U.S. FOOD & DRUG ADMINISTRATION

CENTER FOR VETERINARY MEDICINE

2017

Summary Report

On

Antimicrobials Sold or Distributed for Use in Food-Producing Animals

December, 2018

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Executive Summary

Each year, every sponsor of an approved or conditionally approved new 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 these sales and distribution for the 2017 calendar year.

This 2017 summary report also includes multiple years of domestic sales and distribution data of actively marketed antimicrobial drugs by drug class, medical importance, and route of administration, as well as observations on the changes in the sales and distribution of these drugs from 2016 through 2017.

This 2017 summary report reflects changes in the marketplace since the complete implementation of Guidance for Industry (GFI) #213[2] in January 2017, when all affected products that are medically important in human medicine (specifically, antimicrobials used in feed and water) transitioned from over-the-counter (OTC) marketing status to either prescription (Rx) or Veterinary Feed Directive (VFD) marketing status and all production claims were removed.

Key observations from the report include:

- Domestic sales and distribution of medically important antimicrobials approved for use in food-producing animals:
    - decreased by 33% from 2016 through 2017.
    - decreased by 43% from 2015 (the year of peak sales) through 2017.
    - decreased by 28% from 2009 (the first year of reported sales) through 2017.
    - Tetracyclines, which represent the largest volume of these domestic sales (3,535,701 kg in 2017), decreased by 40% from 2016 through 2017.
- The domestic sales and distribution of medically important antimicrobials approved for use in food-producing animals that have an approved indication for production use decreased from 5,770,655 kg to 0 kg from 2016 through 2017 as a result of the implementation of GFI #213.
- The domestic sales and distribution of medically important antimicrobials approved for use in food-producing animals that are sold OTC decreased from 8,000,326 kg to 271,280 kg from 2016 through 2017 as a result of the implementation of GFI #213.

[1] "Medically importance antimicrobials" are those antimicrobials that have been determined to be medically important to human medicine.

[2] 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

- Of the 2017 domestic sales and distribution of medically important antimicrobials approved for use in food-producing animals:
    - Tetracyclines accounted for 64%, penicillins for 12%, macrolides for 8%, sulfas for 5%, aminoglycosides for 5%, lincosamides for 3%, and cephalosporins and fluoroquinolones each for less than 1%.
    - An estimated 42% was intended for use in cattle, an estimated 36% intended for use in swine, an estimated 12% intended for use in turkeys, an estimated 5% intended for use in chickens, and an estimated 5% intended for use in other species/unknown.
    - An estimated 80% of cephalosporins, 72% of sulfas, 48% of aminoglycocides, and 44% of tetracyclines were intended for use in cattle. An estimated 84% of lincosamides and 40% of macrolides were intended for use in swine. An estimated 61% of penicillins were intended for use in turkeys.

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 adding 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: http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM219560.pdf. 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 public health risks as medically important antimicrobials.

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). The data included in the 2017 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.

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 is 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 are a variety of factors that confound direct comparison of species-specific sales estimates, including differences in population size, weight, lifespan, and drug metabolism.

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. 320 million[3]) compared to the much larger number of animals in each of the many animal species (e.g., approx. 9 billion chickens slaughtered annually[4]).
- The differences in physical characteristics of humans compared to various animal species (e.g., physiology and weight– average adult human, 182 lb[5] vs adult cattle live weight, 1,363 lb[6]).
- 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 human uses with those sold for certain animal 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 2017 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(l)(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.

[3] https://www.census.gov/quickfacts/fact/table/US/PST045216
[4] http://usda.mannlib.cornell.edu/MannUsda/viewDocumentInfo.do?documentID=1497
[5] https://www.cdc.gov/nchs/fastats/body-measurements.htm
[6] http://usda.mannlib.cornell.edu/MannUsda/viewDocumentInfo.do?documentID=1097

II. Data on all marketed antimicrobial drugs

Table 1

Antimicrobial drug classes and active ingredients approved for use in food-producing animals[1]
Actively marketed in 2017

Aminocoumarins (NMI)[3]
Novobiocin

Aminoglycosides (MI)[2]
Dihydrostreptomycin
Gentamicin
Hygromycin B
Neomycin
Spectinomycin

Amphenicols (MI)[2]
Florfenicol

Cephalosporins (MI)[2]
Ceftiofur[1]
Cephapirin

Diaminopyrimidines (MI)[2]
Ormetoprim

Fluoroquinolones (MI)[2]
Danofloxacin
Enrofloxacin

Glycolipids (NMI)[3]
Bambermycins

Ionophores (NMI)[3]
Laidlomycin
Lasalocid
Monensin
Narasin
Salinomycin

Lincosamides (MI)[2]
Lincomycin[1]
Pirlimycin

Macrolides (MI)[2]
Erythromycin
Gamithromycin
Tildipirosin
Tilmicosin
Tulathromycin
Tylosin
Tylvalosin

Orthosomycins (NMI)[3]
Avilamycin

Penicillins (MI)[2]
Amoxicillin
Ampicillin[1]
Cloxacillin
Penicillin[1]

Pleuromutilins (NMI)[3]
Tiamulin

Polymyxins (MI)[2]
Polymyxin B[1]

Polypeptides (NMI)[3]
Bacitracin

Quinoxalines (NMI)[3]
Carbadox

Streptogramins (MI)[2]
Virginiamycin

Sulfonamides (Sulfas) (MI)[2]
Sulfadimethoxine
Sulfamethazine[1]

Tetracyclines (MI)[2]
Chlortetracycline[1]
Oxytetracycline[1]
Tetracycline

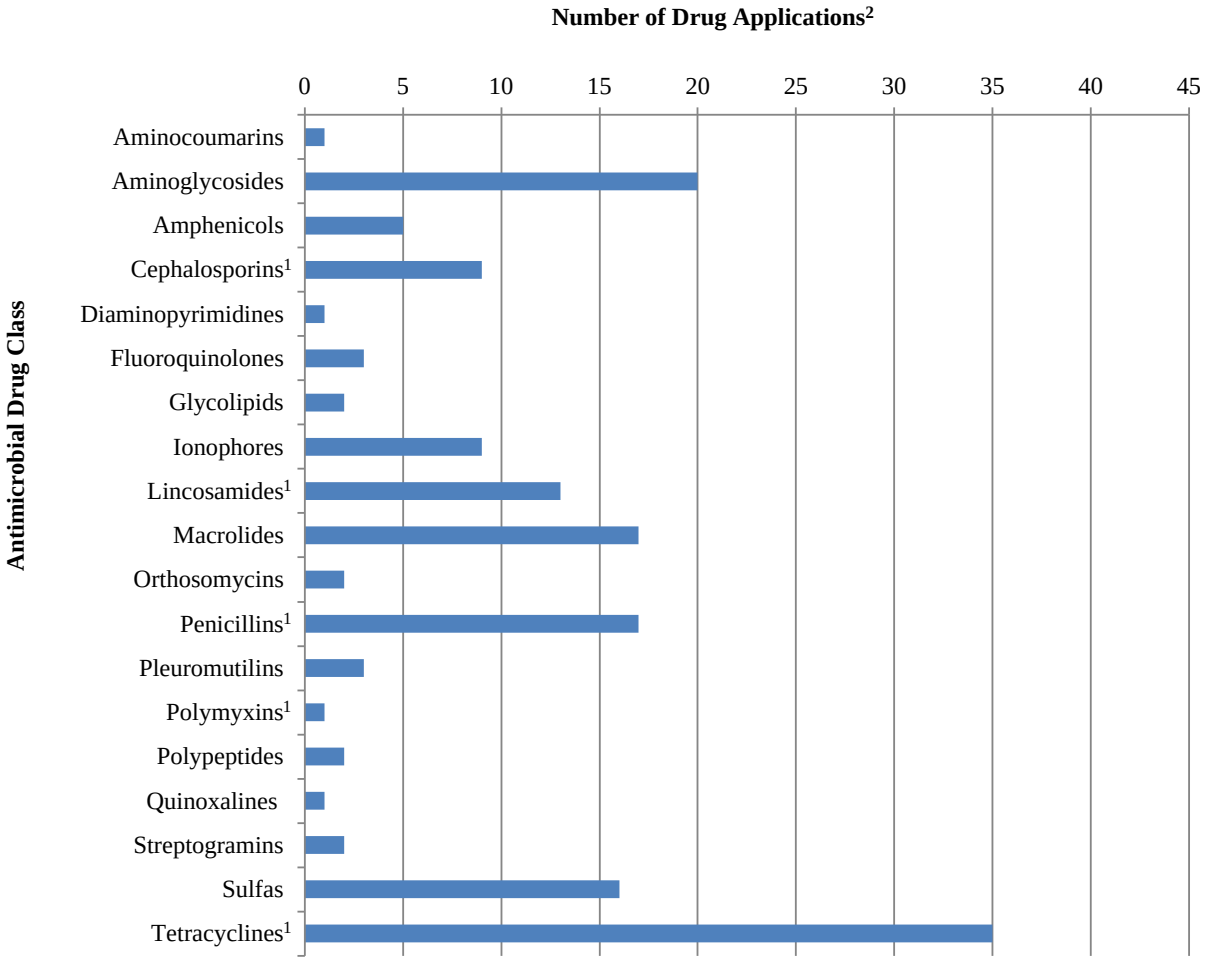
1 Includes antimicrobial drug applications which are approved and labeled for use in both food-producing animals (e.g., cattle and swine) and nonfood-producing animals (e.g., dogs and horses).

2 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.

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

Figure 1a

Antimicrobial drug classes approved for use in food-producing animals[1]
Actively marketed in 2017
Domestic sales and distribution data
Number of drug applications[2]

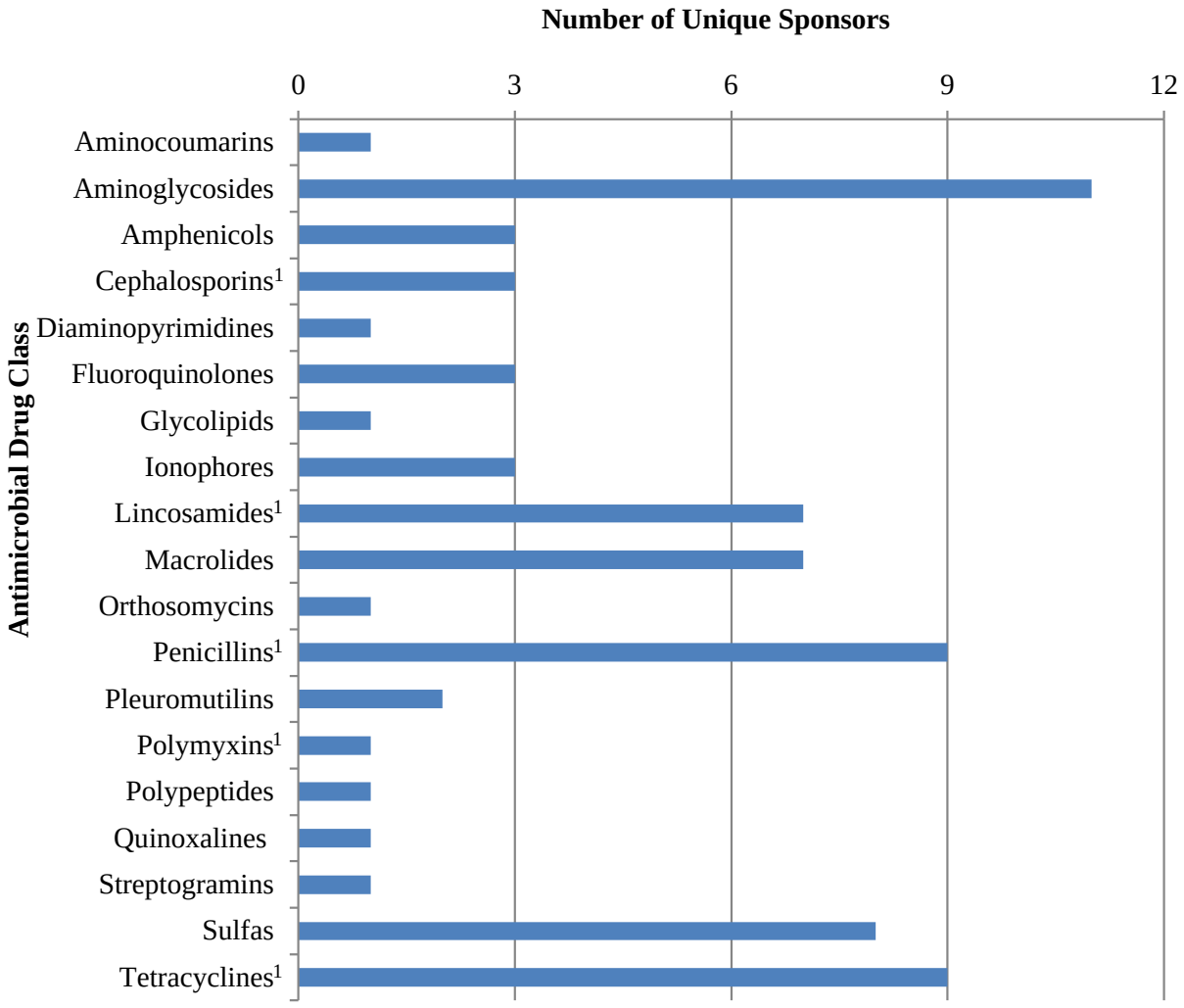


1 Includes antimicrobial drug applications which are approved and labeled for use in both food-producing animals (e.g., cattle and swine) and nonfood-producing animals (e.g., dogs and horses).

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 animals[1]
Actively marketed in 2017
Domestic sales and distribution data
Number of unique sponsors



[1] Includes antimicrobial drug applications which 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 animals[1]
Actively marketed in 2017
Domestic sales and distribution data
Reported by medical importance and drug class

	Drug Class	Annual Totals (kg)[2]	% Subtotal	% Grand Total
Medically Important[3]	*Aminoglycosides*	259,184	5%	2%
	Amphenicols	49,321	1%	<1%
	Cephalosporins[1]	29,369	<1%	<1%
	Fluoroquinolones	22,904	<1%	<1%
	Lincosamides[1]	152,497	3%	1%
	Macrolides	468,794	8%	4%
	Penicillins[1]	690,889	12%	6%
	Sulfas	274,112	5%	3%
	Tetracyclines[1]	3,535,701	64%	32%
	NIR[1,4]	76,440	1%	1%
	Subtotal	***5,559,212***	***100%***	***51%***
Not Medically Important[5]	*Ionophores*	4,394,850	82%	40%
	NIR[6]	979,306	18%	9%
	Subtotal	***5,374,156***	***100%***	***49%***
	Grand Total	***10,933,367***		***100%***

1 Includes antimicrobial drug applications which 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, Pleuromutilins, Polypeptides, and Quinoxalines.

Table 2b

Antimicrobial drugs approved for use in food-producing animals[1]
Actively marketed 2009-2017
Domestic sales and distribution data
Reported by medical importance and drug class

	Drug Class	2009 Annual Totals (kg)[2]	2010 Annual Totals (kg)[2]	2011 Annual Totals (kg)[2]	2012 Annual Totals (kg)[2]	2013 Annual Totals (kg)[2]	2014 Annual Totals (kg)[2]	2015 Annual Totals (kg)[2]	2016 Annual Totals (kg)[2]	2017 Annual Totals (kg)[2]	% Change 2009 - 2017	% Change 2016 - 2017
Medically Important[3]	*Aminoglycosides[1]*	223,117	211,790	214,895	277,854	267,734	304,160	344,120	319,009	259,184	16%	-19%
	Cephalosporins[1]	20,145	24,588	26,611	27,654	28,337	31,722	32,254	31,010	29,369	46%	-5%
	Fluoroquinolones	*	*	*	*	15,099	17,220	20,063	18,502	22,904	**	24%
	Lincosamides[1]	93,330	154,653	190,101	218,140	236,450	233,681	182,543	142,458	152,497	63%	7%
	Macrolides[1]	562,062	553,229	582,836	616,274	563,251	621,769	627,757	554,714	468,794	-17%	-15%
	Penicillins[1]	691,644	884,419	885,304	965,196	828,721	885,975	936,669	842,863	690,889	<1%	-18%
	Sulfas[1]	505,880	517,128	383,105	493,514	383,469	452,224	380,186	369,826	274,112	-46%	-26%
	Tetracyclines[1]	5,260,995	5,602,281	5,652,855	5,954,361	6,514,779	6,604,199	6,881,530	5,861,188	3,535,701	-33%	-40%
	NIR[1,4]	329,391	281,221	319,991	344,428	355,452	328,389	297,822	216,771	125,761	-62%	-42%
	Subtotal	***7,686,564***	***8,229,309***	***8,255,697***	***8,897,420***	***9,193,293***	***9,479,339***	***9,702,943***	***8,356,340***	***5,559,212***	***-28%***	***-33%***
Not Medically Important[5]	*Ionophores*	3,739,352	3,820,004	4,122,397	4,573,795	4,434,657	4,718,650	4,740,615	4,651,491	4,394,850	18%	-6%
	NIR[6]	1,161,541	1,237,784	1,190,943	1,151,532	1,157,095	1,163,571	1,134,382	1,018,305	979,306	-16%	-4%
	Subtotal	***4,900,893***	***5,057,788***	***5,313,340***	***5,725,327***	***5,591,752***	***5,882,221***	***5,874,997***	***5,669,796***	***5,374,156***	***10%***	***-5%***
	Grand Total	***12,587,457***	***13,287,097***	***13,569,037***	***14,622,747***	***14,785,045***	***15,361,560***	***15,577,940***	***14,026,136***	***10,933,367***	***-13%***	***-22%***

1 Includes antimicrobial drug applications which 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.

****** Not reported because there were fewer than three distinct sponsors actively marketing products domestically in 2009 through 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.

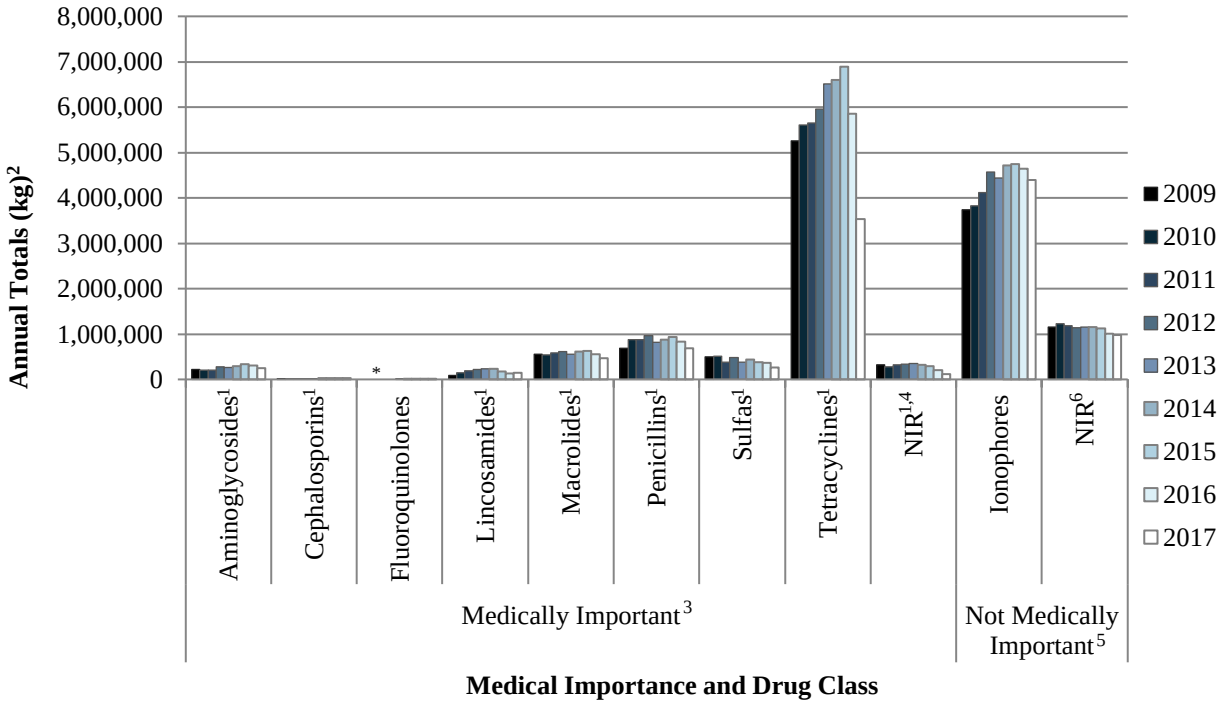
4 NIR = Not Independently Reported. Antimicrobial classes for which there were fewer than three distinct sponsors actively marketing products domestically are not independently reported. These classes include the following: Amphenicols, Diaminopyrimidines, Fluoroquinolones (excluding 2013 through 2017), 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 2009 through 2015), Pleuromutilins, Polypeptides, and Quinoxalines.

Figure 2b

Antimicrobial drugs approved for use in food-producing animals[1]
Actively marketed 2009-2017
Domestic sales and distribution data
Reported by medical importance and drug class



[1] Includes antimicrobial drug applications which 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.

[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, Fluoroquinolones (excluding 2013 through 2017), 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 2009 through 2015), Pleuromutilins, Polypeptides, and Quinoxalines.

Table 3a

Antimicrobial drugs approved for use in food-producing animals[1]
Actively marketed in 2017
Domestic/export sales and distribution data

Domestic/Export	Annual Totals (kg)[2]	% Total
Domestic[1]	10,933,367	100%
Export[1,3]	10,038	<1%
Total	***10,943,406***	***100%***

1 Includes antimicrobial drug applications which 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 animals[1]
Actively marketed in 2009-2017
Domestic/export sales and distribution data

Domestic/ Export	2009 Estimated Annual Totals (kg)[2]	2010 Estimated Annual Totals (kg)[2]	2011 Estimated Annual Totals (kg)[2]	2012 Estimated Annual Totals (kg)[2]	2013 Estimated Annual Totals (kg)[2]	2014 Estimated Annual Totals (kg)[2]	2015 Estimated Annual Totals (kg)[2]	2016 Estimated Annual Totals (kg)[2]	2017 Estimated Annual Totals (kg)[2]	% Change 2009 - 2017	% Change 2016 - 2017
Domestic[1]	12,587,457	13,287,097	13,569,037	14,622,747	14,785,045	15,361,560	15,577,940	14,026,136	10,933,367	-13%	-22%
Export[1,3]	202,556	219,072	202,335	139,173	74,374	30,682	20,861	6,818	10,038	-95%	47%
Total	***12,790,013***	***13,506,168***	***13,771,373***	***14,761,919***	***14,859,419***	***15,392,242***	***15,598,801***	***14,032,953***	***10,943,406***	***-14%***	***-22%***

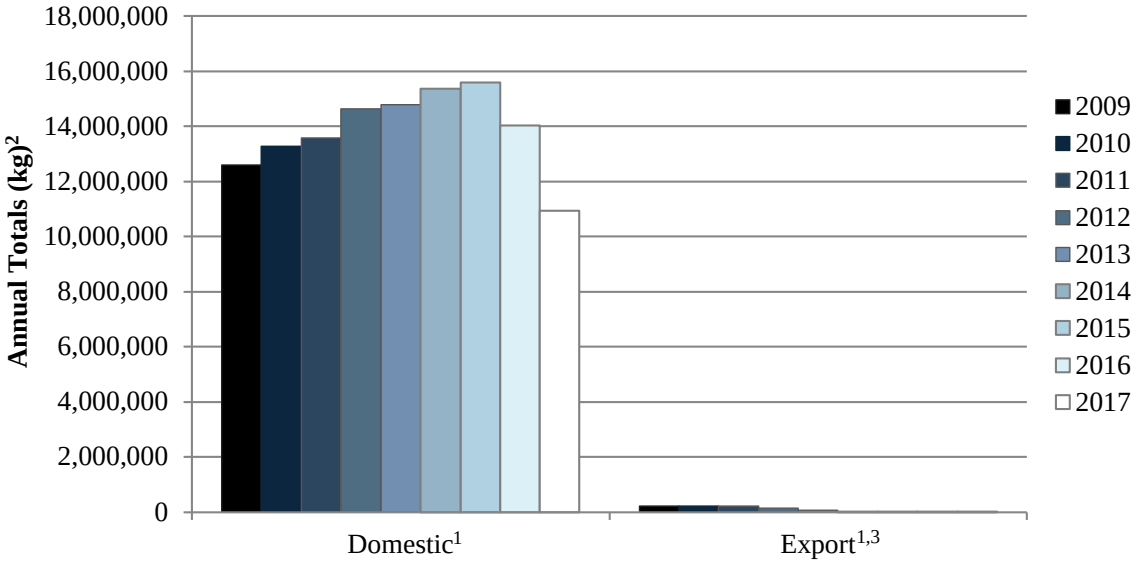
1 Includes antimicrobial drug applications which are approved and labeled for use in both food-producing animals (e.g., cattle and swine) and nonfood-producing animals (e.g., dogs and horses).

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 animals[1]
Actively marketed 2009-2017
Domestic/export sales and distribution data



Domestic/Export[3] and Drug Class

1 Includes antimicrobial drug applications which 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 important[1] antimicrobial drugs approved for use in food-producing animals[2]
Actively marketed in 2017
Domestic sales and distribution data
Reported by species-specific estimated sales

Species	Estimated Annual Totals (kg)[3]	% Total
Cattle	2,333,839	42%
Swine	2,022,932	36%
Chicken	268,047	5%
Turkey	670,831	12%
Other[4]	263,564	5%
Total	***5,559,212***	***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 which 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 important[1] antimicrobial drugs approved for use in food-producing animals[2]
Actively marketed in 2016-2017
Domestic sales and distribution data
Reported by species-specific estimated sales

Species	2016 Estimated Annual Totals (kg)[3]	2017 Estimated Annual Totals (kg)[3]	% Change 2016 - 2017
Cattle	3,605,543	2,333,839	-35%
Swine	3,133,262	2,022,932	-35%
Chicken	508,800	268,047	-47%
Turkey	756,620	670,831	-11%
Other[4]	352,114	263,564	-25%
Total	***8,356,340***	***5,559,212***	***-33%***

[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.

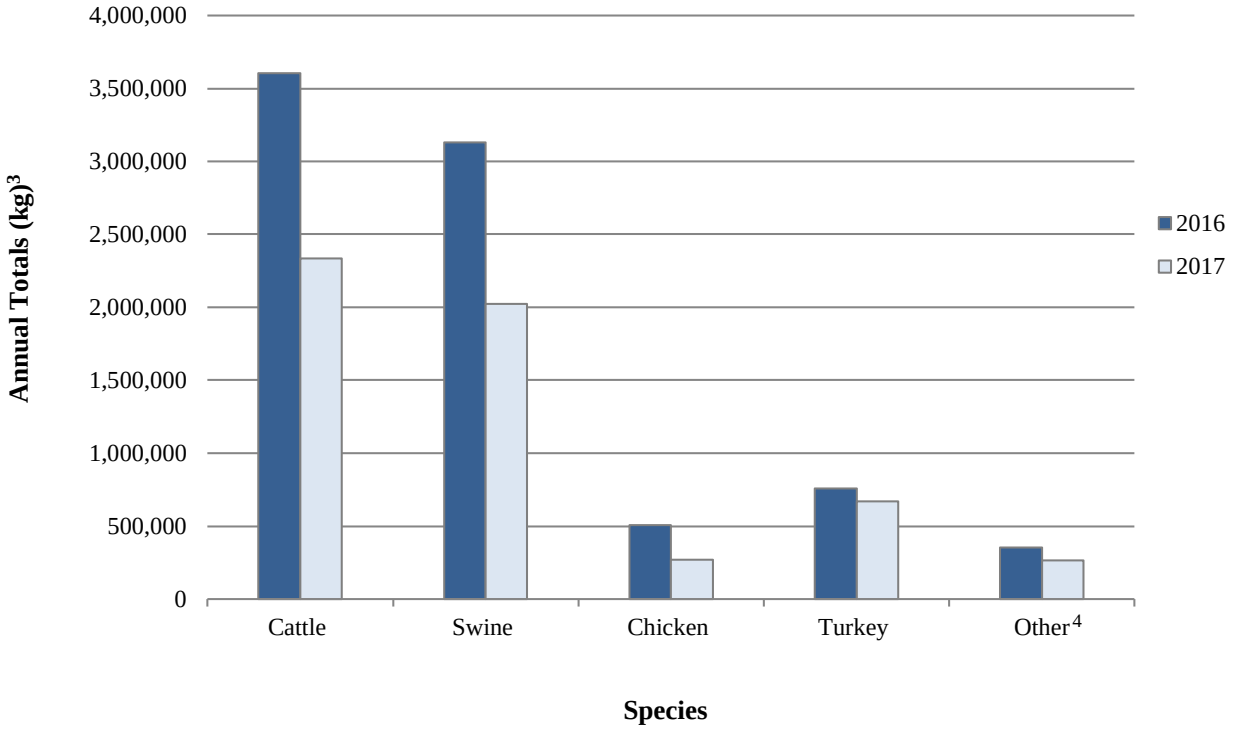
[2] Includes antimicrobial drug applications which are approved and labeled for use in both food-producing animals (e.g., cattle and swine) and nonfood-producing animals (e.g., dogs and horses).

[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 important[1] antimicrobial drugs approved for use in food-producing animals[2]
Actively marketed in 2016-2017
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 which 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 important[1] antimicrobial drugs approved for use in food-producing animals[2]

Actively marketed in 2017

Domestic sales and distribution data

Reported by drug class and species-specific estimated sales

Ingredient Class	Species	Estimated Annual Totals (kg)[3]	% Subtotal
Aminoglycosides	Cattle	124,675	48%
	Swine	63,602	25%
	Chicken	20,185	8%
	Turkey	24,042	9%
	Other[4]	26,680	10%
	Subtotal	***259,184***	***100%***
Amphenicols	All Species[5]	49,321	100%
	Subtotal	***49,321***	***100%***
Cephalosporins[2]	Cattle	23,512	80%
	NIR[6]	5,857	20%
	Subtotal	***29,369***	***100%***
Fluoroquinolones	All Species[7]	22,904	100%
	Subtotal	***22,904***	***100%***
Lincosamides[2]	Swine	128,642	84%
	Chicken	8,213	5%
	NIR[8]	15,642	10%
	Subtotal	***152,497***	***100%***
Macrolides	Cattle	274,479	59%
	Swine	189,503	40%
	Chicken	2,614	1%
	Turkey	1,307	<1%
	Other[4]	891	<1%
	Subtotal	***468,794***	***100%***
Penicillins[2]	Cattle	96,936	14%
	Turkey	423,689	61%
	NIR[9]	170,263	25%
	Subtotal	***690,889***	***100%***
Sulfas	Cattle	196,902	72%
	Swine	31,024	11%
	Chicken	7,319	3%
	Turkey	28,817	11%
	Other[4]	10,050	4%
	Subtotal	***274,112***	***100%***
Tetracyclines[2]	Cattle	1,560,542	44%
	Swine	1,579,145	45%
	Chicken	153,621	4%
	Turkey	192,976	5%
	Other[4]	49,416	1%
	Subtotal	***3,535,701***	***100%***
NIR[2,10]	All Species[11]	76,440	100%
	Subtotal	***76,440***	***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 which are approved and labeled for use in both food-producing animals (e.g., cattle and swine) and nonfood-producing animals (e.g., dogs and horses).

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

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

5 This category includes the following: Cattle, Swine, and Other.

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

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

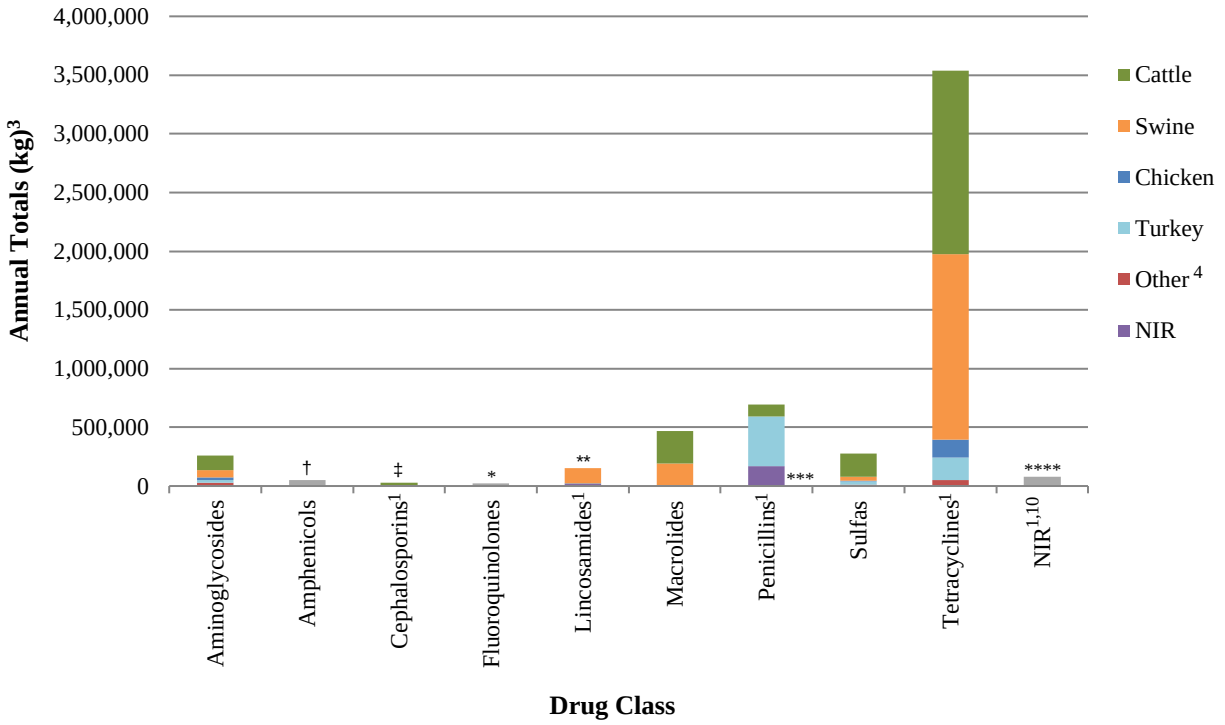
9 This category includes the following: Cattle, Swine, Turkey, and Other.

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.

11 This category includes the following: Cattle, Chicken, and Other.

Figure 5a

Medically important[1] antimicrobial drugs approved for use in food-producing animals[2]
Actively marketed in 2017
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 which 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.

† This category includes the following: Cattle, Swine, and Other.

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

* This category includes the following: Cattle, Swine, and Other.

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

*** This category includes the following: Cattle, Swine, Turkey, 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: Cattle, Chicken, and Other.

Table 5b

Medically important[1] antimicrobial drugs approved for use in food-producing animals[2]

Actively marketed 2016-2017

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]	% Change 2016 - 2017
Aminoglycosides	Cattle	161,646	124,675	-23%
	Swine	65,850	63,602	-3%
	Chicken	24,111	20,185	-16%
	Turkey	22,198	24,042	8%
	Other[4]	45,204	26,680	-41%
	Subtotal	***319,009***	***259,184***	***-19%***
Amphenicols	All Species[5]	0	49,321	N/A
	Subtotal	***0***	***49,321***	***N/A***
Cephalosporins[2]	Cattle	24,677	23,512	-5%
	NIR[6]	6,333	5,857	-8%
	Subtotal	***31,010***	***29,369***	***-5%***
Fluoroquinolones	All Species[7]	18,502	22,904	24%
	Subtotal	***18,502***	***22,904***	***24%***
Lincosamides[2]	Swine	118,916	128,642	8%
	Chicken	8,874	8,213	-7%
	NIR[8]	14,667	15,642	7%
	Subtotal	***142,458***	***152,497***	***7%***
Macrolides	Cattle	194,811	274,479	41%
	Swine	337,295	189,503	-44%
	Chicken	20,718	2,614	-87%
	Turkey	1,176	1,307	11%
	Other[4]	714	891	25%
	Subtotal	***554,714***	***468,794***	***-15%***
Penicillins[2]	Cattle	99,935	96,936	-3%
	Swine	17,958	0	-100%
	Turkey	529,083	423,689	-20%
	Other[4]	195,888	0	-100%
	NIR[9]	0	170,263	N/A
	Subtotal	***842,863***	***690,889***	***-18%***
Sulfas[2]	Cattle	234,955	196,902	-16%
	Swine	40,215	31,024	-23%
	Chicken	21,115	7,319	-65%
	Turkey	41,127	28,817	-30%
	Other[4]	32,414	10,050	-69%
	Subtotal	***369,826***	***274,112***	***-26%***
Tetracyclines[2]	Cattle	2,840,519	1,560,542	-45%
	Swine	2,520,680	1,579,145	-37%
	Chicken	285,513	153,621	-46%
	Turkey	156,617	192,976	23%
	Other[4]	57,859	49,416	-15%
	Subtotal	***5,861,188***	***3,535,701***	***-40%***
NIR[10]	All Species[11]	216,771	76,440	-65%
	Subtotal	***216,771***	***76,440***	***-65%***

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

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

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

5 This category includes the following: Cattle, Swine, and Other.

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

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

9 This category includes the following: Cattle, Swine, Turkey, 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: Amphenicols, Diaminopyrimidines, Polymyxins, and Streptogramins.

11 This category includes the following: Cattle, Swine, Chicken, Turkey, and Other.

Table 6a

Medically important[1] antimicrobial drugs approved for use in food-producing animals[2]
Actively marketed in 2017
Domestic sales and distribution data
Reported by route of administration

Route	Annual Totals (kg)[3]	% Total
Feed[2]	3,432,373	62%
Injection[2]	358,534	6%
Intramammary	17,583	<1%
Oral[2,4] *or Topical*[2]	95,311	2%
Water[5]	1,655,410	30%
Total	***5,559,212***	***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 which 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 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 important[1] antimicrobial drugs approved for use in food-producing animals[2]
Actively marketed 2009-2017
Domestic sales and distribution data
Reported by route of administration

Route	2009 Annual Totals (kg)[3]	2010 Annual Totals (kg)[3]	2011 Annual Totals (kg)[3]	2012 Annual Totals (kg)[3]	2013 Annual Totals (kg)[3]	2014 Annual Totals (kg)[3]	2015 Annual Totals (kg)[3]	2016 Annual Totals (kg)[3]	2017 Annual Totals (kg)[3]	% Change 2009 - 2017	% Change 2016 - 2017
Feed[2]	5,687,084	5,957,748	5,933,440	6,250,770	6,833,526	6,981,097	7,139,853	5,982,351	3,432,373	-40%	-43%
Injection[2]	388,518	421,272	416,775	393,422	352,693	341,790	353,197	348,239	358,534	-8%	3%
Intramammary	23,409	24,692	21,023	25,979	9,875	11,450	16,049	16,172	17,583	-25%	9%
Oral[2,4] *or Topical*[2,5]	120,506	109,839	126,775	113,409	97,952	104,082	121,288	90,464	95,311	-21%	5%
Water[6]	1,467,048	1,715,757	1,757,686	2,113,840	1,899,248	2,040,920	2,072,557	1,919,115	1,655,410	13%	-14%
Total	***7,686,564***	***8,229,309***	***8,255,697***	***8,897,420***	***9,193,293***	***9,479,339***	***9,702,943***	***8,356,340***	***5,559,212***	***-28%***	***-33%***

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 which 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.

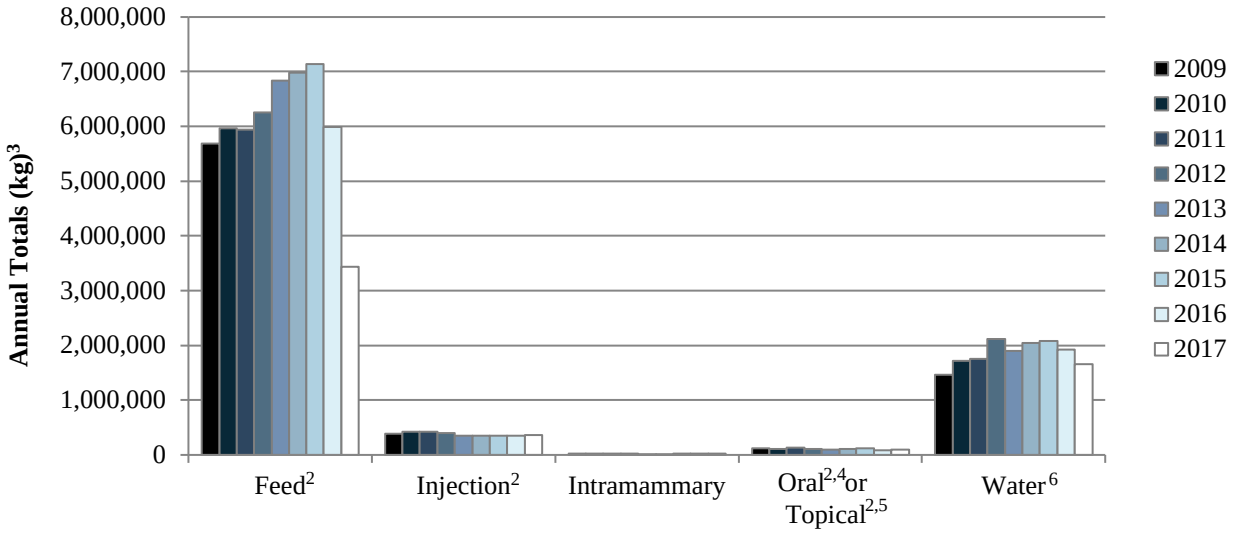
4 Orally administered, excluding administration by means of feed and water.

5 No Topical sales and distribution in 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 important[1] antimicrobial drugs approved for use in food-producing animals[2]
Actively marketed 2009-2017
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 which 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] No Topical sales and distribution in 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 important[1] antimicrobial drugs approved for use in food-producing animals[2]
Actively marketed in 2017
Domestic sales and distribution data
Reported by indications

Indications	Annual Totals (kg)[3]
Therapeutic Indications Only[2,4,5]	5,559,212

[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 which 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 a specific disease).

Table 7b

Medically important[1] antimicrobial drugs approved for use in food-producing animals[2]
Actively marketed 2009-2017
Domestic sales and distribution data
Reported by indications

Indications	2009 Annual Totals (kg)[3]	2010 Annual Totals (kg)[3]	2011 Annual Totals (kg)[3]	2012 Annual Totals (kg)[3]	2013 Annual Totals (kg)[3]	2014 Annual Totals (kg)[3]	2015 Annual Totals (kg)[3]	2016 Annual Totals (kg)[3]	2017 Annual Totals (kg)[3]	% Change 2009 - 2017	% Change 2016 - 2017
Production[4] or Production/Therapeutic[5] Indications[2,6]	5,563,029	5,828,079	5,770,871	6,073,485	6,664,835	6,790,996	6,917,639	5,770,655	0*	-100%	-100%
Therapeutic Indications Only[2,5]	2,123,536	2,401,230	2,484,827	2,823,935	2,528,458	2,688,343	2,785,304	2,585,685	5,559,212*	162%	115%
Total	***7,686,564***	***8,229,309***	***8,255,697***	***8,897,420***	***9,193,293***	***9,479,339***	***9,702,943***	***8,356,340***	***5,559,212***	***-28%***	***-33%***

1 Includes antimicrobial drug applications which 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 which 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.

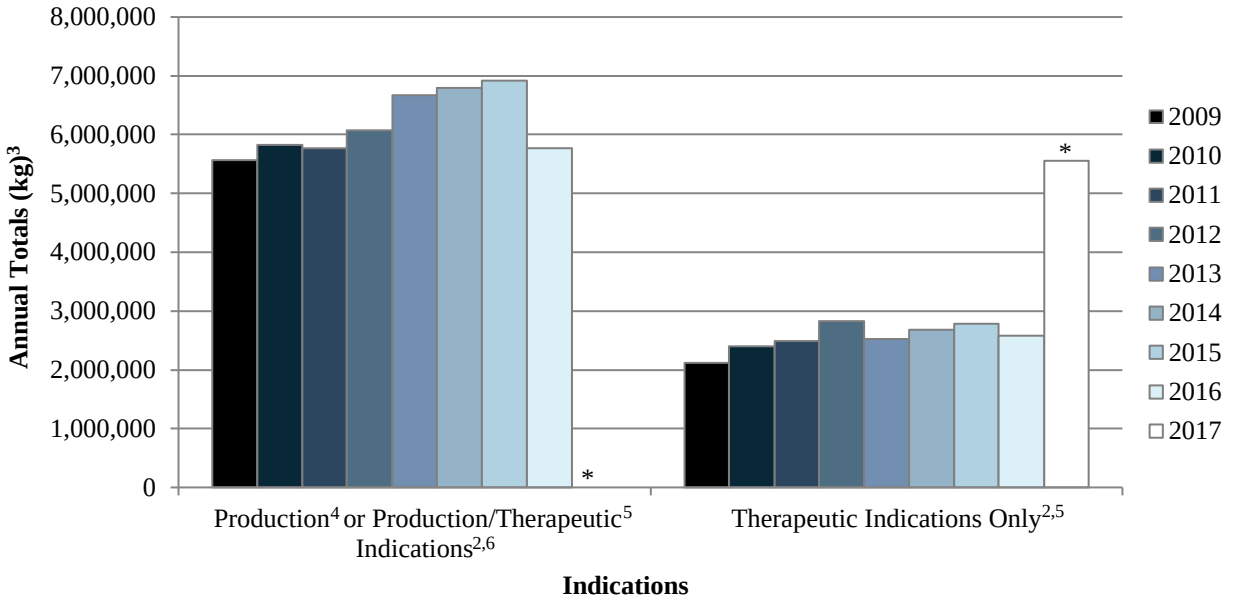
5 Therapeutic Indications (e.g., treatment, control, or prevention of a specific disease).

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

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

Figure 7b

Medically important[1] antimicrobial drugs approved for use in food-producing animals[2]
Actively marketed 2009-2017
Domestic sales and distribution data
Reported by indications



[1] Includes antimicrobial drug applications which 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 which 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.

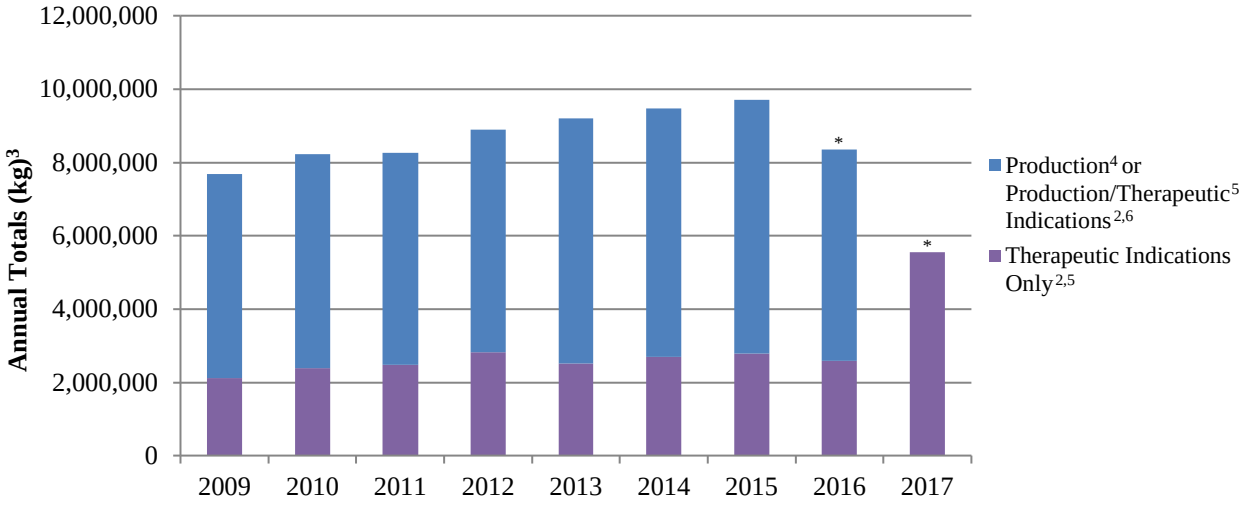
[5] Therapeutic Indications (e.g., treatment, control, or prevention of a specific disease).

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

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

Figure 7c

Medically important[1] antimicrobial drugs approved for use in food-producing animals[2]
Actively marketed 2009-2017
Domestic sales and distribution data
Reported by indications (combined annual totals)



[1] Includes antimicrobial drug applications which 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 which 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 a specific disease).

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

* The quantity reported in 2017 under the production indications category dropped to zero as a result of the implementation of GFI 213.

Applications that were formerly in the Production category were voluntarily withdrawn. Applications that were formerly in the Production/Therapeutic Indications category had production claims eliminated and were moved to the Therapeutic Only Indications category.

Table 8a

Medically important[1] antimicrobial drugs approved for use in food-producing animals[2]
Actively marketed in 2017
Domestic sales and distribution data
Reported by dispensing status

Dispensing Status	Annual Totals (kg)[3]	% Total
OTC[2,4,5]	271,280	5%
RX[2,6]	1,798,290	32%
RX[6]*/OTC*[2,4,7]	57,269	1%
VFD[8]	3,432,373	62%
Total	***5,559,212***	***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 which 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] 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 important[1] antimicrobial drugs approved for use in food-producing animals[2]
Actively marketed 2009-2017
Domestic sales and distribution data
Reported by dispensing status

Dispensing Status	2009 Annual Totals (kg)[3]	2010 Annual Totals (kg)[3]	2011 Annual Totals (kg)[3]	2012 Annual Totals (kg)[3]	2013 Annual Totals (kg)[3]	2014 Annual Totals (kg)[3]	2015 Annual Totals (kg)[3]	2016 Annual Totals (kg)[3]	2017 Annual Totals (kg)[3]	% Change 2009 - 2017	% Change 2016 - 2017
OTC[2,4,5]	7,506,644	8,050,340	8,029,437	8,642,153	8,964,750	9,219,892	9,422,402	8,000,326	271,280*	-96%	-97%
RX[6]/OTC[2,4,7]	44,117	47,901	50,205	54,968	54,942	48,489	56,363	60,705	57,269	30%	-6%
RX[6] or VFD[2,8,9]	135,803	131,068	176,055	200,298	173,600	210,958	224,179	295,309	5,230,663*	3,752%	1,671%
Total	***7,686,564***	***8,229,309***	***8,255,697***	***8,897,420***	***9,193,293***	***9,479,339***	***9,702,943***	***8,356,340***	***5,559,212***	***-28%***	***-33%***

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

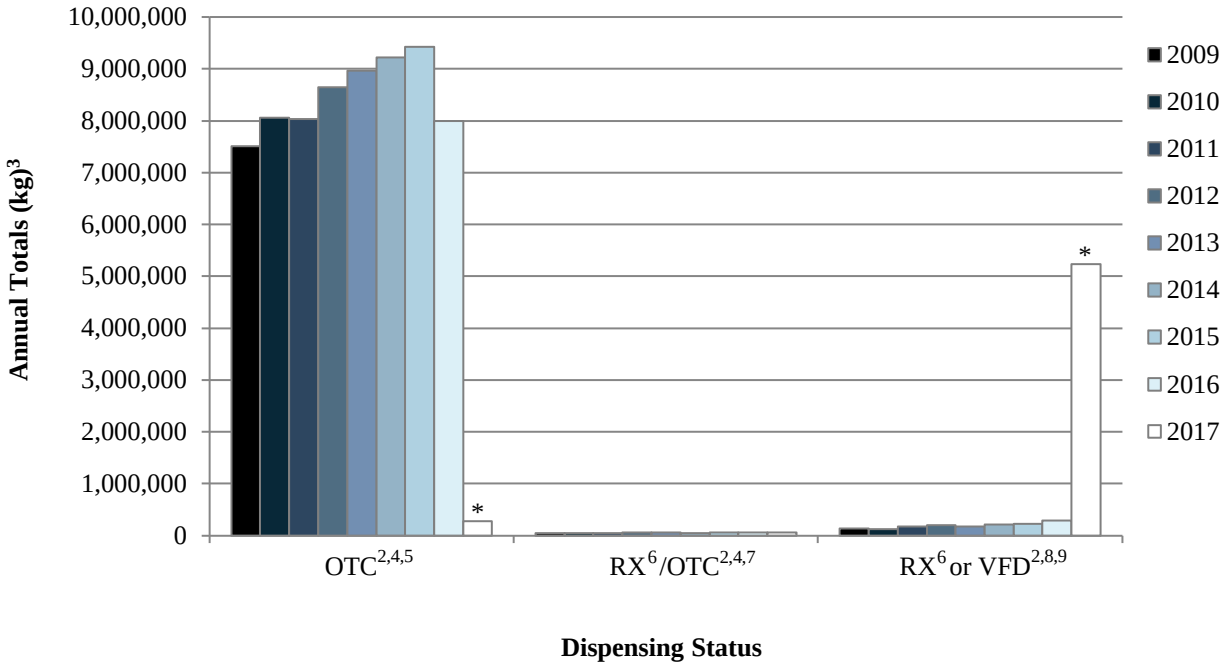
7 Animal drugs that were approved with both a prescription and OTC dispensing status (RX/OTC), with the approved drug being marketed with either a prescription label or an OTC label, depending upon the species and indication on the label.

8 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 The Rx or VFD category includes four VFD products marketed by only two distinct sponsors; therefore, VFD products cannot be independently reported (excluding 2013 through 2017).

Figure 8b

Medically important[1] antimicrobial drugs approved for use in food-producing animals[2]
Actively marketed 2009-2017
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 which 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] Rx = Prescription. Approved animal drugs that require a prescription from a licensed veterinarian.

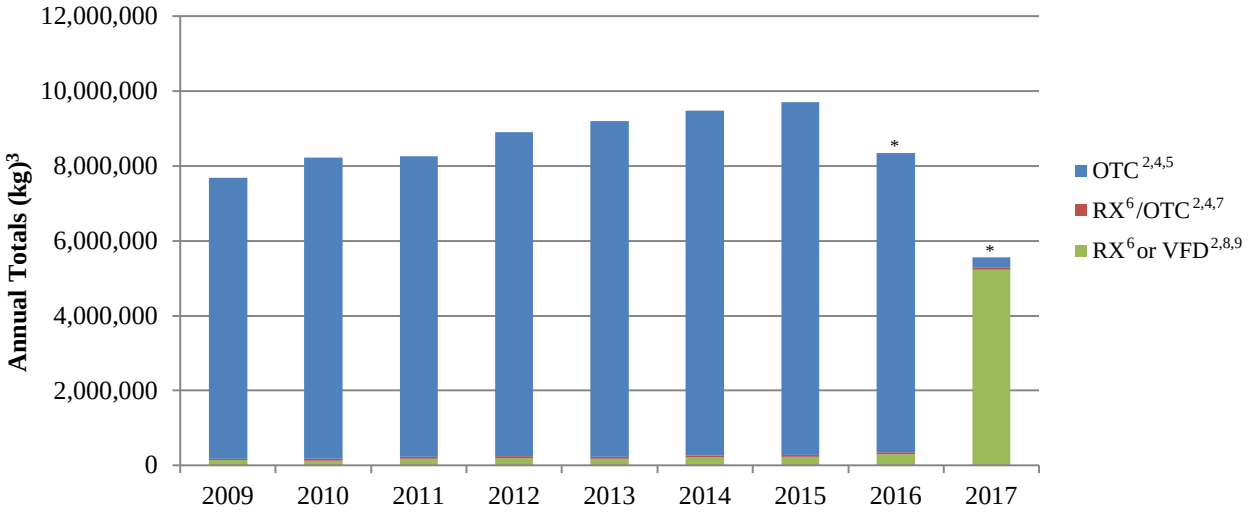
[7] Animal drugs that were approved with both a prescription and OTC dispensing status (RX/OTC), with the approved drug being marketed with either a prescription label or an OTC label, depending upon the species and indication on the label.

[8] 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] The Rx or VFD category includes four VFD products marketed by only two distinct sponsors; therefore, VFD products cannot be independently reported (excluding 2013 through 2017).

Figure 8c

Medically important[1] antimicrobial drugs approved for use in food-producing animals[2]
Actively marketed 2009-2017
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 which 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] 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] 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] The Rx or VFD category includes four VFD products marketed by only two distinct sponsors; therefore, VFD products cannot be independently reported (excluding 2013 through 2017).

Table 9a

Medically important[1] antimicrobial drugs approved for use in food-producing animals[2]
Actively marketed in 2017
Domestic sales and distribution data
Reported by route of administration and drug class

Route	Drug Class	Annual Total (kg)[3]	% Total
Feed	*Sulfas*	21,871	<1%
	Tetracyclines[2]	2,819,727	51%
	Other Drugs[4]	590,775	11%
Water	*Aminoglycosides*	188,684	3%
	Lincosamides	63,959	1%
	Penicillins	559,589	10%
	Sulfas	152,432	3%
	Tetracyclines	625,568	11%
	Other Drug[5]	65,179	1%
Other Routes[6]	*Cephalosporins*[2]	29,369	1%
	Sulfas	99,809	2%
	Tetracyclines[2]	90,406	2%
	Other Drugs[2,7]	251,844	5%
	Total	***5,559,212***	***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 which are approved and labeled for use in both food-producing animals (e.g., cattle and swine) and nonfood-producing animals (e.g., dogs and horses).

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

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

[5] This category includes the following: Amphenicols and Macrolides.

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

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

Table 9b

Medically important[1] antimicrobial drugs approved for use in food-producing animals[2]
Actively marketed 2009-2017
Domestic sales and distribution data
Reported by route of administration and drug class

Route	Drug Class	2009 Annual Total (kg)[3]	2010 Annual Total (kg)[3]	2011 Annual Total (kg)[3]	2012 Annual Total (kg)[3]	2013 Annual Total (kg)[3]	2014 Annual Total (kg)[3]	2015 Annual Total (kg)[3]	2016 Annual Total (kg)[3]	2017 Annual Total (kg)[3]	% Change 2009 - 2017	% Change 2016 - 2017
Feed	*Sulfas*	113,658	109,983	105,400	90,972	90,723	103,243	98,831	77,217	21,871	-81%	-72%
	Tetracyclines[2]	4,594,714	4,921,071	4,848,946	5,085,178	5,699,364	5,811,961	6,033,388	5,109,033	2,819,727	-39%	-45%
	Other Drugs[4]	978,711	926,695	979,093	1,074,620	1,043,439	1,065,893	1,007,634	796,102	590,775	-40%	-26%
Water	*Aminoglycosides*	140,652	153,907	162,672	195,043	198,247	198,505	223,139	233,668	188,684	34%	-19%
	Lincosamides	25,033	41,186	66,510	72,187	88,709	100,057	90,086	57,085	63,959	155%	12%
	Penicillins	448,166	630,946	650,220	753,510	672,131	740,929	793,018	700,779	559,589	25%	-20%
	Sulfas	265,873	289,529	145,972	283,909	192,995	239,582	154,529	199,201	152,432	-43%	-23%
	Tetracyclines	574,408	582,660	710,403	782,959	719,529	712,026	762,411	663,602	625,568	9%	-6%
	Other Drugs[5]	12,916	17,529	21,909	26,233	27,637	49,822	49,374	64,780	65,179	405%	1%
Other Routes[6]	*Cephalosporins*[2]	20,145	24,588	26,611	27,654	28,337	31,722	32,254	31,010	29,369	46%	-5%
	Fluoroquinolones	*	*	*	*	15,099	17,220	20,063	18,502	22,904	**	24%
	Tetracyclines[2]	91,874	98,551	93,506	86,224	95,887	80,211	85,732	88,553	90,406	-2%	2%
	Other Drugs[2,7]	420,414	432,665	444,456	418,933	321,196	328,168	352,485	316,809	328,749	-22%	4%
	Total	***7,686,564***	***8,229,309***	***8,255,697***	***8,897,420***	***9,193,293***	***9,479,339***	***9,702,943***	***8,356,340***	***5,559,212***	***-28%***	***-33%***

[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 which 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), and Streptogramins.

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

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

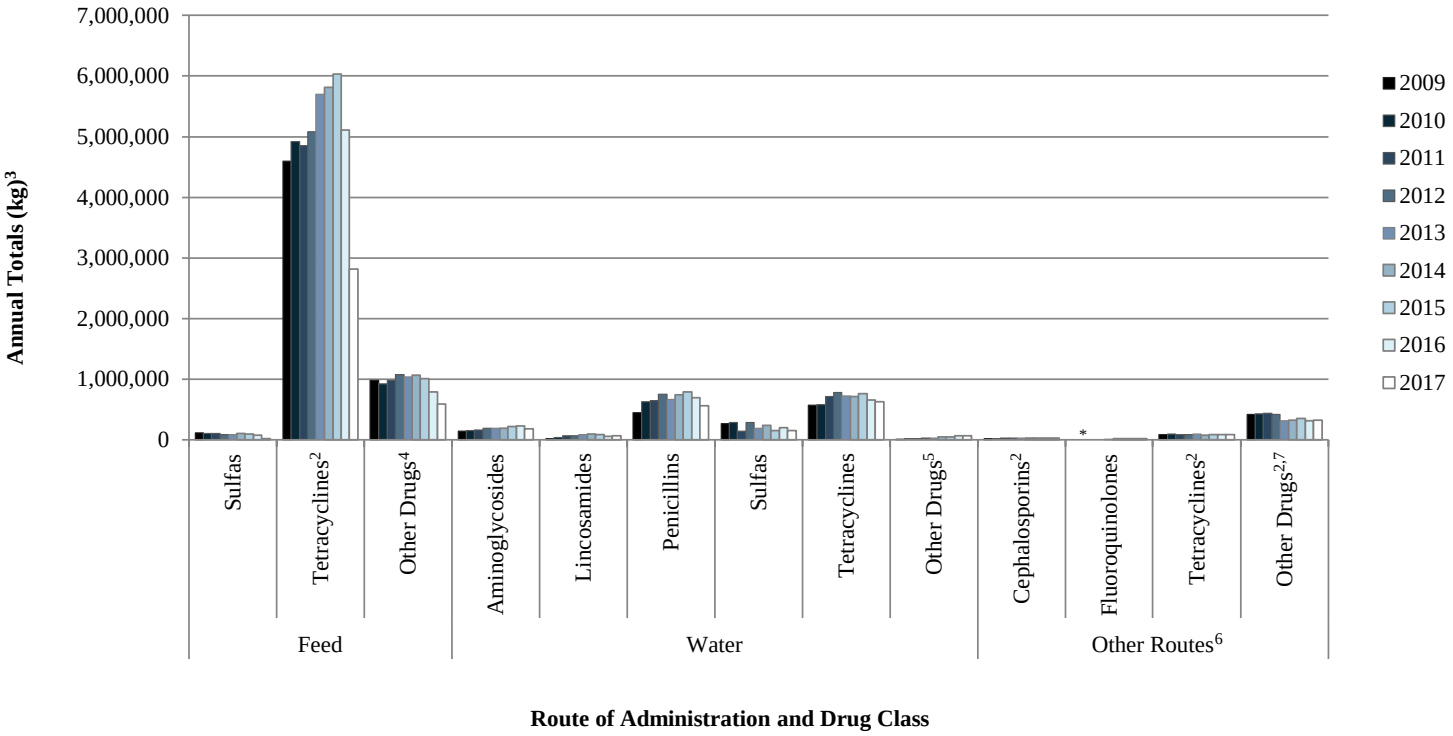
[**] Not reported because there were fewer than three distinct sponsors actively marketing products domestically in 2009 through 2012.

[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, Fluoroquinolones (excluding 2013 through 2017), Lincosamides, Macrolides, Penicillins, Polymyxins (excluding 2012 and 2013), and Sulfonamides.

Figure 9b

Medically important[1] antimicrobial drugs approved for use in food-producing animals[2]
Actively marketed 2009-2017
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 which 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), and Streptogramins.

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

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

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

[7] This category includes the following: Aminoglycosides, Amphenicols, Fluoroquinolones (excluding 2013 through 2017), Lincosamides, Macrolides, Penicillins, Polymyxins (excluding 2012 and 2013), and Sulfonamides.

IV. Data on antimicrobial drugs that are not medically important

Table 10a

Not medically important[1] antimicrobial drugs approved for use in food-producing animals[2]
Actively marketed in 2017
Domestic sales and distribution data
Reported by species-specific estimated sales

Species	Estimated* Annual Totals (kg)[3]	% Total
Cattle	3,139,331	58%
Swine	395,994	7%
Chicken	1,477,197	27%
Turkey	358,774	7%
Other[4]	2,860	<1%
Total	***5,374,156***	***100%***

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

[2] Includes antimicrobial drug applications which 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 10b

Not medically important[1] antimicrobial drugs approved for use in food-producing animals[2]
Actively marketed 2016-2017
Domestic sales and distribution data
Reported by species-specific estimated sales

Species	2016 Estimated Annual Totals (kg)[3]	2017 Estimated Annual Totals (kg)[3]	% Change 2016 - 2017
Cattle	3,164,626	3,139,331	-1%
Swine	425,568	395,994	-7%
Chicken	1,700,124	1,477,197	-13%
Turkey	379,478	358,774	-5%
Other[4]	0	2,860	*
Total	***5,669,796***	***5,374,156***	***-5%***

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

[2] Includes antimicrobial drug applications which 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).

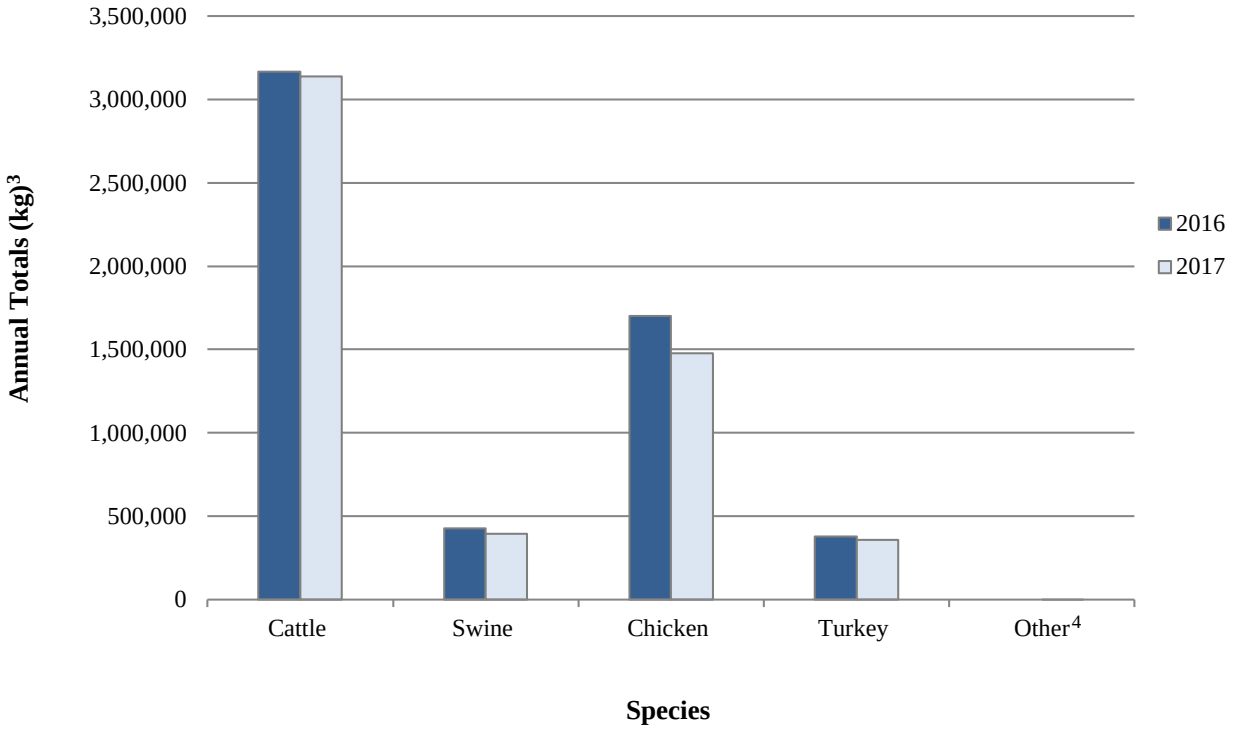
[3] kg = kilogram of active ingredient. Antimicrobial class includes drugs of different molecular weights, with some drugs labeled in different salt forms. Antimicrobials that are labeled in International Units (IU) (e.g., Penicillins) were converted to kg.

[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.

[*] Cannot divide by zero.

Figure 10b

Not medically important[1] antimicrobial drugs approved for use in food-producing animals[2]
Actively marketed in 2017
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] Includes antimicrobial drug applications which 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 11a

Not medically important[1] antimicrobial drugs approved for use in food-producing animals[2]
Actively marketed in 2017
Domestic sales and distribution data
Reported by route of administration

Route	Annual Totals (kg)[3]
All Routes[4]	5,374,156

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

[2] Includes antimicrobial drug applications which 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. Antimicrobials which 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.

[4] This category includes the following: Feed, Intramammary, and Water. In order to protect confidential business information, the routes of administration for the "not medically important" antimicrobial drugs are not separately presented.

Table 11b

Not medically important[1] antimicrobial drugs approved for use in food-producing animals[2]
Actively marketed 2009-2017
Domestic sales and distribution data
Reported by route of administration

Route	2009 Annual Totals (kg)[3]	2010 Annual Totals (kg)[3]	2011 Annual Totals (kg)[3]	2012 Annual Totals (kg)[3]	2013 Annual Totals (kg)[3]	2014 Annual Totals (kg)[3]	2015 Annual Totals (kg)[3]	2016 Annual Totals (kg)[3]	2017 Annual Totals (kg)[3]	% Change 2009 - 2017	% Change 2016 - 2017
All Routes[4]	4,900,893	5,057,788	5,313,340	5,725,327	5,591,752	5,882,221	5,874,997	5,669,796	5,374,156	10%	-5%

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

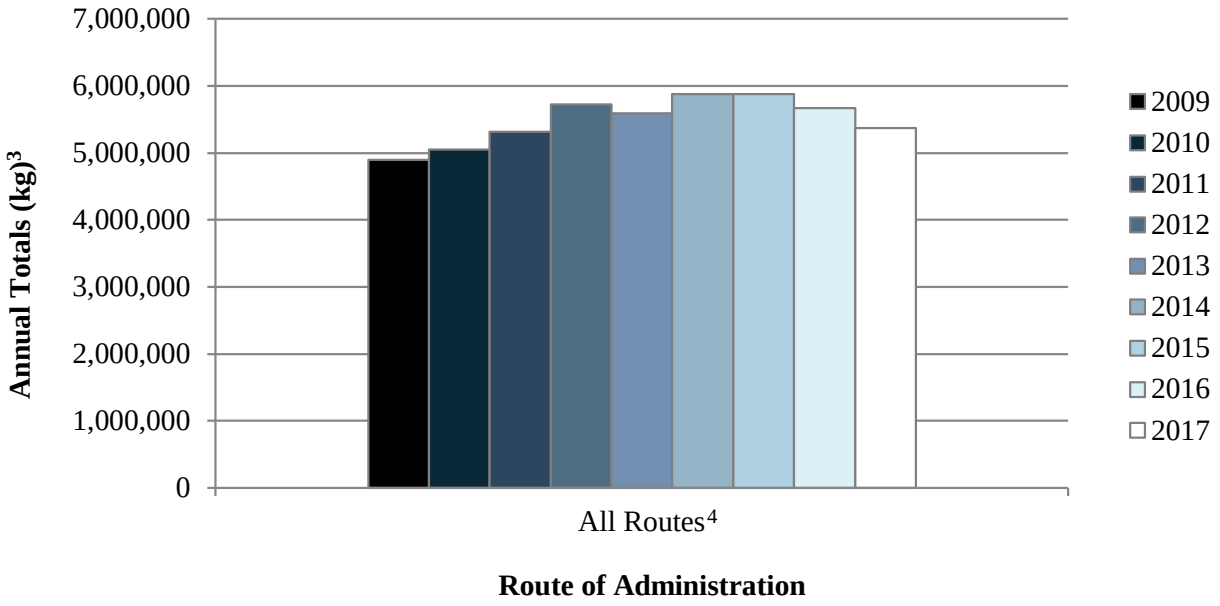
[2] Includes antimicrobial drug applications which are approved and labeled for use in both food-producing animals (e.g., cattle and swine) and nonfood-producing animals (e.g., dogs and horses).

[3] kg = kilogram of active ingredient. Antimicrobials which 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.

[4] This category includes the following: Feed, Intramammary, and Water. In order to protect confidential business information, the routes of administration for the Not Medically Important antimicrobial drugs are not separately presented.

Figure 11b

Not medically important[1] antimicrobial drugs approved for use in food-producing animals[2]
Actively marketed 2009-2017
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] Includes antimicrobial drug applications which 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. Antimicrobials which 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.

[4] This category includes the following: Feed, Intramammary, and Water. In order to protect confidential business information, the routes of administration for the Not Medically Important antimicrobial drugs are not separately presented.

Table 12a

Not medically important[1] antimicrobial drugs approved for use in food-producing animals[2]
Actively marketed in 2017
Domestic sales and distribution data
Reported by indications

Indications	Annual Totals (kg)[3]	% Total
Production Indications Only[4]	87,762	2%
Production[4]*/Therapeutic*[5] *Indications*	4,141,889	77%
Therapeutic Indications Only[5]	1,144,504	21%
Total	***5,374,156***	***100%***

[1] Not Medically Important refers to any antimicrobial class not listed in Appendix A of FDA's Guidance for Industry #152.
[2] Includes antimicrobial drug applications which 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] Production Indications (e.g., increased rate of weight gain or improved feed efficiency).
[5] Therapeutic Indications (e.g., treatment, control, or prevention of a specific disease).

Table 12b

Not medically important[1] antimicrobial drugs approved for use in food-producing animals[2]
Actively marketed 2009-2017
Domestic sales and distribution data
Reported by indications

Indications	2009 Annual Totals (kg)[3]	2010 Annual Totals (kg)[3]	2011 Annual Totals (kg)[3]	2012 Annual Totals (kg)[3]	2013 Annual Totals (kg)[3]	2014 Annual Totals (kg)[3]	2015 Annual Totals (kg)[3]	2016 Annual Totals (kg)[3]	2017 Annual Totals (kg)[3]	% Change 2009 - 2017	% Change 2016 - 2017
Production[4] or Production/Therapeutic[5] Indications[6]	3,562,501	3,622,315	3,790,628	3,972,057	3,900,298	4,259,148	4,329,598	4,350,075	4,229,651	19%	-3%
Therapeutic Indications Only[5]	1,338,391	1,435,473	1,522,712	1,753,270	1,691,454	1,623,073	1,545,399	1,319,721	1,144,504	-14%	-13%
Total	***4,900,893***	***5,057,788***	***5,313,340***	***5,725,327***	***5,591,752***	***5,882,221***	***5,874,997***	***5,669,796***	***5,374,156***	***10%***	***-5%***

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

2 Includes antimicrobial drug applications which 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.

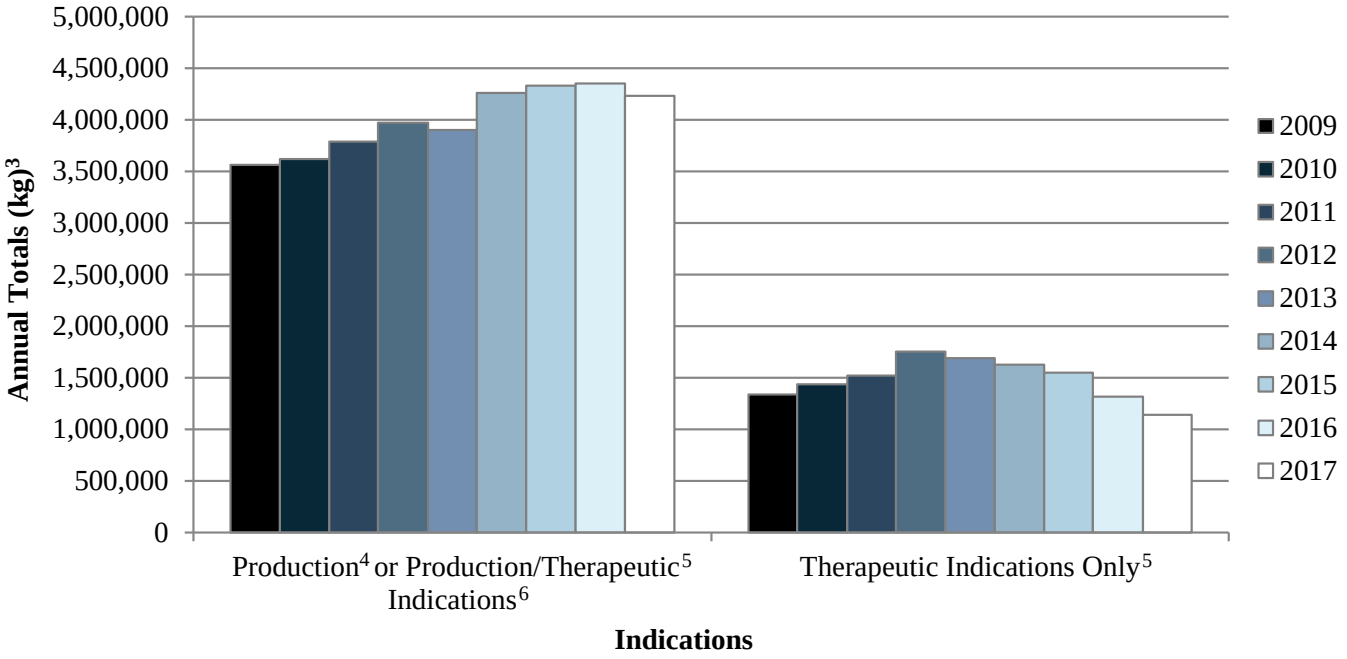
4 Production Indications (e.g., increased rate of weight gain or improved feed efficiency).

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

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

Figure 12b

Not medically important[1] antimicrobial drugs approved for use in food-producing animals[2]
Actively marketed 2009-2017
Domestic sales and distribution data
Reported by indications



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

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

[5] Therapeutic Indications (e.g., treatment, control, or prevention of a specific disease).

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

Table 13a

Not medically important[1] antimicrobial drugs approved for use in food-producing animals[2]
Actively marketed in 2017
Domestic sales and distribution data
Reported by dispensing status

Dispensing Status	Annual Totals (kg)[3]
All Dispensing Statuses[4]	5,374,156

[1] Not Medically Important refers to any antimicrobial class not listed in Appendix A of FDA's Guidance for Industry #152.
[2] Includes antimicrobial drug applications which 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. Antimicrobials which 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.
[4] The All Dispensing Statuses category includes the following: OTC, RX/OTC, and VFD.

Table 13b

Not medically important[1] antimicrobial drugs approved for use in food-producing animals[2]
Actively marketed 2009-2017
Domestic sales and distribution data
Reported by dispensing status

Dispensing Status	2009 Annual Totals (kg)[3]	2010 Annual Totals (kg)[3]	2011 Annual Totals (kg)[3]	2012 Annual Totals (kg)[3]	2013 Annual Totals (kg)[3]	2014 Annual Totals (kg)[3]	2015 Annual Totals (kg)[3]	2016 Annual Totals (kg)[3]	2017 Annual Totals (kg)[3]	% Change 2009 - 2017	% Change 2016 - 2017
All Dispensing Statuses[4]	4,900,893	5,057,788	5,313,340	5,725,327	5,591,752	5,882,221	5,874,997	5,669,796	5,374,156	10%	-5%

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

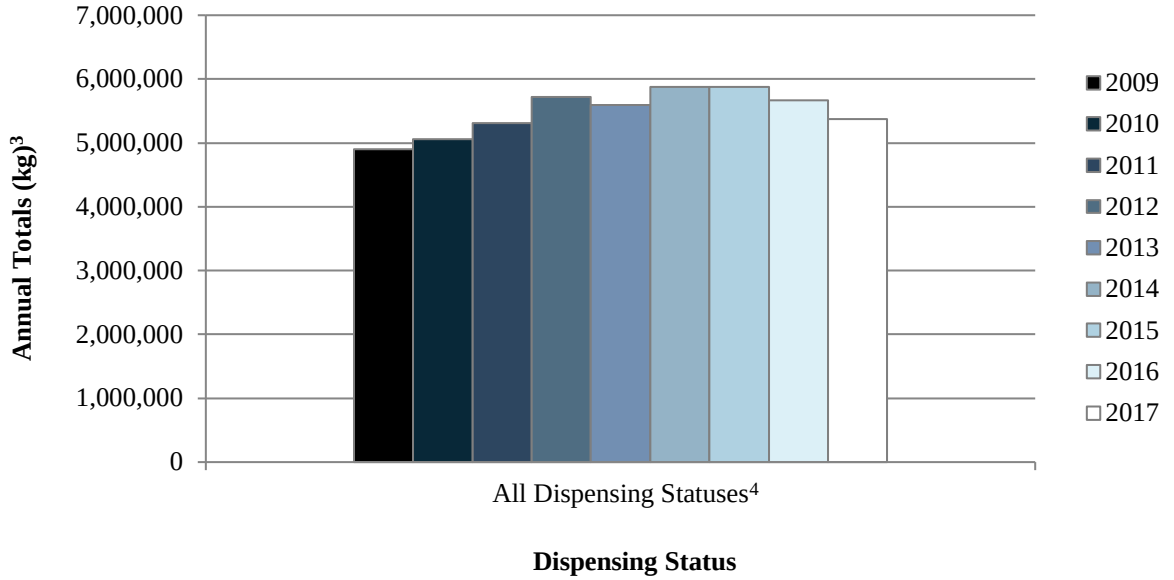
[2] Includes antimicrobial drug applications which are approved and labeled for use in both food-producing animals (e.g., cattle and swine) and nonfood-producing animals (e.g., dogs and horses).

[3] kg = kilogram of active ingredient. Antimicrobials which 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.

[4] The All Dispensing Statuses category includes the following: OTC, RX/OTC, and VFD.

Figure 13b

Not medically important[1] antimicrobial drugs approved for use in food-producing animals[2]
Actively marketed 2009-2017
Domestic sales and distribution data
Reported by dispensing status



[1] Includes antimicrobial drug applications which 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. Antimicrobials which 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] Not Medically Important refers to any antimicrobial class not listed in Appendix A of FDA's Guidance for Industry #152.

[4] The All Dispensing Statuses category includes the following: OTC, RX/OTC, and VFD.

References

- **FDA Webpage on Antimicrobial Resistance**
  - http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm092810.htm

- **FDA/CVM Webpage on Antimicrobial Resistance**
  - http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/default.htm

- **FDA/CVM Webpage on the National Antimicrobial Resistance Monitoring System (NARMS)**
  - http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/NationalAntimicrobialResistanceMonitoringSystem/default.htm

- **FDA/CVM Webpage on Judicious Use of Antimicrobials**
  - http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/JudiciousUseofAntimicrobials/default.htm

- **FDA/CDER Webpage on Antimicrobial Resistance**
  - http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm135344.htm

- **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"
  - http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm052519.pdf

- **FDA Guidance for Industry #209**
  - "The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals"
  - http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM216936.pdf

- **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"
  - http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM299624.pdf

- **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