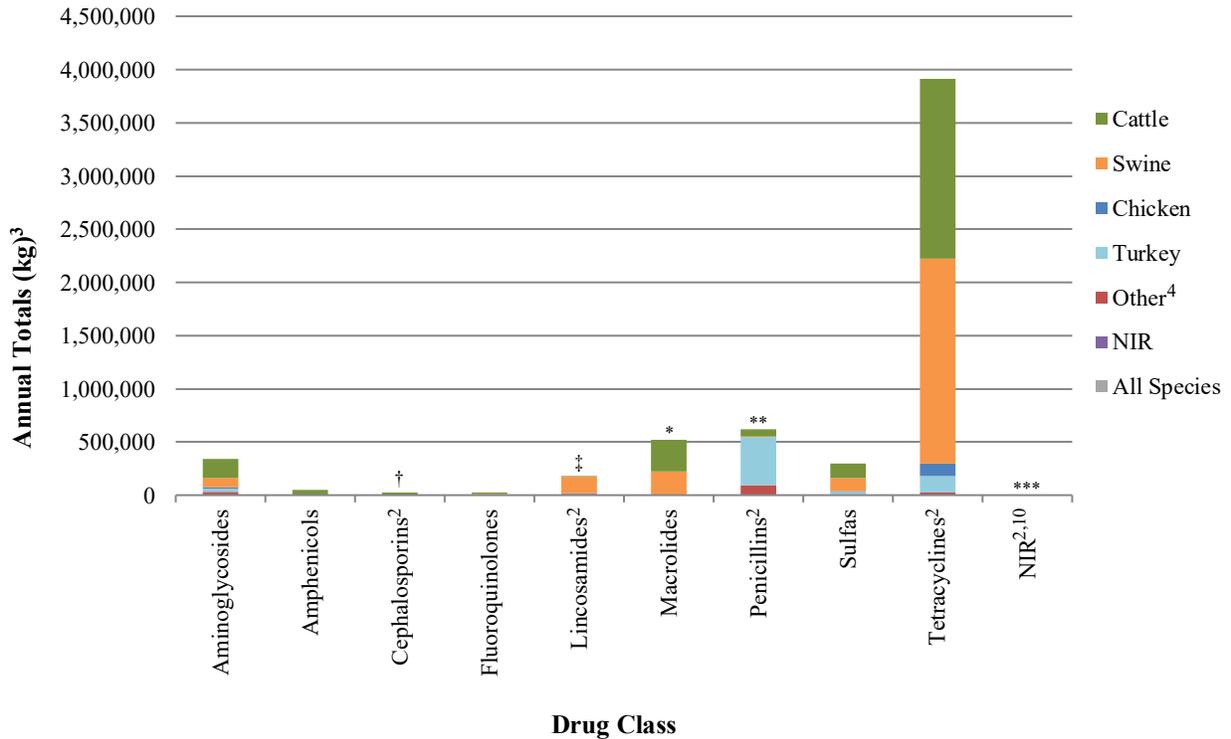
⁸ NIR = Not Independently Reported. Species-specific sales estimates for which there were fewer than three distinct sponsors are not independently reported. This category includes the following: Swine and Other.

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 2021
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: 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.

^{*} 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 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: 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 2016-2021
 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	2021 Estimated Annual Totals (kg) ³	% Change 2016 - 2021	% Change 2020 - 2021
Aminoglycosides	Cattle	161,646	124,675	133,842	139,445	174,132	177,173	10%	2%
	Swine	65,850	63,602	90,708	101,270	72,659	82,329	25%	13%
	Chicken	24,111	20,185	13,430	16,200	17,634	19,588	-19%	11%
	Turkey	22,198	24,042	24,321	25,125	25,265	27,904	26%	10%
	Other ⁴	45,204	26,680	27,154	25,949	33,044	32,115	-29%	-3%
	Subtotal	319,009	259,184	289,455	307,988	322,734	339,109	6%	5%
Amphenicols	Cattle	*	*	*	*	47,609	50,732	**	**
	NIR ⁵	*	49,321	56,056	53,212	4,179	2,244	**	-46%
	Subtotal	*	49,321	56,056	53,212	51,788	52,976	**	2%
Cephalosporins ²	Cattle	24,677	23,512	25,337	24,158	21,007	21,197	-14%	1%
	Swine	*	*	*	*	4,232	4,671	**	**
	NIR ⁶	6,333	5,857	6,111	5,672	1,023	1,131	-82%	11%
	Subtotal	31,010	29,369	31,448	29,830	26,262	26,999	-13%	3%
Fluoroquinolones	Cattle	*	*	*	12,560	12,446	12,086	**	**
	Swine	*	*	*	11,790	11,482	11,930	**	**
	Other ⁴	*	*	*	205	248	367	**	**
	NIR ⁷	18,502	22,904	23,350	*	*	*	**	**
	Subtotal	18,502	22,904	23,350	24,556	24,176	24,383	32%	1%
Lincosamides ²	Swine	118,916	128,642	104,527	114,398	128,562	158,036	33%	23%
	Chicken	8,874	8,213	8,780	6,409	7,299	7,721	-13%	6%
	NIR ⁸	14,667	15,642	12,208	14,156	11,165	11,943	-19%	7%
	Subtotal	142,458	152,497	125,514	134,962	147,026	177,700	25%	21%
Macrolides	Cattle	194,811	274,479	274,837	286,438	247,581	303,371	56%	23%
	Swine	337,295	189,503	192,175	195,441	180,537	213,027	-37%	18%
	Chicken	20,718	2,614	2,971	2,760	2,194	2,346	-89%	7%
	Turkey	1,176	1,307	1,653	1,944	*	*	**	**
	Other ⁴	714	891	1,403	1,498	*	*	**	**
	NIR ⁹	*	*	*	*	3,082	5,445	**	**
	Subtotal	554,714	468,794	473,038	488,082	433,394	524,188	-6%	21%
Penicillins ²	Cattle	99,935	96,936	96,591	78,887	82,008	66,347	-34%	-19%
	Swine	17,958	*	*	*	*	*	**	**
	Turkey	529,083	423,689	463,939	471,660	486,322	447,073	-16%	-8%
	Other ⁴	195,888	*	*	*	177,348	*	**	**
	Subtotal	842,863	690,889	731,863	716,525	762,888	619,840	-26%	-19%
Sulfonamides ²	Cattle	234,955	196,902	187,603	197,486	161,220	136,147	-42%	-16%
	Swine	40,215	31,024	45,581	72,126	91,981	126,771	215%	38%
	Chicken	21,115	7,319	*	5,903	6,230	7,088	-66%	**
	Turkey	41,127	28,817	30,446	14,908	15,660	26,478	-36%	69%
	Other ⁴	32,414	10,050	*	13,905	7,481	5,207	-84%	**
	Subtotal	369,826	274,112	278,562	304,327	282,572	301,691	-18%	7%
Tetracyclines ²	Cattle	2,840,519	1,560,542	1,732,416	1,741,883	1,703,391	1,693,680	-40%	-1%
	Swine	2,520,680	1,579,145	1,902,950	2,062,275	1,943,871	1,924,177	-24%	-1%
	Chicken	285,513	153,621	140,561	149,295	105,817	115,887	-59%	10%
	Turkey	156,617	192,976	150,749	131,034	161,909	156,338	<1%	-3%
	Other ⁴	57,859	49,416	47,502	32,545	33,757	26,783	-54%	-21%
	Subtotal	5,861,188	3,535,701	3,974,179	4,117,031	3,948,745	3,916,864	-33%	-1%
NIR ^{2,12}	All Species ¹³	216,771	76,440	48,832	12,746	2,470	5,973	-97%	142%
	Subtotal	216,771	76,440	48,832	12,746	2,470	5,973	-97%	142%

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 and 2021), Swine (excluding 2016 and 2021), 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, Swine (excluding 2020 and 2021), 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 through 2021), Swine (excluding 2019 through 2021), and Other (excluding 2019 through 2021).

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, 2020, and 2021), 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 and 2021), 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, and 2019 through 2021) and Other (excluding 2016, 2017, and 2019 through 2021).

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, 2020 and 2021), Swine, Chicken, Turkey (excluding 2017 through 2021), and Other.

Table 6a

Medically important¹ antimicrobial drugs approved for use in food-producing animals²
Actively marketed in 2021
Domestic sales and distribution data
Reported by route of administration

Route	Annual Totals (kg)³	% Total
<i>Feed²</i>	3,852,725	64%
<i>Injection²</i>	290,303	5%
<i>Intramammary</i>	17,241	<1%
<i>Oral^{2,4} or Topical^{2,5}</i>	62,185	1%
<i>Water⁶</i>	1,767,268	30%
<i>Total</i>	<i>5,989,721</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 2012-2021
Domestic sales and distribution data
Reported by route of administration

Route	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	2021 Annual Totals (kg)³	% Change 2012 - 2021	% Change 2020 - 2021
<i>Feed²</i>	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	3,852,725	-38%	3%
<i>Injection²</i>	393,422	352,693	341,790	353,197	348,239	358,534	355,994	311,562	337,919	290,303	-26%	-14%
<i>Intramammary</i>	25,979	9,875	11,450	16,049	16,172	17,583	14,056	16,155	15,645	17,241	-34%	10%
<i>Oral²⁻⁴ or Topical^{2,5}</i>	113,409	97,952	104,082	121,288	90,464	95,311	88,609	72,486	82,331	62,185	-45%	-24%
<i>Water⁶</i>	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	1,767,268	-16%	-3%
Total	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	5,989,721	-33%	<1%

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.

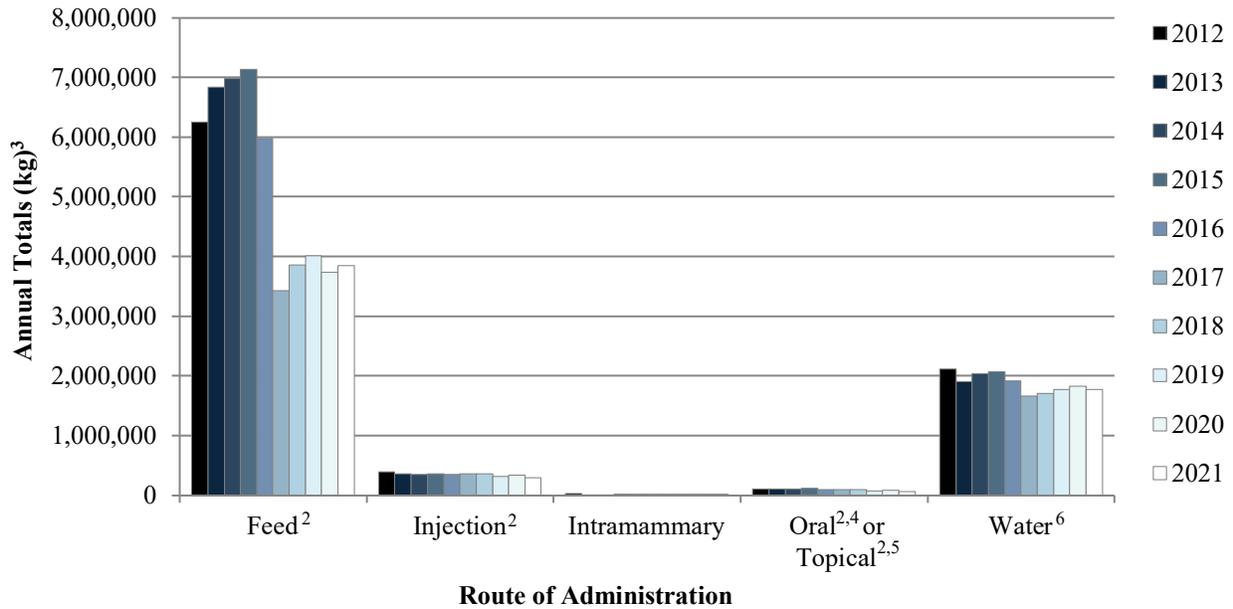
⁴ Orally administered, excludes administration by means of feed and water.

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 2012-2021
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 2012-2021
Domestic sales and distribution data
Reported by indications**

Indications	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	2021 Annual Totals (kg) ³	% Change 2012 - 2021	% Change 2020 - 2021
<i>Production⁴ or Production/Therapeutic⁵ Indications^{2,6}</i>	6,073,485	6,664,835	6,790,996	6,917,639	5,770,655	0*	0*	0*	0*	0*	**	**
<i>Therapeutic Indications Only^{2,5}</i>	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	5,989,721	112%	<1%
Total	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	5,989,721	-33%	<1%

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).

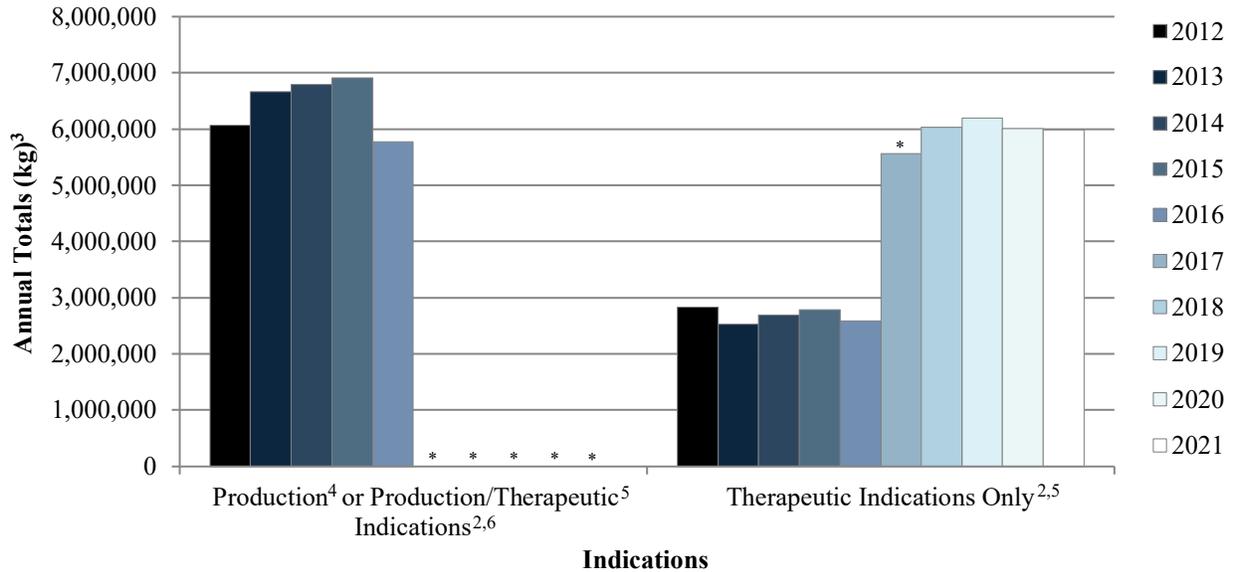
⁶ There were fewer than three distinct sponsors marketing antimicrobial animal drugs with only production indications (i.e., with no therapeutic indications). To protect confidential business information these data cannot be independently reported and are, therefore, combined with the data for drugs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

* The quantities reported in 2017 through 2021 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 2012-2021
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 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 2021 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 2012-2021
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 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 2021
Domestic sales and distribution data
Reported by dispensing status**

Dispensing Status	Annual Totals (kg)³	% Total
<i>OTC^{2,4,5}</i>	178,145	3%
<i>Rx^{2,6} or Rx/OTC^{2,4,7,8}</i>	1,958,851	33%
<i>VFD^{2,9}</i>	3,852,725	64%
<i>Total</i>	<i>5,989,721</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 2012-2021
Domestic sales and distribution data
Reported by dispensing status**

Dispensing Status	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	2021 Annual Totals (kg) ³	% Change 2012 - 2021	% Change 2020 - 2021
<i>OTC^{2,4,5}</i>	8,642,153	8,964,750	9,219,892	9,422,402	8,000,326	271,280*	262,678	223,753	240,986	178,145	-98%	-26%
<i>Rx/OTC^{2,4,6} or Rx^{2,7} or VFD^{2,8,9}</i>	255,267	228,543	259,447	280,541	356,014	1,798,290*	5,769,620	5,965,506	5,761,070	5,811,576	2177%	1%
Total	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	5,989,721	-33%	<1%

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 OC = 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.

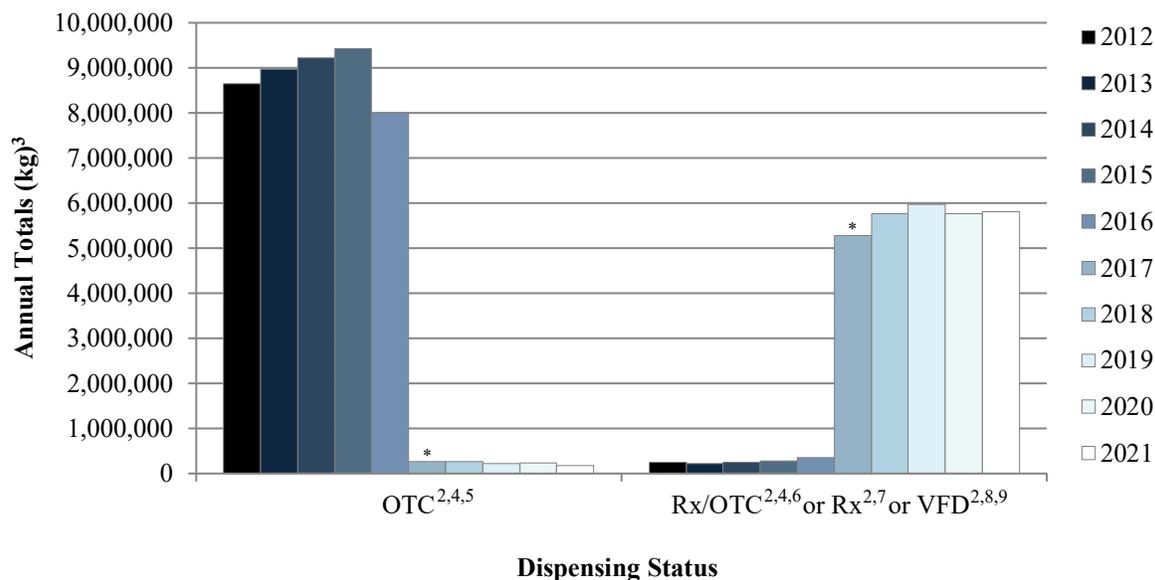
⁷ Rx = Prescription. Approved animal drugs that require a prescription from a licensed veterinarian.

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 2012-2021
 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.

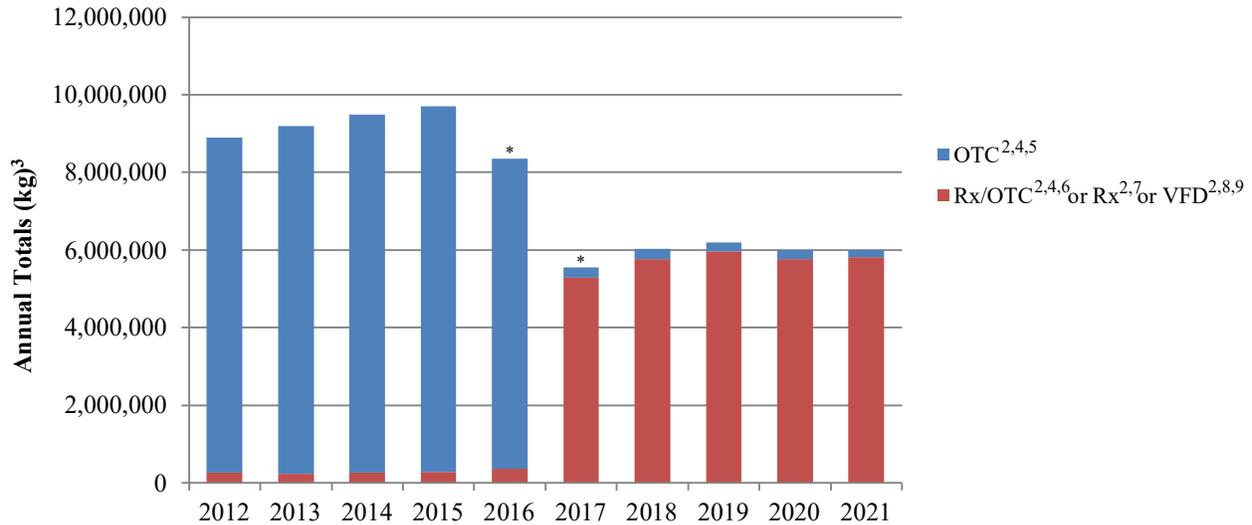
⁷ Rx = Prescription. Approved animal drugs that require a prescription from a licensed veterinarian.

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 2012-2021
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 2021
 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>	25,368	<1%
	<i>Tetracyclines²</i>	3,285,900	55%
	<i>Other Drugs⁴</i>	541,457	9%
Water	<i>Aminoglycosides</i>	264,692	4%
	<i>Lincosamides</i>	74,369	1%
	<i>Macrolides</i>	120,133	2%
	<i>Penicillins</i>	538,350	9%
	<i>Sulfonamides</i>	211,169	4%
	<i>Tetracyclines</i>	558,554	9%
Other Routes⁵	<i>Cephalosporins²</i>	26,999	<1%
	<i>Sulfonamides</i>	91,467	2%
	<i>Tetracyclines²</i>	72,411	1%
	<i>Other Drugs^{2,6}</i>	178,852	3%
Total		5,989,721	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: Injection, Intramammary, Oral (excluding administration by means of feed or water), and Topical.

⁶ This category includes the following: Aminoglycosides, Fluoroquinolones, Lincosamides, Macrolides, Penicillins, and Polymyxins.

Table 9b

**Medically important¹ antimicrobial drugs approved for use in food-producing animals²
Actively marketed 2012-2021
Domestic sales and distribution data
Reported by route of administration and drug class**

Route	Drug Class	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	2021 Annual Total (kg) ³	% Change 2012 - 2021	% Change 2020 - 2021
Feed	<i>Sulfonamides</i>	90,972	90,723	103,243	98,831	77,217	21,871	28,838	34,510	20,915	25,368	-72%	21%
	<i>Tetracyclines</i> ²	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	3,285,900	-35%	1%
	<i>Other Drugs</i> ⁴	1,074,620	1,043,439	1,065,893	1,007,634	796,102	590,775	551,656	535,524	458,831	541,457	-50%	18%
Water	<i>Aminoglycosides</i>	195,043	198,247	198,505	223,139	233,668	188,684	204,826	215,980	254,448	264,692	36%	4%
	<i>Lincosamides</i>	72,187	88,709	100,057	90,086	57,085	63,959	63,249	70,444	62,297	74,369	3%	19%
	<i>Penicillins</i>	753,510	672,131	740,929	793,018	700,779	559,589	599,409	607,741	655,060	538,350	-29%	-18%
	<i>Sulfonamides</i>	283,909	192,995	239,582	154,529	199,201	152,432	158,257	197,631	*	211,169	-26%	**
	<i>Tetracyclines</i>	782,959	719,529	712,026	762,411	663,602	625,568	609,430	598,052	591,722	558,554	-29%	-6%
	<i>Other Drugs</i> ⁵	26,233	27,637	49,822	49,374	64,780	65,179	75,881	85,627	266,369	120,133	358%	-55%
Other Routes ⁶	<i>Cephalosporins</i> ²	27,654	28,337	31,722	32,254	31,010	29,369	31,448	29,830	26,262	26,999	-2%	3%
	<i>Fluoroquinolones</i>	*	15,099	17,220	20,063	18,502	22,904	23,350	24,556	*	24,383	**	**
	<i>Tetracyclines</i> ²	86,224	95,887	80,211	85,732	88,553	90,406	82,657	75,433	100,505	72,411	-16%	-28%
	<i>Other Drugs</i> ^{2,7}	418,933	321,196	328,168	352,485	316,809	328,749	321,205	270,385	309,128	245,937	-41%	-20%
Total		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	5,989,721	-33%	<1%

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 2021), and Streptogramins.

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

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

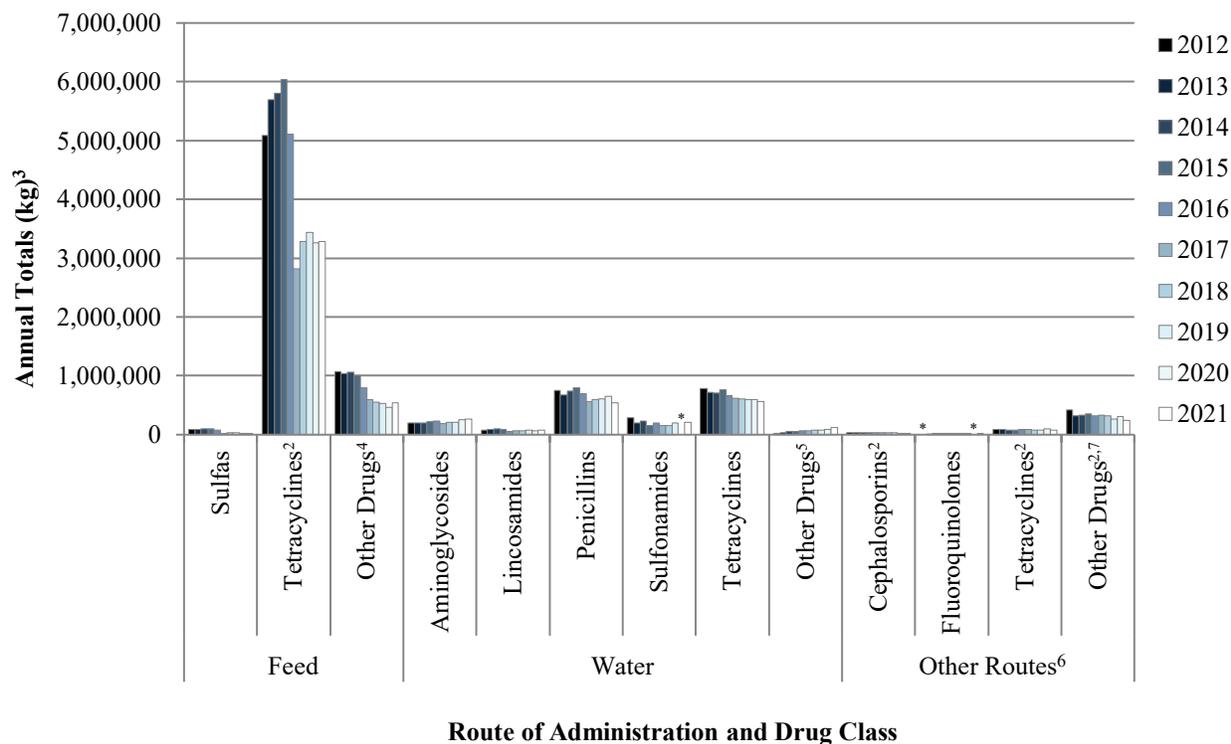
⁵ This category includes the following: Amphenicols (excluding 2013, 2016, and 2021) and Macrolides (excluding 2021).

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 and 2021), Lincosamides, Macrolides, Penicillins, Polymyxins (excluding 2012 and 2013), and Sulfonamides (excluding 2012 through 2014, 2016 through 2019, and 2021).

Figure 9b

Medically important¹ antimicrobial drugs approved for use in food-producing animals²
 Actively marketed 2012-2021
 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 2021), and Streptogramins.

⁵ This category includes the following: Amphenicols (excluding 2013, 2016, and 2021) and Macrolides (excluding 2021).

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

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 and 2021), Lincosamides, Macrolides, Penicillins, Polymyxins (excluding 2012 and 2013), and Sulfonamides (excluding 2012 through 2014, 2016 through 2019, and 2021).

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 2021
Domestic sales and distribution data
Reported by species-specific estimated sales

Species	Estimated Annual Totals (kg)²	% Total
<i>Cattle</i>	3,290,231	64%
<i>Swine</i>	612,622	12%
<i>Chicken</i>	983,331	19%
<i>Turkey</i>	226,721	4%
<i>Other³</i>	2,205	<1%
<i>Total</i>	<i>5,115,111</i>	<i>100%</i>

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 2016-2021
 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	2021 Estimated Annual Totals (kg)²	% Change 2016 - 2021	% Change 2020 - 2021
<i>Cattle</i>	3,164,626	3,139,331	3,376,063	3,246,667	2,758,786	3,290,231	4%	19%
<i>Swine</i>	425,568	395,994	414,170	404,343	381,212	612,622	44%	61%
<i>Chicken</i>	1,700,124	1,477,197	1,401,759	1,315,354	1,074,451	983,331	-42%	-8%
<i>Turkey</i>	379,478	358,774	335,826	310,426	230,425	226,721	-40%	-2%
<i>Other³</i>	0	2,860	2,965	2,308	2,545	2,205	*	-13%
Total	5,669,796	5,374,156	5,530,784	5,279,098	4,447,420	5,115,111	-10%	15%

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

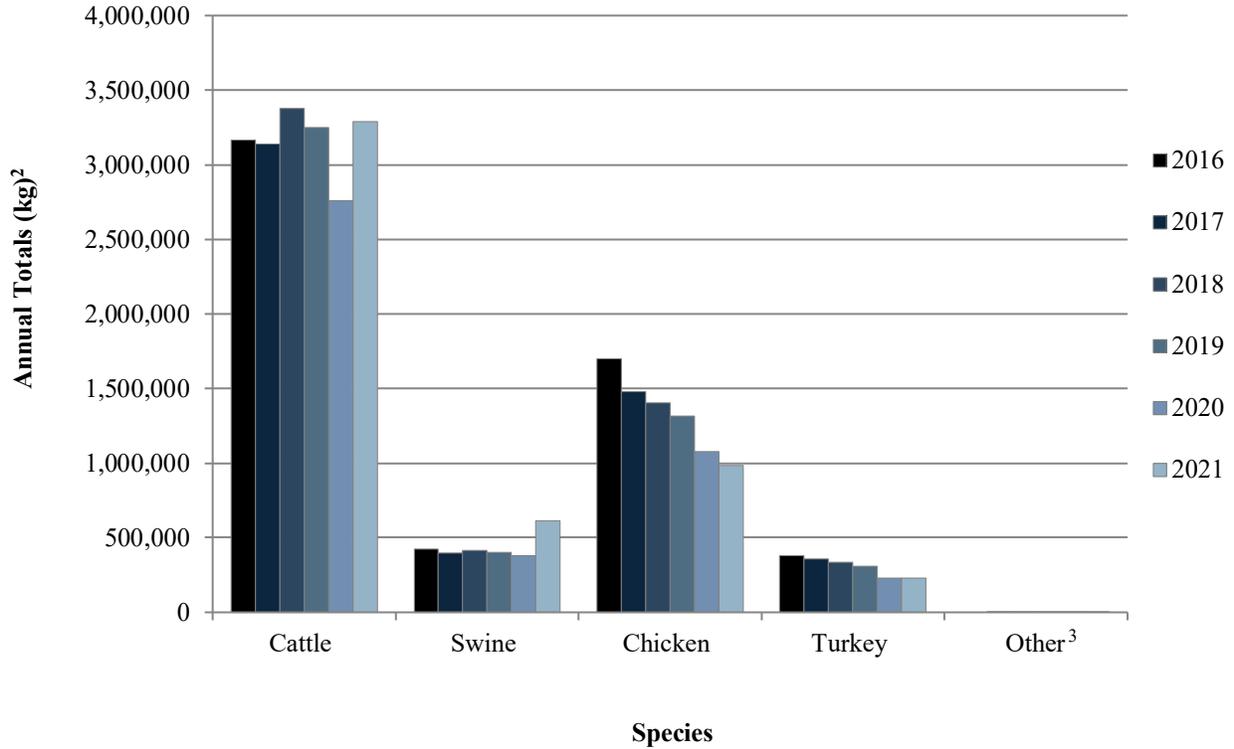
² kg = kilogram of active ingredient. Antimicrobial class includes drugs of different molecular weights, with some drugs labeled in different salt forms. Antimicrobials that are labeled in International Units (IU) (e.g., Penicillins) were converted to kg.

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 2021
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 2012-2021
Domestic sales and distribution data
Reported by route of administration

Route	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	2021 Annual Totals (kg) ²	% Change 2012 - 2021	% Change 2020 - 2021
<i>All Routes³</i>	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	5,115,111	-11%	15%

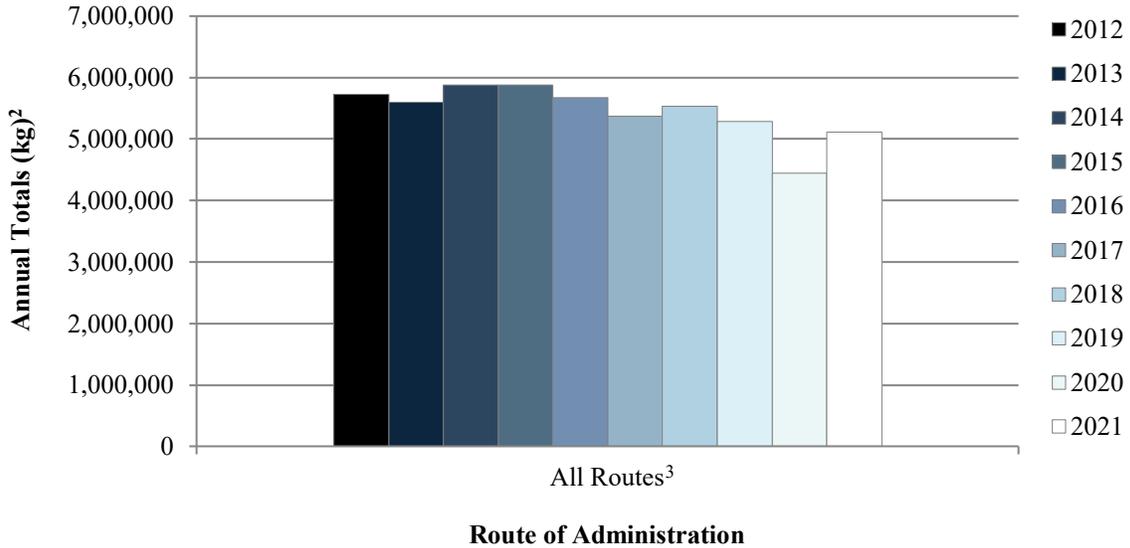
¹ Not Medically Important refers to any antimicrobial class not listed in Appendix A of FDA's Guidance for Industry #152.

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 2012-2021
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 2021
Domestic sales and distribution data
Reported by indications

Indications	Annual Totals (kg)²	% Total
<i>Production Indications Only³</i>	153,965	3%
<i>Production/Therapeutic⁴ Indications</i>	3,943,678	77%
<i>Therapeutic Indications Only⁴</i>	1,017,468	20%
Total	5,115,111	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 2012-2021
Domestic sales and distribution data
Reported by indications**

Indications	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	2021 Annual Totals (kg) ²	% Change 2012 - 2021	% Change 2020 - 2021
<i>Production³ or Production/Therapeutic⁴ Indications⁵</i>	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	4,097,643	3%	14%
<i>Therapeutic Indications Only⁴</i>	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	1,017,468	-42%	19%
Total	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	5,115,111	-11%	15%

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.

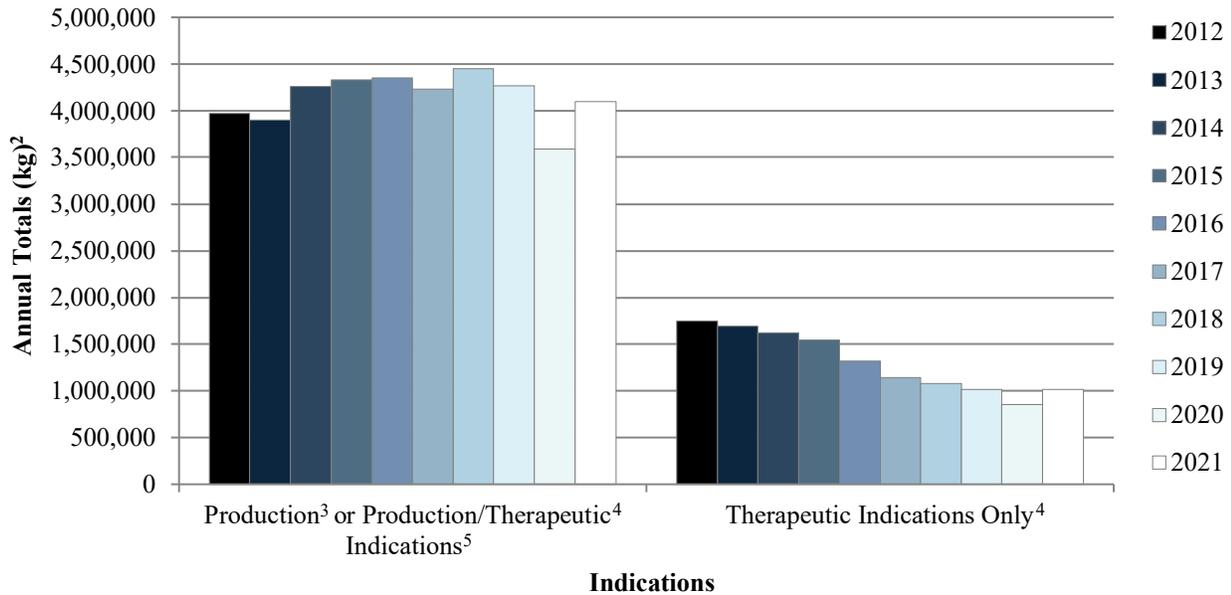
³ Production Indications (e.g., increased rate of weight gain or improved feed efficiency).

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

⁵ There were fewer than three distinct sponsors 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 2012-2021
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 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 2012-2021
 Domestic sales and distribution data
 Reported by dispensing status

Dispensing Status	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	2021 Annual Totals (kg) ²	% Change 2012 - 2021	% Change 2020 - 2021
<i>All Dispensing Statuses³</i>	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	5,115,111	-16%	-16%

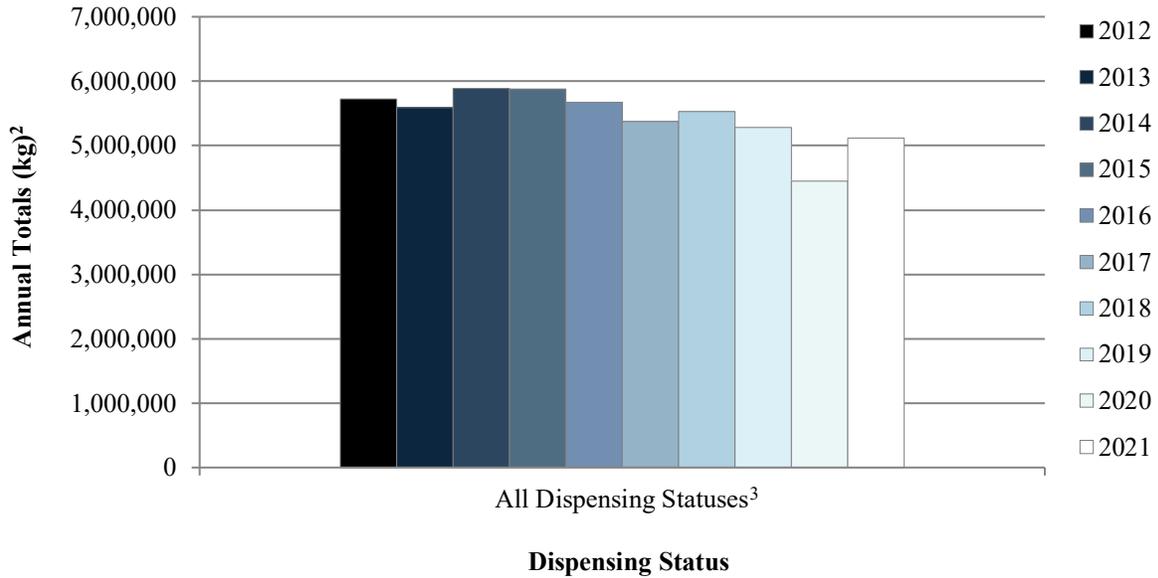
¹ Not Medically Important refers to any antimicrobial class not listed in Appendix A of FDA's Guidance for Industry #152.

² kMARKg = 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 2012 through 2015 and 2019 through 2021), and VFD (excluding 2012 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 2012-2021
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 2012 through 2015 and 2019 through 2021), and VFD (excluding 2012 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.

References

- **FDA Webpage on Antimicrobial Resistance**
 - <https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/antimicrobial-resistance-information-fda>
- **FDA/CVM Webpage on Antimicrobial Resistance**
 - <https://www.fda.gov/animal-veterinary/safety-health/antimicrobial-resistance>
- **FDA/CVM Webpage on the National Antimicrobial Resistance Monitoring System (NARMS)**
 - <https://www.fda.gov/animal-veterinary/antimicrobial-resistance/national-antimicrobial-resistance-monitoring-system>
- **FDA/CVM Webpage on Judicious Use of Antimicrobials**
 - <https://www.fda.gov/animal-veterinary/antimicrobial-resistance/judicious-use-antimicrobials>
- **FDA/CDER Webpage on Antimicrobial Resistance**
 - <https://www.fda.gov/drugs/information-drug-class/antimicrobial-resistance-information-consumers-and-health-professionals>
- **FDA Guidance for Industry #152**
 - “Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern”
 - <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-152-evaluating-safety-antimicrobial-new-animal-drugs-regard-their-microbiological-effects>
- **FDA Guidance for Industry #209**
 - “The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals”
 - <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-209-judicious-use-medically-important-antimicrobial-drugs-food-producing-animals>
- **FDA Guidance for Industry #213**
 - “New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209”
 - <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-213-new-animal-drugs-and-new-animal-drug-combination-products-administered-or-medicated-feed>
- **FDA Final Rule on Antimicrobial Animal Drug Sales and Distribution Reporting**
 - <https://www.federalregister.gov/documents/2016/05/11/2016-11082/antimicrobial-animal-drug-sales-and-distribution-reporting>
- **FDA Proposed Rule on Antimicrobial Animal Drug Sales and Distribution Reporting**
 - <https://www.federalregister.gov/documents/2015/05/20/2015-12081/antimicrobial-animal-drug-sales-and-distribution-reporting>