U.S. FOOD & DRUG ADMINISTRATION

CENTER FOR VETERINARY MEDICINE

2016

SUMMARY REPORT

On

Antimicrobials Sold or Distributed for Use in Food-Producing Animals

December, 2017

TABLE OF CONTENTS

Multi-Year Trends of Sales and Distribution Information

Overview

Each year, every sponsor of an approved or conditionally approved application for a new animal drug 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 the 2016 calendar year 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. The species-specific estimates are new to this year's report and are the result of rulemaking implemented in 2016.

This 2016 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 2015 through 2016.

With the complete implementation of Guidance for Industry (GFI) #213 in January 2017, all affected products, antimicrobials used in feed and water, transitioned from OTC to either Rx or VFD marketing status and all production claims were removed. This 2016 Summary Report does not represent the effect of those January 2017 changes. Rather, next year's 2017 Summary Report will reflect the changes due to GFI #213 on drug sales and distribution.

Several trends observed from 2015 through 2016 include:

1. Domestic sales and distribution of antimicrobials approved for use in food-producing animals decreased by 10% from 2015 through 2016.
2. In 2016, it is estimated that 43% of the domestic sales and distribution of medically important antimicrobials was intended for use in cattle, 37% intended for use in swine, 9% intended for use in turkeys, 6% intended for use in chickens, and 4% intended for use in other species/unknown.
3. In 2016, domestic sales and distribution of medically important antimicrobials accounted for 60% of the domestic sales of all antimicrobials approved for use in food-producing animals. Tetracyclines accounted for 70% of these sales, penicillins for 10%, macrolides for 7%, sulfas for 4%, aminoglycosides for 4%, lincosamides for 2%, and cephalosporins and fluoroquinolones each for less than 1%.
4. In 2016, it is estimated that 80% of domestic sales and distribution of cephalosporins, 64% of sulfas, 51% of aminoglycocides, and 49% of tetracyclines was intended for use in cattle. It is estimated that 83% of domestic sales and distribution of lincosamides and 61% of macrolides was intended for use in swine. It is estimated that 63% of domestic sales and distribution of penicillins was intended for use in turkeys.
5. Domestic sales and distribution of medically important antimicrobials approved for use in food-producing animals decreased by 14% from 2015 through 2016, with decreases represented in all

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

individual drug classes.

- Tetracycline sales represent the largest volume of these domestic sales (5,866,588 kg in 2016), decreasing 15% from 2015 through 2016.
- Cephalosporin sales volume decreased by 4% from 2015 through 2016.
- Lincosamide sales volume showed the greatest percentage decrease in domestic sales (22%) from 2015 through 2016.

6. The percentage of 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 71% to 69% from 2015 through 2016.[2] This number does not represent sales attributable to products used solely for production indications because most of these products are also approved for therapeutic indications and FDA does not have indication-specific sales and distribution data.
7. The percentage of domestic sales and distribution of medically important antimicrobials approved for use in food-producing animals that are sold over-the-counter (OTC) decreased from 97% to 96% from 2015 through 2016.[3]

For more discussion of trends, see **Section VI.B. Multi-Year Trends (2009-2016)** below.

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

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[2] As part of the implementation of Guidance for Industry (GFI) #213, production indications (e.g., increased rate of weight gain or improved feed efficiency) of some of the medically important antimicrobial products affected by GFI #213 started to be removed from product labeling during 2016. Sales and distribution data for each product are reported to FDA broken out for each month of the calendar year; thus, the sales data in this summary report reflect the indication(s) on the labeling of each product as reported to FDA for any particular month. The implementation of GFI #213 was completed in January 2017; all remaining affected products removed production indications from their labeling at that time. The 2017 Summary Report will reflect the full removal of production indications from the labeling of all medically important antimicrobials affected by GFI #213.

[3] As part of the implementation of Guidance for Industry (GFI) #213, the dispensing status of some of the medically important antimicrobial products affected by GFI #213 started to change from OTC to either Rx or VFD during 2016. Sales and distribution data for each product are reported to FDA broken out for each month of the calendar year; thus, the sales data in this summary report reflect the dispensing status of each product as reported to FDA for any particular month. The implementation of GFI #213 was completed in January 2017; all remaining affected products transitioned from OTC to either Rx or VFD marketing status at that time. The 2017 Summary Report will reflect the full transition of all medically important antimicrobials affected by GFI #213 from OTC to either Rx or VFD.

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. 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.

II. 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 scenerios 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 2016 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.

III. 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" (e.g., Table 7).

IV. 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., in what species and 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 Section V.A. 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. Many of the applications are approved and labeled for use in multiple species, for multiple indications, and with multiple dosage regimens. In addition, some applications are approved for multiple

routes of administration, and as OTC and prescription drugs. 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. Regarding the collection and reporting of species-specific data, it is important to note that 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 (e.g., that collected under the USDA National Animal Health Monitoring System). Because of all these variations, assumptions cannot be made about actual product use.

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[4]) compared to the much larger number of animals in each of the many animal species (e.g., approx. 9 billion chickens slaughtered annually[5]).
- The differences in physical characteristics of humans compared to various animal species (e.g., physiology and weight– average adult human, 182 lb[6] vs adult cattle live weight, 1,363 lb[7]).
- 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.

V. Description of Tables and Figures

The information presented in the following tables is based on 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

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

after the March 31 deadline. Therefore, minor variations in tabular data may occur over time depending on when these summary data are generated.

A. Current Reporting Year Sales and Distribution Information

Table 1 – Actively Marketed Antimicrobial Drugs, Listed by Class

Figure 1a – Actively Marketed Antimicrobial Drugs, Reported by Number of Drug Applications

Figure 1b – Actively Marketed Antimicrobial Drugs, Reported by Number of Unique Sponsors

Table 1 provides a list of all antimicrobial active ingredients approved for use in food-producing animals, broken out by antimicrobial drug classes, that were actively marketed during the current reporting year. There are various active ingredients and drug classes that are approved for use in food-producing animals but for which products have not been marketed in any given year for a variety of reasons (some have not been marketed for decades). These non-marketed active ingredients and drug classes are not represented in this table or in the other tables in this summary report. For a listing of all FDA-approved animal drugs, regardless of their marketing status, see "Animal Drugs@FDA" (https://animaldrugsatfda.fda.gov/) or the in the "Green Book," (http://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/default.htm).

Table 1 also identifies those antimicrobial active ingredients and drug classes that are considered to be "medically important" in human medical therapy. The basis of these designations is provided in FDA Guidance for Industry (GFI) #213, which states that all antimicrobial drugs and their associated classes listed in Appendix A of the FDA's GFI #152 are considered "medically important." Hyperlinks to these documents can be found at the end of this document.

Conversely, for the purposes of this summary report, antimicrobial active ingredients and drug classes not listed in Appendix A of GFI #152 are considered to be "not medically important" in human medical therapy. Some of the active ingredients and drug classes that fall into this category are only used in veterinary medicine, e.g., ionophores, and are not generally associated with antimicrobial resistance issues.

Table 1 also identifies those active ingredients that are components of animal drug applications approved for use in both food-producing animals (e.g., cattle and swine) and nonfood-producing animals (e.g., dogs and horses). While FDA generally no longer approves single products for use in both categories of animals, a limited number of such products still remain on the market. The "medically important" active ingredients associated with applications approved for both food- and nonfood-producing species include ceftiofur, lincomycin, ampicillin, penicillin, polymyxin B, sulfamethazine, chlortetracycline, and oxytetracycline. Please note that product sales volume for these applications is very small compared to product sales volume for other applications with the same active ingredients that are approved for use solely in food-producing animals. The two other data compilations associated with Table 1, Figures 1a and 1b, provide additional summary data for classes of antimicrobial drugs approved for use in food-producing animals that were actively marketed in the current reporting year. Figure 1a provides the number of approved animal drug applications for products currently being marketed for each antimicrobial drug class listed in Table 1. The reader should note that some animal drug applications include more than one antimicrobial active ingredient. These applications are commonly referred to as "combination" applications. Some combination applications contain more than one antimicrobial

active ingredient, each of which is normally associated with a different antimicrobial drug class. Because all of the antimicrobial active ingredients included in a multiple-ingredient application are represented in Figure 1a, such applications will be represented more than once. It should also be noted that the number of animal drug applications represented for an antimicrobial active ingredient does not necessarily correlate with the volume of sales and distribution for those active ingredients.

Figure 1b provides the number of distinct sponsors of the approved animal drug applications for products that are currently marketed for each antimicrobial drug class listed in Table 1.

Click here for narrative observations regarding the current reporting year (2016): Actively marketed antimicrobial drug sponsors and applications

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Table 2a – Domestic/Export Sales and Antimicrobial Drug Class

Figure 2a – Domestic/Export Sales and Antimicrobial Drug Class

Table 2b – Domestic Sales: Medical Importance and Estimated Species

Figure 2b – Domestic Sales: Medical Importance and Estimated Species

Figure 2c – Percentages of Domestic Sales: Medical Importance and Estimated Species

Table 2a and Figure 2a provide total annual domestic and export sales and distribution data of antimicrobial active ingredients approved for use in food-producing animals, reported by antimicrobial drug class. Table 2b and Figure 2b provide domestic sales and distribution data of antimicrobial active ingredients approved for use in food-producing animals, reported by: (1) importance in human medical therapy [see Table 1 discussion on "medical importance"]; and (2) species-specific sales and distribution estimates. Figure 2c provides the species-specific estimates as a percentage of domestic sales and distribution.

Click here for narrative observations regarding the current reporting year (2016): Actively marketed antimicrobial drugs

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Table 3a – Domestic Sales: Medical Importance and Antimicrobial Drug Class

Figure 3a – Domestic Sales: Medical Importance and Antimicrobial Drug Class

Table 3b – Domestic Sales: Medical Importance, Antimicrobial Drug Class, and Estimated Species

Figure 3b – Domestic Sales: Medical Importance, Antimicrobial Drug Class, and Estimated Species

Figure 3c – Percentages of Domestic Sales: Medical Importance, Antimicrobial Drug Class, and Estimated Species

Table 3a and Figure 3a provide total annual domestic sales and distribution data of antimicrobial drugs approved for use in food-producing animals categorized by: (1) importance in human medical therapy [see Table 1 discussion on "medical importance"]; and (2) antimicrobial drug class. Table 3b and Figure 3b provide domestic sales and distribution data of antimicrobial active ingredients approved for use in food-producing animals, reported by: (1) importance in human medical therapy; (2) antimicrobial drug class; and (3) species-specific sales and distribution estimates. Figure 3c provides the species-specific estimates as a percentage of domestic sales and distribution of each antimicrobial class.

Click here for narrative observations regarding the current reporting year (2016): Domestic Sales - Medically important antimicrobial drugs and drug class

Click here for narrative observations regarding the current reporting year (2016): Domestic Sales - Antimicrobial drugs not medically important and drug class

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Table 4 – Domestic Sales: Medical Importance and Route of Administration

Figure 4 – Domestic Sales: Medical Importance and Route of Administration

Table 4 and Figure 4 provide data on the total annual domestic sales and distribution of antimicrobial drugs approved for use in food-producing animals categorized by: (1) importance in human medical therapy [see Table 1 discussion on "medical importance"]; and (2) route of administration.

Click here for narrative observations regarding the current reporting year (2016): Domestic Sales - Medically important antimicrobial drugs and route of administration

Click here for narrative observations regarding the current reporting year (2016): Domestic Sales - Antimicrobial drugs not medically important and route of administration

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Table 5 – Domestic Sales: Medical Importance and Indications

Figure 5 – Domestic Sales: Medical Importance and Indications

Table 5 and Figure 5 provide total annual domestic sales and distribution data of antimicrobial drugs approved for use in food-producing animals categorized by: (1) importance in human

medical therapy [see Table 1 discussion on "medical importance"]; and (2) approved label indications. Indications are either therapeutic (e.g., treatment, prevention, or control of disease) or for production (e.g., increased weight gain or improved feed efficiency). Please note that most products approved for production indications are also approved for therapeutic indications.

Click here for narrative observations regarding the current reporting year (2016): Domestic Sales - Medically important antimicrobial drugs and indications

Click here for narrative observations regarding the current reporting year (2016): Domestic Sales - Antimicrobial drugs not medically important and indications

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Table 6 – Domestic Sales: Medical Importance and Dispensing Status

Figure 6 – Domestic Sales: Medical Importance and Dispensing Status

Table 6 and Figure 6 provide total annual domestic sales and distribution data of antimicrobial drugs approved for use in food-producing animals categorized by: (1) importance in human medical therapy [see Table 1 discussion on "medical importance"]; and (2) dispensing status (i.e., prescription, OTC, or VFD). A prescription product requires a valid prescription order from a licensed veterinarian to be dispensed. An OTC product can be dispensed to anyone without an order from a veterinarian. Under 21 CFR 558.3(a)(6), a VFD drug is a drug provided through feed that requires a written statement from a veterinarian in the context of a valid veterinarian-client-patient relationship in order to be dispensed. Certain applications are approved with both a prescription and OTC dispensing status (Rx/OTC).

Click here for narrative observations regarding the current reporting year (2016): Domestic Sales - Medically important antimicrobial drugs and dispensing status

Click here for narrative observations regarding the current reporting year (2016): Domestic Sales - Antimicrobial drugs not medically important and dispensing status

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Table 7 – Domestic Sales: Medical Importance, Route of Administration, and Drug Class

Figure 7 – Domestic Sales: Medical Importance, Route of Administration, and Drug Class

Table 7 and Figure 7 provide total annual domestic sales and distribution data of antimicrobial drugs approved for use in food-producing animals categorized by: (1) importance in human medical therapy [see Table 1 discussion on "medical importance"]; (2) route of administration; and (3) antimicrobial drug class. In effect, Table 7 and Figure 7 provide another level of stratification (i.e., antimicrobial drug class) than provided in Table 4 and Figure 4. Given the requirement in section 512(l)(3) of the Act [21 U.S.C. 360b(l)(3)] for FDA to protect confidential business information, this additional stratification by antimicrobial drug class necessitates that the

number of categories reported out for route of administration is fewer compared to those reported out in Table 4.

Click here for narrative observations regarding the current reporting year (2016): Domestic Sales - Medically important antimicrobial drugs by route of administration and drug class

Click here for narrative observations regarding the current reporting year (2016): Domestic Sales - Antimicrobial drugs not medically important by route of administration and drug class

B. Multi-Year Trends of Sales and Distribution Information

The purpose of the multi-year trend information is to demonstrate patterns or trends of the sales and distribution of antimicrobial drugs approved for use in food-producing animals over time. It should be noted that from year to year, various categories may expand or combine as the number of sponsors in any given category go above or below three, the number considered critical for protecting confidential business information.

Figure 8a – Domestic Sales: Actively Marketed Antimicrobial Drugs, Reported by Number of Drug Applications

Figure 8b – Domestic Sales: Actively Marketed Antimicrobial Drugs, Reported by Number of Unique Sponsors

These figures provide information regarding domestic sales and distribution of antimicrobial drugs approved for use in food-producing animals for multiple years in the same manner as described in Figures 1a and 1b. Figure 8a provides the number of approved animal drug applications for products marketed in each reported year for every antimicrobial drug class listed in Table 1 of that year's Summary Report. The reader should note that some animal drug applications include more than one active ingredient. These applications are commonly referred to as "combination" applications. Some combination applications contain more than one antimicrobial active ingredient, each of which is normally associated with a different antimicrobial drug class. Because all of the antimicrobial active ingredients included in a multiple-ingredient application are represented in Figure 8a, such applications will be represented more than once. It should also be noted that the number of animal drug applications represented for an antimicrobial active ingredient does not necessarily correlate with the volume of sales and distribution for those active ingredients.

Figure 8b provides the number of distinct sponsors of the approved animal drug applications for products marketed in each reported year for every antimicrobial drug class listed in Table 1 of that year's Summary Report.

Click here for narrative observations regarding multi-year trends (2009-2016): Domestic Sales - Actively marketed antimicrobial drug sponsors and applications

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Table 9 – Domestic/Export Sales and Antimicrobial Drug Class

Figure 9 – Domestic/Export Sales and Antimicrobial Drug Class

This table and figure provide total annual domestic and export sales and distribution data of antimicrobial drugs approved for use in food-producing animals for multiple years in the same manner as described in Table 2 and Figure 2 (i.e., categorized by antimicrobial drug class).

Click here for narrative observations regarding multi-year trends (2009-2016): Domestic Sales - Actively marketed antimicrobial drugs

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Table 10 – Domestic Sales: Medical Importance and Antimicrobial Drug Class

Figure 10 – Domestic Sales: Medical Importance and Antimicrobial Drug Class

This table and figure provide total annual domestic sales and distribution data of antimicrobial drugs approved for use in food-producing animals for multiple years in the same manner as described in Table 3 and Figure 3 (i.e., categorized by: (1) importance in human medical therapy [see Table 1 discussion on "medical importance"]; and (2) antimicrobial drug class).

Click here for narrative observations regarding multi-year trends (2009-2016): Medically important antimicrobial drugs and drug class

Click here for narrative observations regarding multi-year trends (2009-2016): Antimicrobial drugs not medically important and drug class

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Table 11a – Domestic Sales: Medical Importance and Route of Administration

Figure 11a – Domestic Sales: Medical Importance and Route of Administration

Table 11b – Percentages of Domestic Sales: Medical Importance and Route of Administration

Figure 11b – Percentages of Domestic Sales: Medical Importance and Route of Administration

These tables and figures provide total annual domestic sales and distribution data of antimicrobial drugs approved for use in food-producing animals for multiple years in the same manner as described in Table 4 and Figure 4 (i.e., categorized by: (1) importance in human medical therapy [see Table 1 discussion on "medical importance"]; and (2) route of administration). They also provide data on the relative percentage of domestic sales and distribution data of medically important antimicrobial drugs approved for use in food-producing animals for multiple years broken out by route of administration.

Click here for narrative observations regarding multi-year trends (2009-2016): Domestic Sales - Medically important antimicrobials and route of administration

Click here for narrative observations regarding multi-year trends (2009-2016): Domestic Sales - Antimicrobials not medically important and route of administration

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Table 12a – Domestic Sales: Medical Importance and Indications

Figure 12a – Domestic Sales: Medical Importance and Indications

Table 12b – Percentages of Domestic Sales: Medical Importance and Indications

Figure 12b – Percentages of Domestic Sales: Medical Importance and Indications

These tables and figures provide total annual domestic sales and distribution data of antimicrobial drugs approved for use in food-producing animals for multiple years in the same manner as described in Table 5 and Figure 5 (i.e., categorized by: (1) importance in human medical therapy [see Table 1 discussion on "medical importance"]; and (2) approved label indications). They also provide data on the relative percentage of domestic sales and distribution data of medically important antimicrobial drugs approved for use in food-producing animals for multiple years broken out by approved label indications. Indications are either therapeutic (e.g., treatment, prevention, or control of disease) or for production (e.g., increased weight gain or improved feed efficiency). Please note that most products approved for production indications are also approved for therapeutic indications.

Click here for narrative observations regarding multi-year trends (2009-2016): Domestic Sales - Medically important antimicrobials and indications

Click here for narrative observations regarding multi-year trends (2009-2016): Domestic Sales - Antimicrobials not medically important and indications

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Table 13a – Domestic Sales: Medical Importance and Dispensing Status

Figure 13a – Domestic Sales: Medical Importance and Dispensing Status

Table 13b – Percentages of Domestic Sales: Medical Importance and Dispensing Status

Figure 13b – Percentages of Domestic Sales: Medical Importance and Dispensing Status

These tables and figures provide total annual domestic sales and distribution data of antimicrobial drugs approved for use in food-producing animals for multiple years in the same manner as described in Table 6 and Figure 6 (i.e., categorized by: (1) importance in human medical therapy [see Table 1 discussion on "medical importance"]; and (2) dispensing status (i.e., prescription, OTC, or VFD)). They also provide data on the relative percentage of domestic sales and distribution data of medically important antimicrobial drugs approved for use in food-producing

animals for multiple years broken out by dispensing status. A prescription product requires a valid prescription order from a licensed veterinarian to be dispensed. An OTC product can be dispensed to anyone without an order from a veterinarian. Under 21 CFR 558.3(a)(6), a VFD drug is a drug provided through feed that requires a written statement from a veterinarian in the context of a valid veterinarian-client-patient relationship in order to be dispensed. Certain applications are approved with both a prescription and OTC dispensing status (Rx/OTC).

Click here for narrative observations regarding multi-year trends (2009-2016): Domestic Sales - Medically important antimicrobials and dispensing status

Click here for narrative observations regarding multi-year trends (2009-2016): Domestic Sales - Antimicrobials not medically important and dispensing status

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Table 14 – Domestic Sales: Medical Importance, Route of Administration, and Drug Class

Figure 14 – Domestic Sales: Medical Importance, Route of Administration, and Drug Class

This table and figure provide total annual domestic sales and distribution data of antimicrobial drugs approved for use in food-producing animals for multiple years in the same manner as described in Table 7 and Figure 7 (i.e., categorized by: (1) importance in human medical therapy [see Table 1 discussion on "medical importance"]; (2) route of administration; and (3) antimicrobial drug class).

Click here for narrative observations regarding multi-year trends (2009-2016): Domestic Sales - Medically important antimicrobials by route of administration and drug class

Click here for narrative observations regarding multi-year trends (2009-2016): Domestic Sales - Antimicrobials not medically important by route of administration and drug class

VI. Sales and Distribution Observations

A. Current Reporting Year (2016)

In 2016, there were 21 sponsors of 153 actively marketed new animal drug applications for antimicrobials approved for use in food-producing animals (Table 1, Figure 1a, and Figure 1b).

In 2016, sales and distribution (domestic and export) of antimicrobials approved for use in food-producing animals was approximately 14 million kilograms. Domestic sales and distribution of antimicrobials approved for use in food-producing animals was approximately 13.98 million kilograms (approximately 100%), and export sales and distribution was approximately 7 thousand kilograms (0.05%) (Table 2a and Figure 2a). Tetracyclines accounted for 42% and ionophores for 33% of domestic sales.

1. Domestic sales and distribution of antimicrobials not medically important

In 2016, domestic sales and distribution of antimicrobials that are not medically important (NMI) accounted for 40% of the domestic sales of all antimicrobials approved for use in food-producing animals; 82% of these were ionophores. Because of confidentiality constraints, sales and distribution data for other drug classes of NMI antimicrobials approved for use in food-producing animals cannot be further reported (Table 3a and Figure 3a). Of the domestic sales and distribution of antimicrobials that are not medically important, it is estimated that 55% of sales were intended for use in cattle, 30% intended for use in chickens, 8% intended for use in swine, 7% intended for use in turkeys, and 0% intended for use in other species/unknown (Table 2b and Figure 2c). Because of confidentiality constraints, sales and distribution of ionophores and other NMI drug classes cannot be further reported by species-specific sales estimates (Table 3b and Figure 3c).

Because of confidentiality constraints, sales and distribution data for NMI antimicrobials approved for use in food-producing animals cannot be further reported by route of administration (Table 4 and Figure 4).

In 2016, domestic sales and distribution of NMI antimicrobials that are approved for use in food-producing animals and are labeled solely for production indications accounted for 2% of the domestic sales of all NMI antimicrobials approved for use in food-producing animals. In 2016, domestic sales and distribution of NMI antimicrobials that are approved for use in food-producing animals and are labeled for both production and therapeutic indications accounted for 75% of the domestic sales of all NMI antimicrobials approved for use in food-producing animals. Domestic sales and distribution of NMI antimicrobials that are approved for use in food-producing animals and labeled solely for therapeutic indications accounted for 23% of domestic sales of all NMI antimicrobials approved for use in food-producing animals (Table 5 and Figure 5).

Because of confidentiality constraints, sales and distribution data for NMI antimicrobials approved for use in food-producing animals cannot be broken out by dispensing status (Table 6 and Figure 6).

Because of confidentiality constraints, sales and distribution data for NMI antimicrobials approved for use in food-producing animals cannot be broken out by route of administration and drug class (Table 7 and Figure 7).

2. Domestic sales and distribution of medically important antimicrobials

In 2016, domestic sales and distribution of medically important antimicrobials accounted for 60% of the domestic sales of all antimicrobials approved for use in food-producing animals. Of these sales, tetracyclines accounted for 70%, penicillins for 10%, macrolides for 7%, sulfonamides (sulfas) for 4%, aminoglycosides for 4%, lincosamides for 2%, fluoroquinolones for less than 1%, and cephalosporins for less than 1%. Because of confidentiality constraints, sales and distribution data for other drug classes of medically important antimicrobials approved for use in food-producing animals cannot be further reported (Table 3a and Figure 3a). Of the domestic sales and distribution of antimicrobials that are medically important, it is estimated that 43% of the domestic sales and distribution of medically important antimicrobials was intended for use in cattle, 37%

intended for use in swine, 9% intended for use in turkeys, 6% intended for use in chickens, and 4% intended for use in other species/unknown. (Table 2b and Figure 2c).

In 2016, it is estimated that 51% of the domestic sales and distribution of aminoglycosides were intended for use in cattle, 21% intended for use in swine, 8% intended for use in chickens, and 7% intended for use in turkeys. It is estimated that 14% of the domestic sales and distribution of aminoglycosides were intended for use in other species/unknown.

It is estimated that 80% of the domestic sales and distribution of cephalosporins were intended for use in cattle. Swine, chickens, and other species/unknown accounted for the remainder of species-specific estimates of domestic sales and distribution of cephalosporin products.

Because of confidentiality constraints, the domestic sales and distribution of fluoroquinolones cannot be further reported.

It is estimated that 83% of the domestic sales and distribution of lincosamides were sold intended for use in swine, and 6% intended for use in chickens. Cattle and other species/unknown accounted for the remainder of the species-specific estimates of domestic sales and distribution of lincosamides.

It is estimated that 61% of the domestic sales and distribution of macrolides were sold intended for use in swine, 35% intended for use in cattle, and 4% intended for use in chickens. It is estimated that less than 1% of the domestic sales and distribution of macrolides were sold intended for use in turkeys and in other species/unknown.

It is estimated that 63% of the domestic sales and distribution of penicillins were sold intended for use in turkeys, 12% intended for use in cattle, and 2% intended for use in swine. It is estimated that 23% of the domestic sales and distribution of penicillins were sold intended for use in other species/unknown.

It is estimated that 64% of the domestic sales and distribution of sulfas were sold intended for use in cattle, 11% intended for use in swine, 11% intended for use in turkeys, and 6% intended for use in chickens. It is estimated that 9% of the domestic sales and distribution of sulfas were sold intended for use in other species/unknown.

It is estimated that 49% of the domestic sales and distribution of tetracyclines were sold intended for use in cattle, 43% intended for use in swine, 5% intended for use in chickens, and 3% intended for use in turkeys. It is estimated that 1% of the domestic sales and distribution of tetracyclines were for sold intended for use in other species/unknown. (Table 3b and Figure 3c).

In 2016, domestic sales and distribution of medically important antimicrobials approved for use in food-producing animals administered in feed accounted for 72% of the domestic sales of all medically important antimicrobials for use in food-producing animals, while products administered by water accounted for 23%. Domestic sales and distribution of products administered by means of injection, intramammary, oral, and topical accounted for approximately 5% of the domestic sales of all medically important antimicrobials for use in food-producing animals (Table 4 and Figure 4).

In 2016, domestic sales and distribution of medically important antimicrobials that are approved for use in food-producing animals and are labeled for both production and therapeutic indications accounted for 69% of the domestic sales of all medically important antimicrobials approved for use in food-producing animals. In 2016, domestic sales and distribution of medically important antimicrobials that are approved for use in food-producing animals and are labeled solely for therapeutic indications accounted for 31% of the domestic sales of all medically important antimicrobials approved for use in food-producing animals (Table 5 and Figure 5).

In 2016, domestic sales and distribution of medically important antimicrobials approved for use in food-producing animals labeled with solely an OTC dispensing status accounted for 96% of the domestic sales of all medically important antimicrobials for use in food-producing animals. In 2016, domestic sales and distribution of medically important antimicrobials approved for use in food-producing animals labeled with an Rx, Rx/OTC, or VFD dispensing status accounted for approximately 4% of the domestic sales of all medically important antimicrobials for use in food-producing animals (Table 6 and Figure 6).

In 2016, tetracyclines administered by feed accounted for 61% of domestic sales and distribution of medically important antimicrobials approved for use in food-producing animals, sulfas for 1%, and all other medically important antimicrobials for 10%. In 2016, tetracyclines administered by water accounted for 8% of domestic sales and distribution of medically important antimicrobials approved for use in food-producing animals, penicillins for 8%, sulfas for 2%, aminoglycosides for 3%, lincosamides for 1%, and macrolides for 1%. Because of confidentiality constraints, FDA cannot provide sales and distribution data separately for medically important antimicrobial drug products broken out by other routes of administration (Table 7 and Figure 7).

B. Multi-Year Trends (2009-2016)

This 2016 summary report includes multiple years of domestic sales and distribution data of actively marketed antimicrobial drugs, as well as observations on the changes in the sales and distribution of the subject drugs for the period from 2009 through 2016, and from 2015 through 2016.

From 2009 through 2016, the number of animal drug sponsors of actively marketed new animal drug applications for antimicrobials approved for use in food-producing animals declined from 25 to 21. The number of actively marketed new animal drug applications for antimicrobials approved for use in food-producing animals declined from 157 to 153 (Figure 8a and Figure 8b).

From 2009 through 2016, sales and distribution (domestic and export) of antimicrobials approved for use in food-producing animals increased by 9%, but decreased by 10% from 2015 through 2016. From 2009 through 2016, domestic sales and distribution of antimicrobials approved for use in food-producing animals increased by 11%, but decreased by 10% from 2015 through 2016 (Table 9 and Figure 9). From 2009 through 2016, export sales and distribution of antimicrobials approved for use in food-producing animals decreased by 97%, and decreased by 67% from 2015 through 2016; however, it should be noted that export sales are a small fraction (approximately 0.05% for 2016) of the total sales of such

antimicrobials (Table 9 and Figure 9). Because of confidentiality constraints, export sales and distribution data for antimicrobials approved for use in food-producing animals cannot be further reported.

1. Domestic sales and distribution of antimicrobials not medically important

From 2009 through 2016, domestic sales and distribution of antimicrobials approved for use in food-producing animals that are not medically important (NMI) increased by 15%, but decreased by 4% from 2015 through 2016. The increase of 15% from 2009 through 2016 reflects a 23% increase in sales and distribution of ionophores. Because of confidentiality constraints, FDA cannot provide sales and distribution data separately for NMI antimicrobial drug products broken out by other drug classes (Table 10 and Figure 10).

Because of confidentiality constraints, sales and distribution data for NMI antimicrobials approved for use in food-producing animals cannot be further reported by route of administration (Table 11a and Figure 11a).

Because of confidentiality constraints, FDA cannot provide sales and distribution data for products labeled solely for production indications; therefore, products labeled for either production indications only or for both production and therapeutic indications are combined into a single category. From 2009 through 2016, the domestic sales and distribution of NMI antimicrobials that are approved for use in food-producing animals and are labeled solely for production indications or for both production and therapeutic indications increased by 21%, but decreased by 1% from 2015 through 2016. From 2009 through 2016, the domestic sales and distribution of NMI antimicrobials that are approved for use in food-producing animals and are labeled solely for therapeutic indications decreased by 1%, and decreased by 15% from 2015 through 2016 (Table 12a and Figure 12a).

Because of confidentiality constraints, sales and distribution data for NMI antimicrobials approved for use in food-producing animals cannot be further reported by dispensing status (Table 13a and Figure 13a).

Because of confidentiality constraints, sales and distribution data for NMI antimicrobials approved for use in food-producing animals cannot be broken out by route of administration and drug class (Table 14 and Figure 14).

2. Domestic sales and distribution of medically important antimicrobials

From 2009 through 2016, domestic sales and distribution of medically important antimicrobials approved for use in food-producing animals increased by 9%, but decreased by 14% from 2015 through 2016 (Table 10 and Figure 10). From 2009 through 2016, the domestic sales and distribution of medically important antimicrobials administered by water increased from 19% to 23% of the domestic sales of all medically important antimicrobials approved for use in food-producing animals, while the percentage of domestic sales of products administered by feed decreased from 74% to 72% (Table 11b and Figure 11b). Also during this same period, domestic sales of medically important antimicrobials labeled solely for therapeutic indications increased

from 28% to 31% of the domestic sales of all medically important antimicrobials approved for use in food-producing animals (Table 12b and Figure 12b).

Domestic sales and distribution of medically important antimicrobials by route of administration and drug class[8]

From 2009 through 2016, domestic sales and distribution of tetracycline products approved for use in food-producing animals increased by 12%, but decreased by 15% from 2015 through 2016 (Table 10 and Figure 10). The increase of 12% from 2009 through 2016 reflects a 11% increase in sales and distribution of tetracyclines administered by feed, a 16% increase for tetracyclines administered by water, and a 4% decrease for tetracyclines administered by other routes (Table 14 and Figure 14). During the same period, the number of actively marketed tetracycline products for use in food-producing animals decreased from 41 to 38 (Figure 8a), and the number of unique sponsors of these products decreased from 13 to 9 (Figure 8b).

From 2009 through 2016, domestic sales and distribution of penicillin products approved for use in food-producing animals increased by 22%, but decreased by 10% from 2015 through 2016 (Table 10 and Figure 10). The increase of 22% from 2009 through 2016 reflects a 56% increase in sales and distribution of penicillins administered by water (Table 14 and Figure 14). Changes in sales and distribution of penicillin products administered by other routes cannot be reported because of confidentiality constraints. During the same period, the number of actively marketed penicillin products for use in food-producing animals decreased from 23 to 21 (Figure 8a), and the number of unique drug sponsors of these products decreased from 11 to 10 (Figure 8b).

From 2009 through 2016, domestic sales and distribution of macrolide products approved for use in food-producing animals decreased by 1%, and decreased by 12% from 2015 through 2016 (Table 10 and Figure 10). The overall decrease in sales and distribution of macrolides of 1% from 2009 through 2016 cannot be further reported by routes of administration because of confidentiality constraints (Table 14 and Figure 14). During the same period, the number of actively marketed macrolide products for use in food-producing animals increased from 10 to 18 (Figure 8a), and the number of unique drug sponsors of these products increased from 5 to 7 (Figure 8b).

From 2009 through 2016, domestic sales and distribution of sulfa products approved for use in food-producing animals decreased by 27%, and decreased by 3% from 2015 through 2016 (Table 10 and Figure 10). The decrease of 27% from 2009 through 2016 reflects a 32% decrease in sales and distribution of sulfas administered by feed, and a 25% decrease by water (Table 14 and Figure 14). During the same period, the number of actively marketed sulfa products for use in food-producing animals decreased from 27 to 19 (Figure 8a), and the number of unique drug sponsors of these products decreased from 11 to 9 (Figure 8b).

From 2009 through 2016, domestic sales and distribution of aminoglycoside products

[8]All classes of antimicrobials discussed in this section include 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).

approved for use in food-producing animals increased by 43%, but decreased by 7% from 2015 through 2016 (Table 10 and Figure 10). The increase of 43% from 2009 through 2016 reflects a 66% increase in sales and distribution of aminoglycosides administered by water (Table 14 and Figure 14). Changes in sales and distribution of aminoglycoside products administered by other routes cannot be reported because of confidentiality constraints. During the same period, the number of actively marketed aminoglycoside products for use in food-producing animals decreased from 22 to 18 (Figure 8a), and the number of unique drug sponsors of these products decreased from 12 to 11 (Figure 8b).

From 2009 through 2016, domestic sales and distribution of lincosamide products approved for use in food-producing animals increased by 53%, and decreased by 22% from 2015 through 2016 (Table 9 and Figure 9). The increase of 53% from 2009 through 2016 reflects a 128% increase in sales and distribution of lincosamides administered by water (Table 14 and Figure 14). Changes in sales and distribution of lincosamide products administered by other routes cannot be reported because of confidentiality constraints. During the same period, the number of actively marketed lincosamide products for use in food-producing animals decreased from 15 to 13 (Figure 8a), and the number of unique drug sponsors of these products remained unchanged at 7 (Figure 8b).

From 2009 through 2016, domestic sales and distribution of cephalosporin products approved for use in food-producing animals increased by 54%, and decreased by 4% from 2015 through 2016 (Table 10 and Figure 10). The overall increase in sales and distribution of cephalosporins of 54% from 2009 through 2016, and decrease of 4% from 2015 through 2016, cannot be further reported by routes of administration because of confidentiality constraints (Table 14 and Figure 14). From 2009 through 2016, the number of actively marketed cephalosporin products for use in food-producing animals decreased from 10 to 9 (Figure 8a). During the same period, the number of unique drug sponsors remained the same at 3 (Figure 8b).

Domestic sales and distribution of medically important antimicrobials by route of administration

Because of confidentiality constraints, FDA cannot provide sales and distribution data separately for products administered orally and topically; therefore, products approved for oral or topical means of administration have been combined into a single category. From 2009 through 2016, the percentage of domestic sales and distribution of medically important antimicrobials approved for use in food-producing animals administered by water increased from 19% to 23%, while products administered by feed decreased from 74% to 72%. During the same period the percentage of domestic sales and distribution of products administered by means of injection decreased from 5% to 4%, those administered orally or topically decreased from 2% to 1%, and those administered by means of intramammary remained unchanged at less than 1% (Table 11b and Figure 11b).

Domestic sales and distribution of medically important antimicrobials by indication

Because of confidentiality constraints, FDA cannot provide sales and distribution data for products labeled solely for production indications; therefore, products labeled for either production indications only or for both production and therapeutic indications are

combined into a single category. From 2009 through 2016, the percentage of domestic sales and distribution of medically important antimicrobials approved for use in food-producing animals labeled solely for production indications or for both production and therapeutic indication decreased from 72% to 69%. During the same period, the percentage of domestic sales and distribution of medically important antimicrobials approved for use in food-producing animals labeled solely for therapeutic indications increased from 28% to 31% (Table 12b and Figure 12b).

Please note that, as part of the implementation of Guidance for Industry (GFI) #213, production indications of some of the medically important antimicrobial products affected by GFI #213 started to be removed from product labeling during 2016. Sales and distribution data for each product are reported to FDA broken out for each month of the calendar year; thus, the sales data in this summary report reflect the indication(s) on the labeling of each product as reported to FDA for any particular month. The implementation of GFI #213 was completed in January 2017; all remaining affected products removed production indications from their labeling at that time. The 2017 Summary Report will reflect the full removal of production indications from the labeling of all medically important antimicrobials affected by GFI #213.

Domestic sales and distribution of medically important antimicrobials by dispensing status

Because of confidentiality constraints, FDA cannot provide sales and distribution data for products labeled with a VFD dispensing status; therefore, products labeled with either a VFD dispensing status or Rx dispensing status are combined into a single category. The summary report does provide sales and distribution data for products approved with an OTC dispensing status. From 2009 through 2016, the percentage of domestic sales and distribution of medically important antimicrobials approved for use in food-producing animals labeled solely with an OTC dispensing status decreased from 98% to 96% (Table 13b and Figure 13b).

Please note that, as part of the implementation of Guidance for Industry (GFI) #213, the dispensing status of some of the medically important antimicrobial products affected by GFI #213 started to change from OTC to either Rx or VFD during 2016. Sales and distribution data for each product are reported to FDA broken out for each month of the calendar year; thus, the sales data in this summary report reflect the dispensing status of each product as reported to FDA for any particular month. The implementation of GFI #213 was completed in January 2017; all remaining affected products transitioned from OTC to either Rx or VFD marketing status at that time. The 2017 Summary Report will reflect the full transition of all medically important antimicrobials affected by GFI #213 from OTC to either Rx or VFD.

TABLE 1

ANTIMICROBIAL DRUG CLASSES AND ACTIVE INGREDIENTS
APPROVED FOR USE IN FOOD-PRODUCING ANIMALS[1]
ACTIVELY MARKETED IN 2016

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

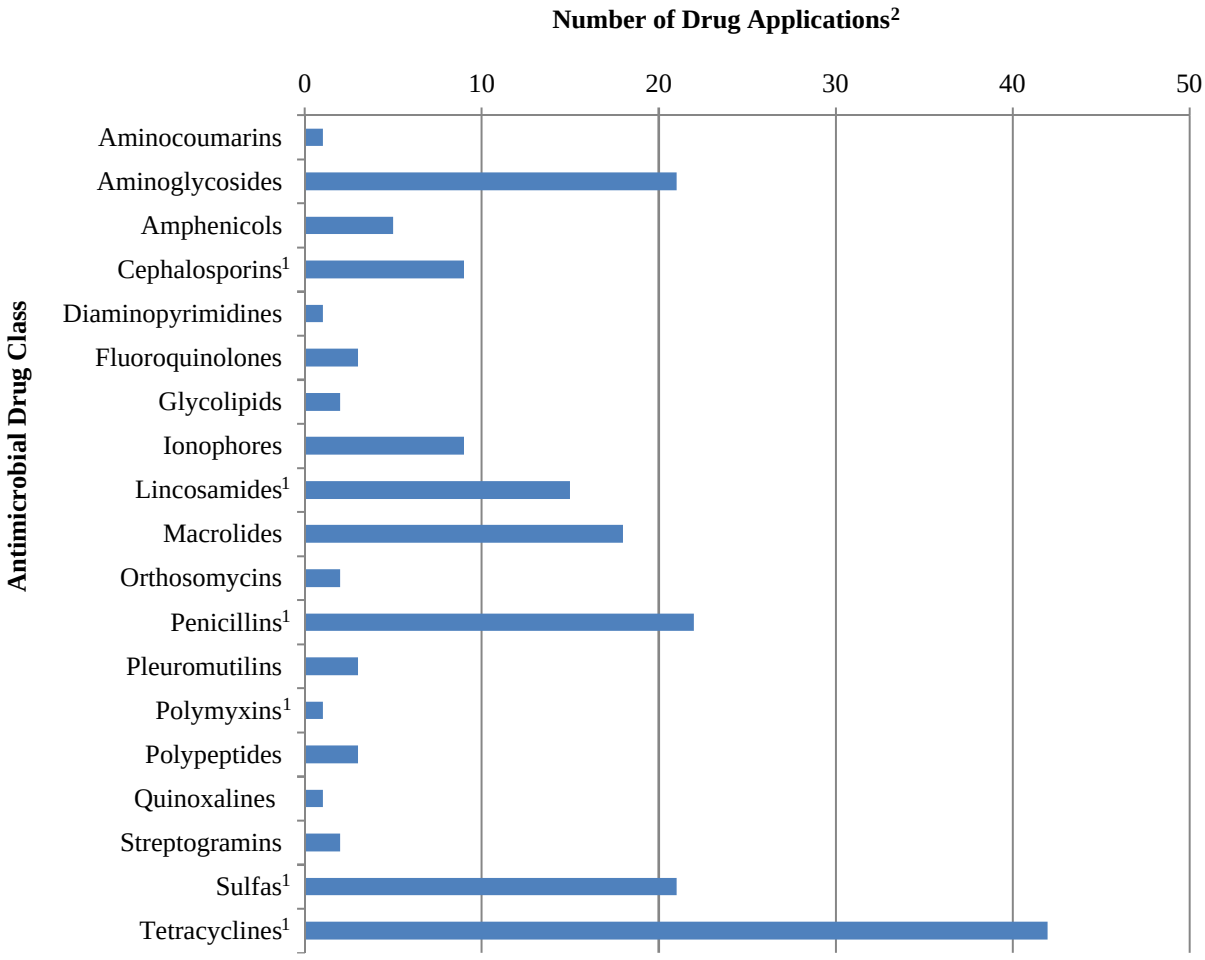
[1] Includes antimicrobial drug applications which are approved and labeled for use in both food-producing animals (e.g., cattle and swine) and nonfood-producing animals (e.g., dogs and horses).

[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 2016 (DOMESTIC SALES)
NUMBER OF DRUG APPLICATIONS[2]

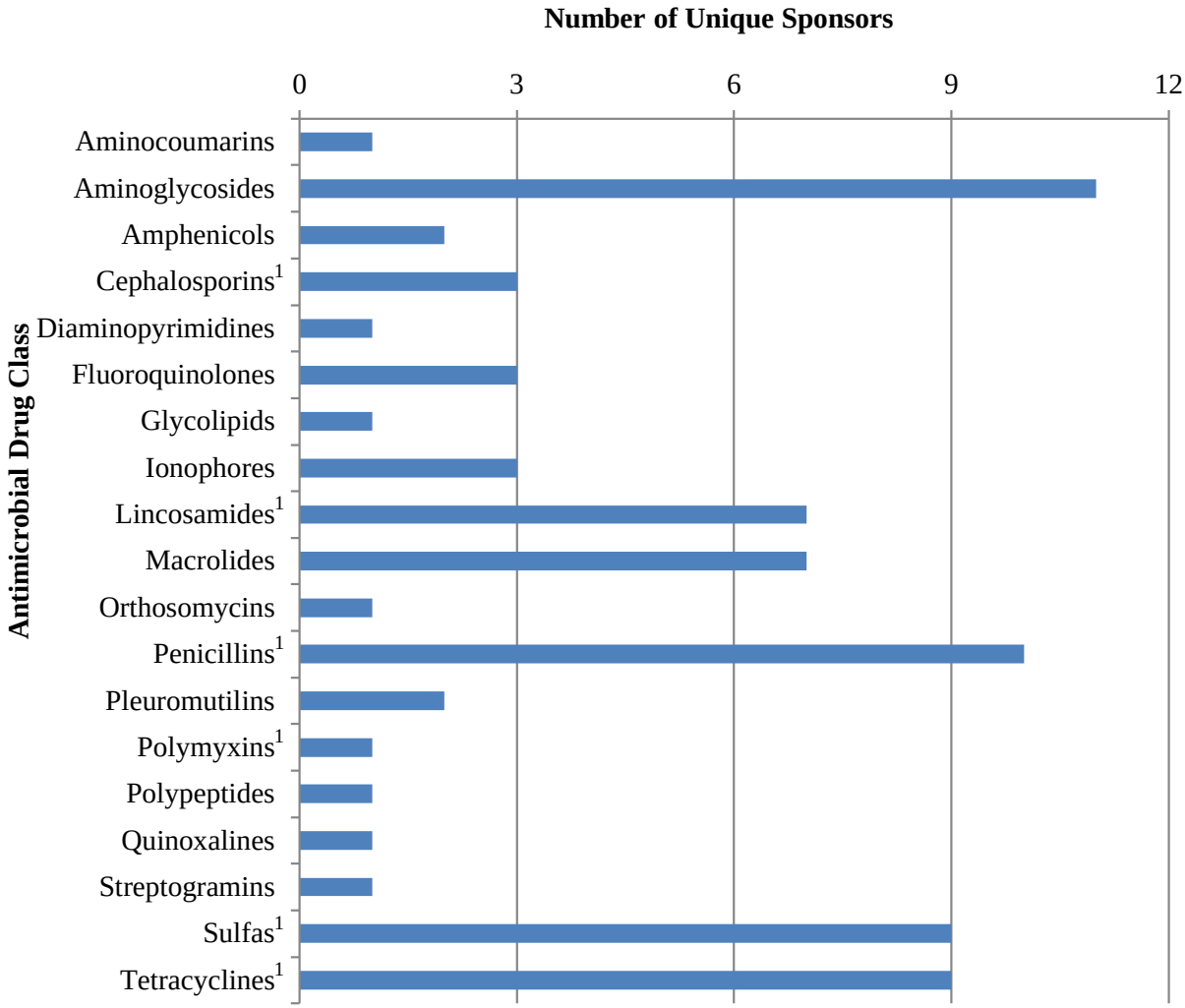


[1] Includes antimicrobial drug applications which are approved and labeled for use in both food-producing animals (e.g., cattle and swine) and nonfood-producing animals (e.g., dogs and horses).

[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 2016 (DOMESTIC SALES)
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 2016
SALES AND DISTRIBUTION DATA
REPORTED BY DRUG CLASS

	Drug Class	Annual Totals (kg)[2]	% Subtotal	% Grand Total
Domestic	*Aminoglycosides*	319,009	2%	2%
	Cephalosporins[1]	31,010	<1%	<1%
	Fluoroquinolones	18,502	<1%	<1%
	Ionophores	4,602,971	33%	33%
	Lincosamides[1]	142,458	1%	1%
	Macrolides	554,714	4%	4%
	Penicillins[1]	842,863	6%	6%
	Sulfas[1]	369,826	3%	3%
	Tetracyclines[1]	5,866,588	42%	42%
	NIR[1,4]	1,235,076	9%	9%
	Subtotal	***13,983,016***	***100%***	***100%***
Export[3]	*NIRE*[1,5]	6,818	100%	<1%
	Subtotal	***6,818***	***100%***	***<1%***
	Grand Total	***13,989,834***		***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. 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.

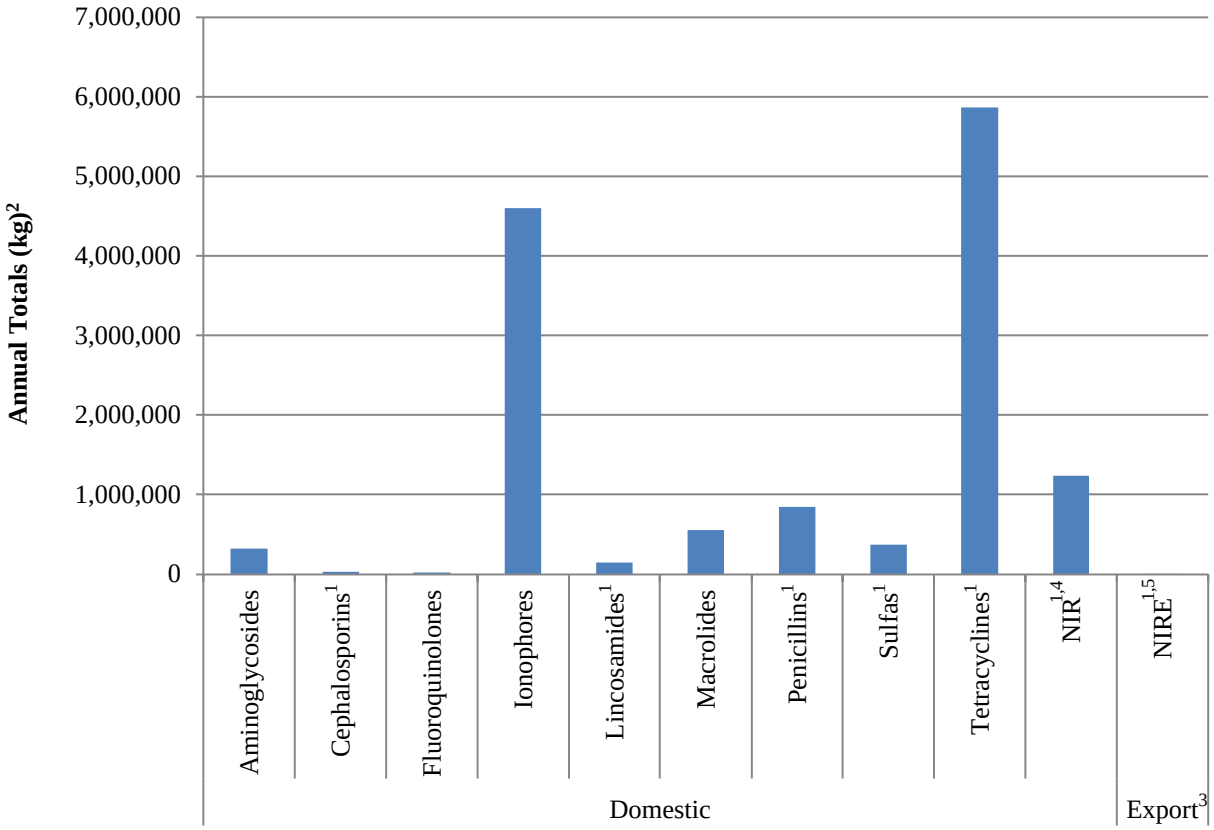
3 Only includes exports of FDA-approved, US-labeled antimicrobial drugs approved for use in food-producing animals.

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: Aminocoumarins, Amphenicols, Diaminopyrimidines, Glycolipids, Orthosomycins, Pleuromutilins, Polymyxins, Polypeptides, Quinoxalines, Streptogramins.

5 NIRE = Not Independently Reported Export. Antimicrobial classes for which there were fewer than three distinct sponsors exporting products are not independently reported. These classes include the following: Amphenicols, Cephalosporins, Diaminopyrimidines, Ionophores, Lincosamides, Macrolides, Penicillins, Polymyxins, Sulfonamides, and Tetracyclines.

FIGURE 2a

ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS[1]
ACTIVELY MARKETED IN 2016
SALES AND DISTRIBUTION DATA
REPORTED BY DRUG CLASS



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

[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: Aminocoumarins, Amphenicols, Diaminopyrimidines, Glycolipids, Orthosomycins, Pleuromutilins, Polymyxins, Polypeptides, Quinoxalines, Streptogramins.

[5] NIRE = Not Independently Reported Export. Antimicrobial classes for which there were fewer than three distinct sponsors exporting products are not independently reported. These classes include the following: Amphenicols, Cephalosporins, Diaminopyrimidines, Ionophores, Lincosamides, Macrolides, Penicillins, Polymyxins, Sulfonamides, and Tetracyclines.

TABLE 2b

ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS[1]
ACTIVELY MARKETED IN 2016
DOMESTIC SALES AND DISTRIBUTION DATA
REPORTED BY SPECIES-SPECIFIC ESTIMATED SALES

	Species	Estimated Annual Totals (kg)[1]	% Subtotal	% Grand Total
Medically Important[3]	Cattle	3,610,943	43%	26%
	Swine	3,133,262	37%	22%
	Chicken	508,800	6%	4%
	Turkey	756,620	9%	5%
	Other[2]	352,114	4%	3%
	Subtotal	***8,361,740***	***100%***	***60%***
Not Medically Important[4]	Cattle	3,116,106	55%	22%
	Swine	425,568	8%	3%
	Chicken	1,700,124	30%	12%
	Turkey	379,478	7%	3%
	Subtotal	***5,621,276***	***100%***	***40%***
	Grand Total	***13,983,016***		***100%***

1 kg = kilogram of active ingredient. Antimicrobials were reported in number of units sold or distributed and were converted to kg. Antimicrobial class includes drugs of different molecular weights, with some drugs reported in different salt forms.

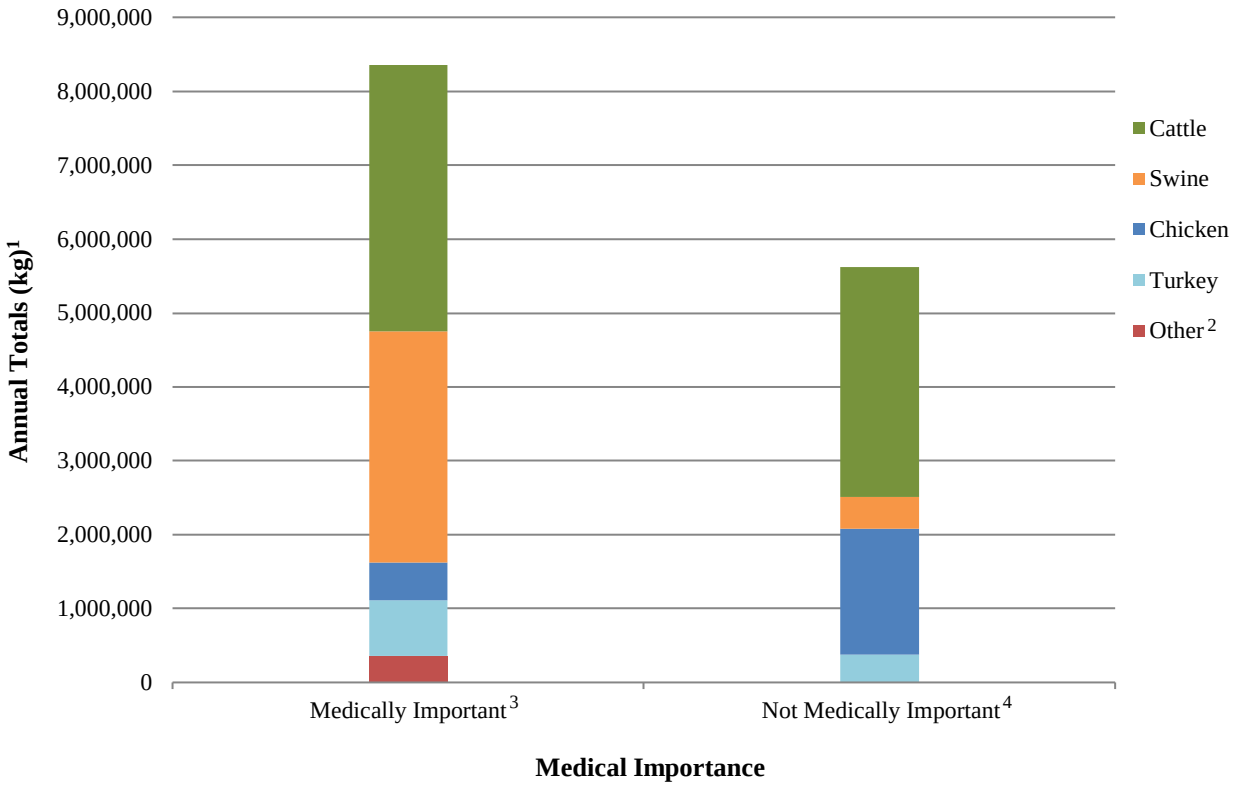
2 The Other category includes estimates of product sales intended for use in (1) species listed on the approved label other than cattle, swine, chickens, and turkeys, including nonfood-producing animal species (e.g., dogs and horses) and minor food-producing species (e.g., fish); (2) other species not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

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

FIGURE 2b

ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS[1]
ACTIVELY MARKETED IN 2016
DOMESTIC SALES AND DISTRIBUTION DATA
REPORTED BY SPECIES-SPECIFIC ESTIMATED SALES



[1] kg = kilogram of active ingredient. Antimicrobials were reported in number of units sold or distributed and were converted to kg. Antimicrobial class includes drugs of different molecular weights, with some drugs reported in different salt forms.

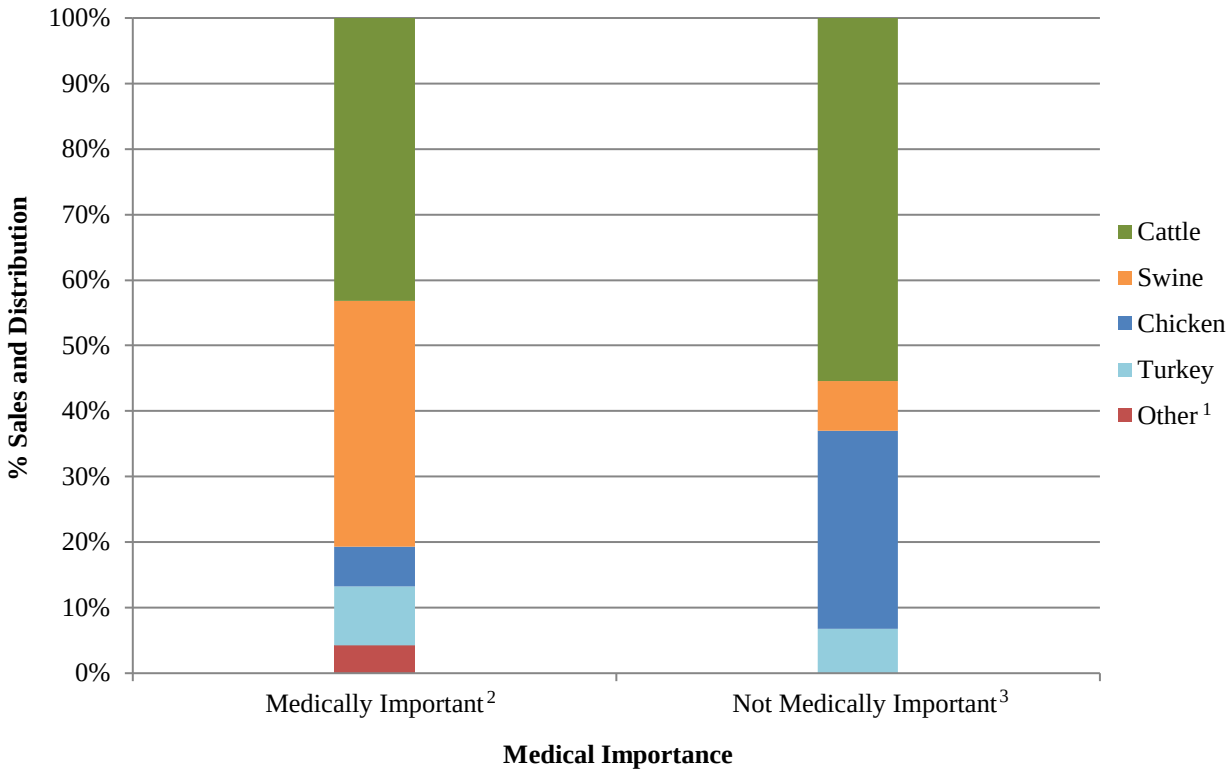
[2] The Other category includes estimates of product sales intended for use in (1) species listed on the approved label other than cattle, swine, chickens, and turkeys, including nonfood-producing animal species (e.g., dogs and horses) and minor food-producing species (e.g., fish); (2) other species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

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

FIGURE 2c

ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS[1]
ACTIVELY MARKETED IN 2016
PERCENTAGE OF DOMESTIC SALES AND DISTRIBUTION
REPORTED BY SPECIES-SPECIFIC ESTIMATED SALES



[1] 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.

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

TABLE 3a

ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS[1]
ACTIVELY MARKETED IN 2016
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*	319,009	4%	2%
	Cephalosporins[1]	31,010	<1%	<1%
	Fluoroquinolones	18,502	<1%	<1%
	Lincosamides[1]	142,458	2%	1%
	Macrolides	554,714	7%	4%
	Penicillins[1]	842,863	10%	6%
	Sulfas[1]	369,826	4%	3%
	Tetracyclines[1]	5,866,588	70%	42%
	NIR[1,5]	216,771	3%	2%
	Subtotal	***8,361,740***	***100%***	***60%***
Not Medically Important[4]	*Ionophores*	4,602,971	82%	33%
	NIR[6]	1,018,305	18%	7%
	Subtotal	***5,621,276***	***100%***	***40%***
	Grand Total	***13,983,016***		***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. 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 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.

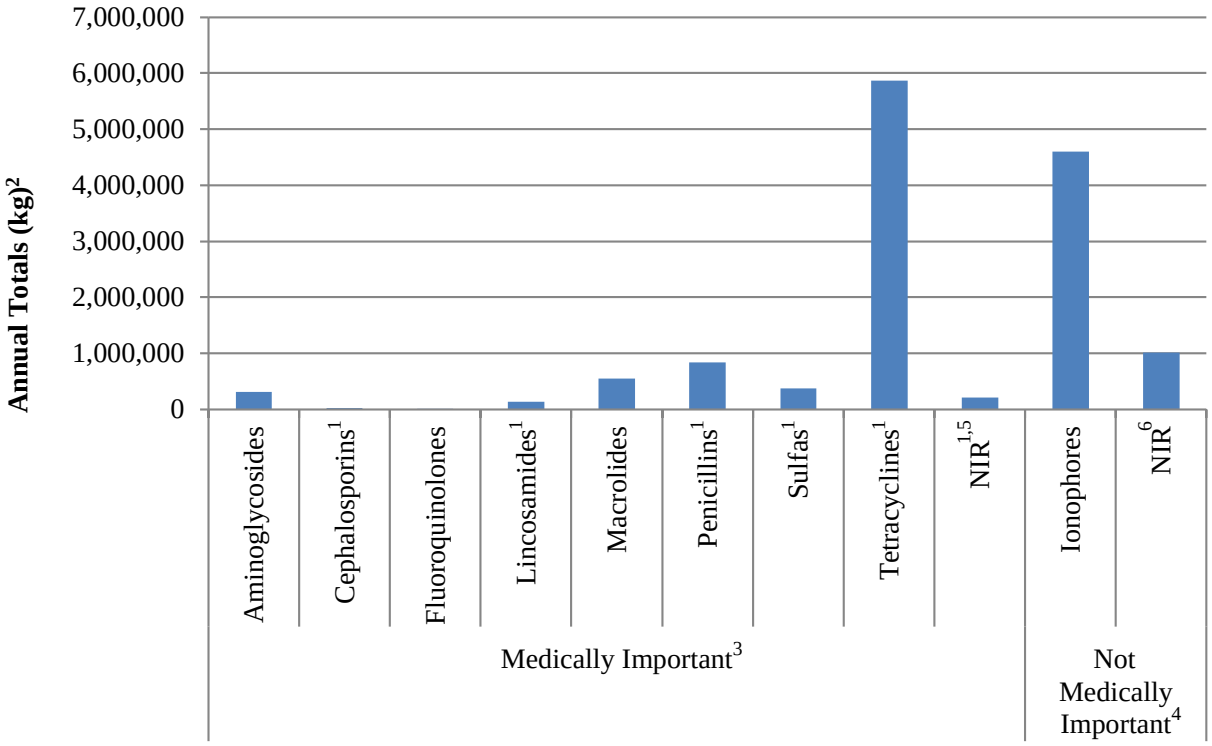
4 Not Medically Important refers to any antimicrobial class not listed in Appendix A of FDA's Guidance for Industry #152.

5 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.

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.

FIGURE 3a

ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS[1]
ACTIVELY MARKETED IN 2016
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. 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 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 Not Medically Important refers to any antimicrobial class not listed in Appendix A of FDA's Guidance for Industry #152.

5 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.

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 3b

ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS[1]
ACTIVELY MARKETED IN 2016
DOMESTIC SALES AND DISTRIBUTION DATA
REPORTED BY MEDICAL IMPORTANCE, DRUG CLASS, AND SPECIES-SPECIFIC ESTIMATED SALES

	Ingredient Class	Species	Estimated Annual Totals (kg)[1]	% Subtotal	% Grand Total
Medically Important[3]	*Aminoglycosides*	Cattle	161,646	51%	1%
		Swine	65,850	21%	<1%
		Chicken	24,111	8%	<1%
		Turkey	22,198	7%	<1%
		Other[2]	45,204	14%	<1%
		Subtotal	***319,009***	***100%***	***2%***
	Cephalosporins	Cattle	24,677	80%	<1%
		NIR[7]	6,333	20%	<1%
		Subtotal	***31,010***	***100%***	***<1%***
	Fluoroquinolones	All Species[9]	18,502	100%	<1%
		Subtotal	***18,502***	***100%***	***<1%***
	Lincosamides	Swine	118,916	83%	1%
		Chicken	8,874	6%	<1%
		NIR[8]	14,667	10%	<1%
		Subtotal	***142,458***	***100%***	***1%***
	Macrolides	Cattle	194,811	35%	1%
		Swine	337,295	61%	2%
		Chicken	20,718	4%	<1%
		Turkey	1,176	<1%	<1%
		Other[2]	714	<1%	<1%
		Subtotal	***554,714***	***100%***	***4%***
	Penicillins	Cattle	99,935	12%	1%
		Swine	17,958	2%	<1%
		Turkey	529,083	63%	4%
		Other[2]	195,888	23%	1%
		Subtotal	***842,863***	***100%***	***6%***
	Sulfas	Cattle	234,955	64%	2%
		Swine	40,215	11%	<1%
		Chicken	21,115	6%	<1%
		Turkey	41,127	11%	<1%
		Other[2]	32,414	9%	<1%
		Subtotal	***369,826***	***100%***	***3%***
	Tetracyclines	Cattle	2,845,919	49%	20%
		Swine	2,520,680	43%	18%
		Chicken	285,513	5%	2%
		Turkey	156,617	3%	1%
		Other[2]	57,859	1%	<1%
		Subtotal	***5,866,588***	***100%***	***42%***
	NIR[5]	All Species[10]	216,771	100%	2%
		Subtotal	***216,771***	***100%***	***2%***
Not Medically Important[4]	*Ionophores*	All Species[11]	4,602,971	100%	33%
		Subtotal	***4,602,971***	***100%***	***33%***
	NIR[6]	All Species[12]	1,018,305	100%	7%
		Subtotal	***1,018,305***	***100%***	***7%***
		Grand Total	***13,983,016***		***100%***

1 kg = kilogram of active ingredient. Antimicrobials were reported in number of units sold or distributed and were converted to kg. Antimicrobial class includes drugs of different molecular weights, with some drugs reported in different salt forms.

2 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.

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

5 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.

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.

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

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

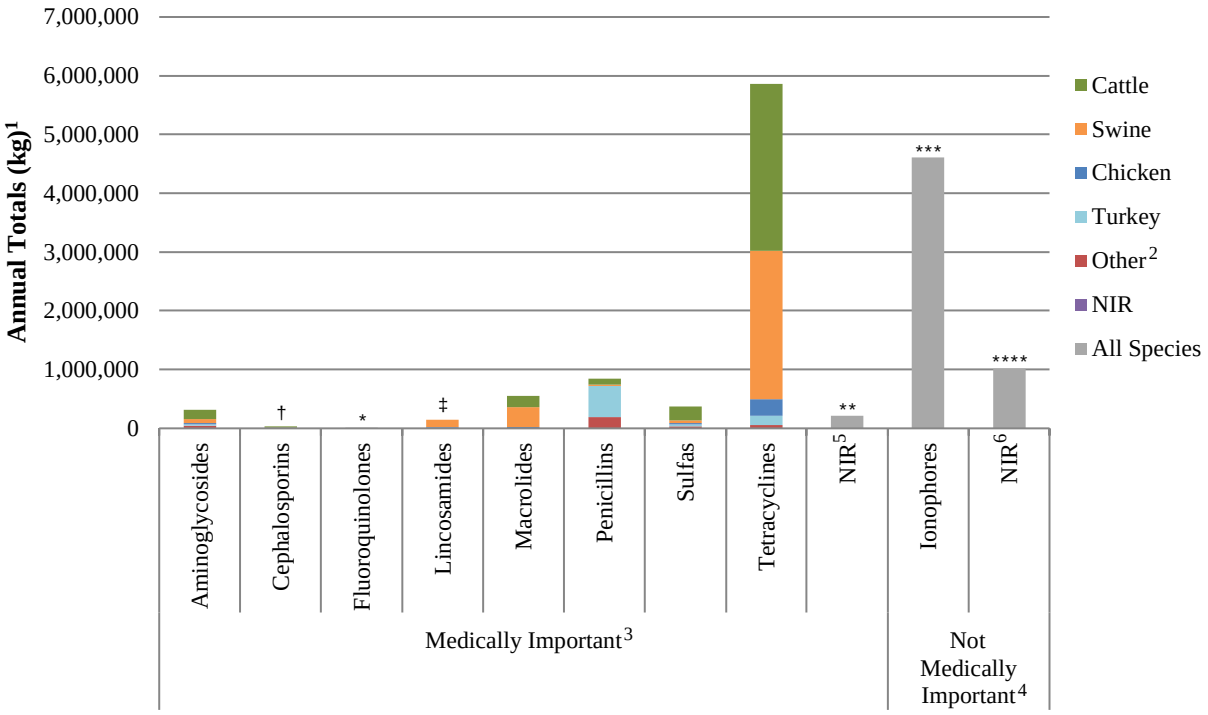
10 This category includes the following: Cattle, Swine, Chicken, Turkey, and Other.

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

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

FIGURE 3b

ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS[1]
ACTIVELY MARKETED IN 2016
DOMESTIC SALES AND DISTRIBUTION DATA
REPORTED BY MEDICAL IMPORTANCE, DRUG CLASS, AND SPECIES-SPECIFIC ESTIMATED SALES



Medical Importance, Drug Class, and Estimated Species

[1] kg = kilogram of active ingredient. Antimicrobials were reported in number of units sold or distributed and were converted to kg. Antimicrobial class includes drugs of different molecular weights, with some drugs reported in different salt forms.

[2] 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.

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

[5] 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.

[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.

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

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

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

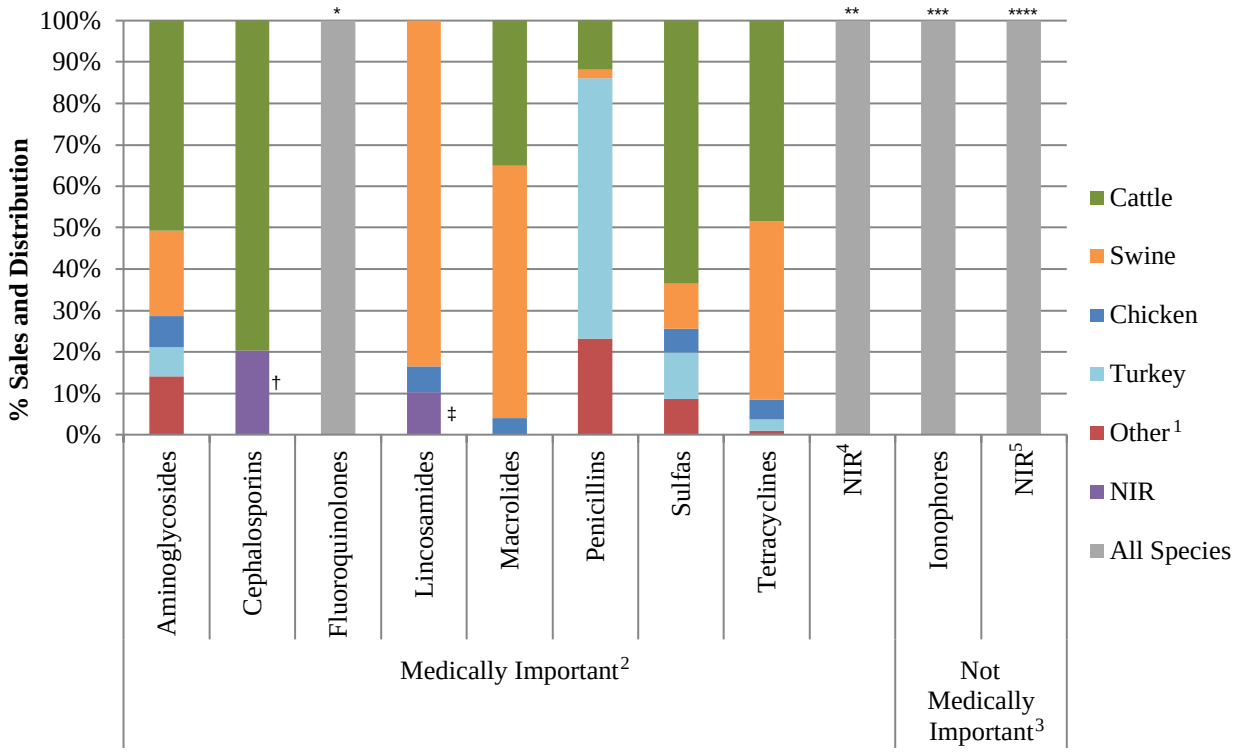
**** This category includes the following: Cattle, Swine, Chicken, and Turkey.

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

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

FIGURE 3c

ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS[1]
ACTIVELY MARKETED IN 2016
PERCENTAGE OF DOMESTIC SALES AND DISTRIBUTION
REPORTED BY MEDICAL IMPORTANCE, DRUG CLASS, AND SPECIES-SPECIFIC ESTIMATED SALES



1 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.

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

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

5 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.

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

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

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

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

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

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

TABLE 4

ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS[1]
ACTIVELY MARKETED IN 2016
DOMESTIC SALES AND DISTRIBUTION DATA
REPORTED BY MEDICAL IMPORTANCE AND ROUTE OF ADMINISTRATION

	Route	Annual Totals (kg)[2]	% Subtotal	% Grand Total
Medically Important[3]	*Feed*[1]	5,987,751	72%	43%
	Injection[1]	348,239	4%	2%
	Intramammary	16,172	<1%	<1%
	Oral[1,5] *or Topical*[1]	90,464	1%	1%
	Water[6]	1,919,115	23%	14%
	Subtotal	***8,361,740***	***100%***	***60%***
Not Medically Important[4]	*All Routes*[7]	5,621,276		40%
	Grand Total	***13,983,016***		***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. 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 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 Not Medically Important refers to any antimicrobial class not listed in Appendix A of FDA's Guidance for Industry #152.

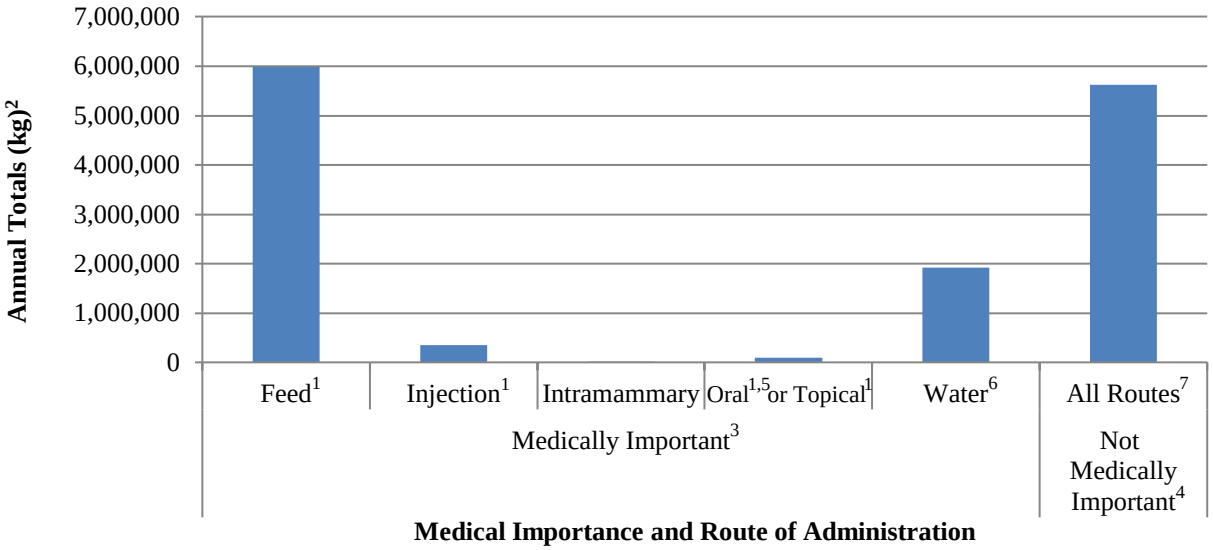
5 Orally administered, excluding administration by means of feed and water.

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.

7 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 4

ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS[1]
ACTIVELY MARKETED IN 2016
DOMESTIC SALES AND DISTRIBUTION DATA
REPORTED BY MEDICAL IMPORTANCE AND ROUTE OF ADMINISTRATION



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

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

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.

7 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 5

ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS[1]
ACTIVELY MARKETED IN 2016
DOMESTIC SALES AND DISTRIBUTION DATA
REPORTED BY MEDICAL IMPORTANCE AND INDICATIONS

	Indications	Annual Totals (kg)[2]	% Subtotal	% Grand Total
Medically Important[3]	*Production[5,6]/Therapeutic[7] Indications[1]*	5,776,055	69%	41%
	Therapeutic Indications Only[1,7]	2,585,685	31%	18%
	Subtotal	***8,361,740***	***100%***	***60%***
Not Medically Important[4]	*Production Indications Only[5]*	98,820	2%	1%
	Production[5]/Therapeutic[7] Indications	4,202,735	75%	30%
	Therapeutic Indications Only[7]	1,319,721	23%	9%
	Subtotal	***5,621,276***	***100%***	***40%***
	Grand Total	***13,983,016***		***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. 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 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 Not Medically Important refers to any antimicrobial class not listed in Appendix A of FDA's Guidance for Industry #152.

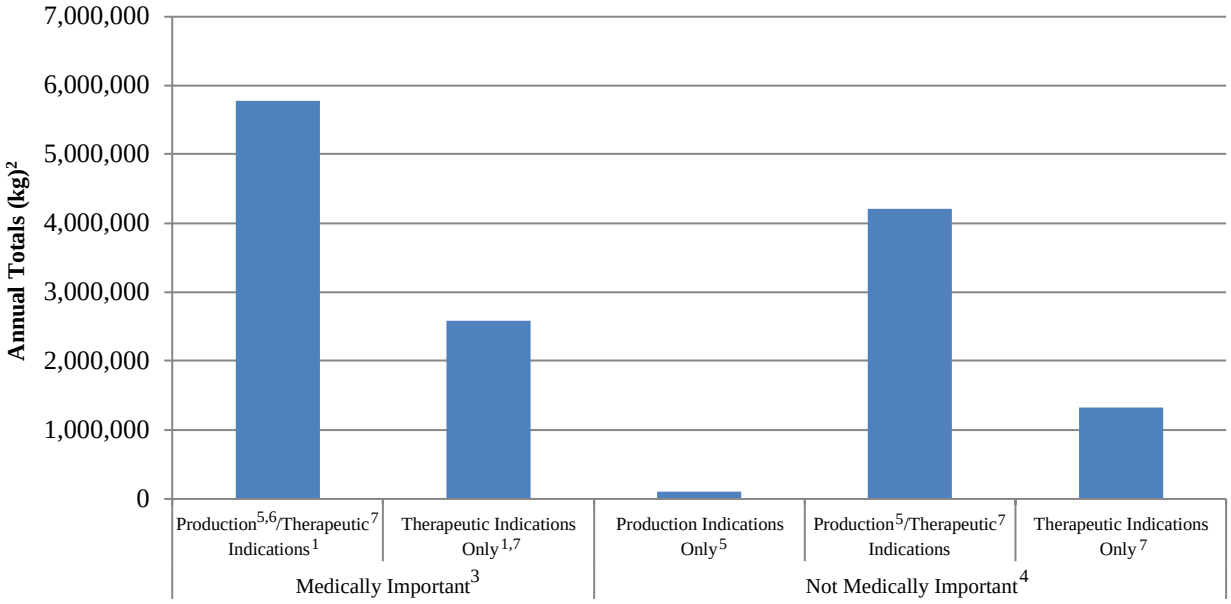
5 Production Indications (e.g., increased rate of weight gain or improved feed efficiency).

6 As part of the implementation of Guidance for Industry (GFI) #213, production indications of some of the medically important antimicrobial products affected by GFI #213 started to be removed from product labeling during 2016. Sales and distribution data for each product are reported to FDA broken out for each month of the calendar year; thus, the sales data in this summary report reflect the indication(s) on the labeling of each product as reported to FDA for any particular month. The implementation of GFI #213 was completed in January 2017; all remaining affected products removed production indications from their labeling at that time. The 2017 Summary Report will reflect the full removal of production indications from the labeling of all medically important antimicrobials affected by GFI #213.

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

FIGURE 5

ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS[1]
ACTIVELY MARKETED IN 2016
DOMESTIC SALES AND DISTRIBUTION DATA
REPORTED BY MEDICAL IMPORTANCE AND INDICATIONS



Medical Importance and 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. 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 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.

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

6 As part of the implementation of Guidance for Industry (GFI) #213, production indications of some of the medically important antimicrobial products affected by GFI #213 started to be removed from product labeling during 2016. Sales and distribution data for each product are reported to FDA broken out for each month of the calendar year; thus, the sales data in this summary report reflect the indication(s) on the labeling of each product as reported to FDA for any particular month. The implementation of GFI #213 was completed in January 2017; all remaining affected products removed production indications from their labeling at that time. The 2017 Summary Report will reflect the full removal of production indications from the labeling of all medically important antimicrobials affected by GFI #213.

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

TABLE 6

ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS[1]
ACTIVELY MARKETED IN 2016
DOMESTIC SALES AND DISTRIBUTION DATA
REPORTED BY MEDICAL IMPORTANCE AND DISPENSING STATUS

	Dispensing Status	Annual Totals (kg)[2]	% Subtotal	% Grand Total
Medically Important[3]	*OTC[1,5,10]*	8,005,726	96%	57%
	RX[1,6]	237,366	3%	2%
	RX[6]/OTC[1,5,7]	60,705	1%	<1%
	VFD[8]	57,943	1%	<1%
	Subtotal	***8,361,740***	***100%***	***60%***
Not Medically Important[4]	*All Dispensing Statuses[9]*	5,621,276		40%
	Grand Total	***13,983,016***		***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. 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 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 Not Medically Important refers to any antimicrobial class not listed in Appendix A of FDA's Guidance for Industry #152.

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

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.

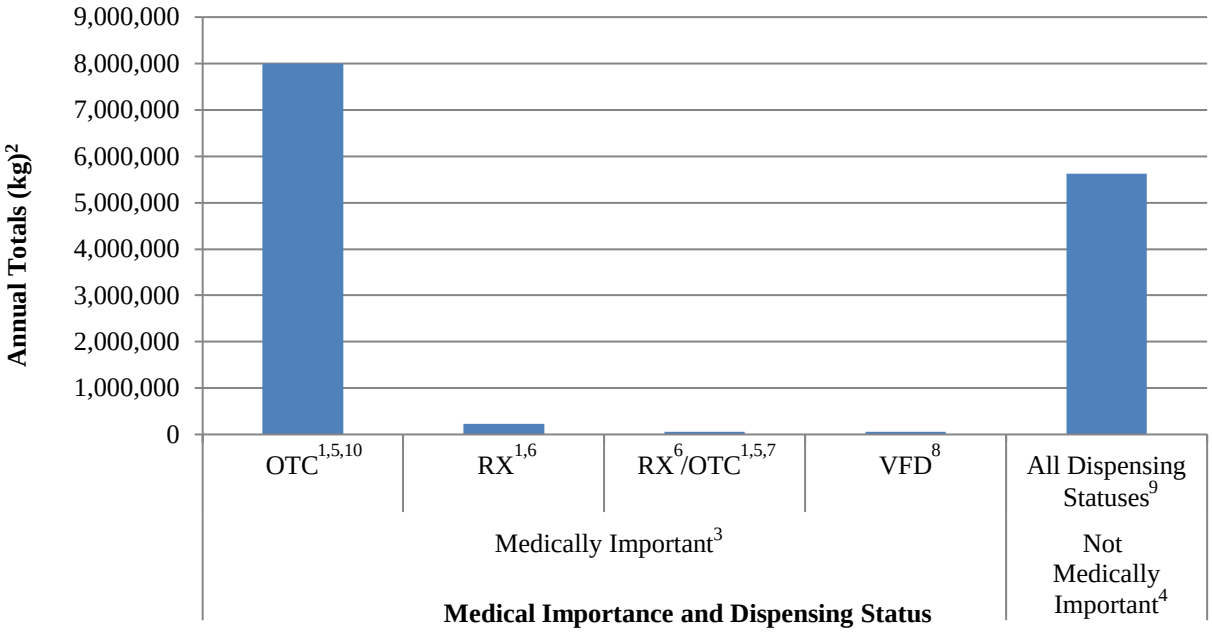
8 VFD = Veterinary Feed Directive. Approved animal drugs that are intended for use in or on animal feed and must be used under the professional supervision of a licensed veterinarian.

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

10 As part of the implementation of Guidance for Industry (GFI) #213, the dispensing status of some of the medically important antimicrobial products affected by GFI #213 started to change from OTC to either Rx or VFD during 2016. Sales and distribution data for each product are reported to FDA broken out for each month of the calendar year; thus, the sales data in this summary report reflect the dispensing status of each product as reported to FDA for any particular month. The implementation of GFI #213 was completed in January 2017; all remaining affected products transitioned from OTC to either Rx or VFD marketing status at that time. The 2017 Summary Report will reflect the full transition of all medically important antimicrobials affected by GFI #213 from OTC to either Rx or VFD.

FIGURE 6

ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS[1]
ACTIVELY MARKETED IN 2016
DOMESTIC SALES AND DISTRIBUTION DATA
REPORTED BY MEDICAL IMPORTANCE AND 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 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 Not Medically Important refers to any antimicrobial class not listed in Appendix A of FDA's Guidance for Industry #152.

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

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 All Dispensing Statuses category includes the following: OTC, RX/OTC, and VFD.

10 As part of the implementation of Guidance for Industry (GFI) #213, the dispensing status of some of the medically important antimicrobial products affected by GFI #213 started to change from OTC to either Rx or VFD during 2016. Sales and distribution data for each product are reported to FDA broken out for each month of the calendar year; thus, the sales data in this summary report reflect the dispensing status of each product as reported to FDA for any particular month. The implementation of GFI #213 was completed in January 2017; all remaining affected products transitioned from OTC to either Rx or VFD marketing status at that time. The 2017 Summary Report will reflect the full transition of all medically important antimicrobials affected by GFI #213 from OTC to either Rx or VFD.

TABLE 7

ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS[1]
ACTIVELY MARKETED IN 2016
DOMESTIC SALES AND DISTRIBUTION DATA
REPORTED BY MEDICAL IMPORTANCE, ROUTE OF ADMINSTRATION, AND DRUG CLASS

	Route	Drug Class	Annual Total (kg)[2]	% Subtotal	% Grand Total
Medically Important[3]	**Feed**	*Sulfas*	77,217	1%	1%
		Tetracyclines[1]	5,114,433	61%	37%
		Other Drugs[7]	796,102	10%	6%
	Water	*Aminoglycosides*	233,668	3%	2%
		Lincosamides	57,085	1%	<1%
		Macrolides	64,780	1%	<1%
		Penicillins	700,779	8%	5%
		Sulfas	199,201	2%	1%
		Tetracyclines	663,602	8%	5%
	Other Routes[5]	*Cephalosporins*[1]	31,010	<1%	<1%
		Sulfas[1]	93,409	1%	1%
		Tetracyclines[1]	88,553	1%	1%
		Other Drugs[1,8]	241,902	3%	2%
		Subtotal	***8,361,740***	***100%***	***60%***
Not Medically Important[4]	**All Routes**[6]	*All Drugs*[9]	5,621,276		40%
		Grand Total	***13,983,016***		***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. 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 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 Not Medically Important refers to any antimicrobial class not listed in Appendix A of FDA's Guidance for Industry #152.

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

6 This category includes the following: Feed, Intramammary, and Water.

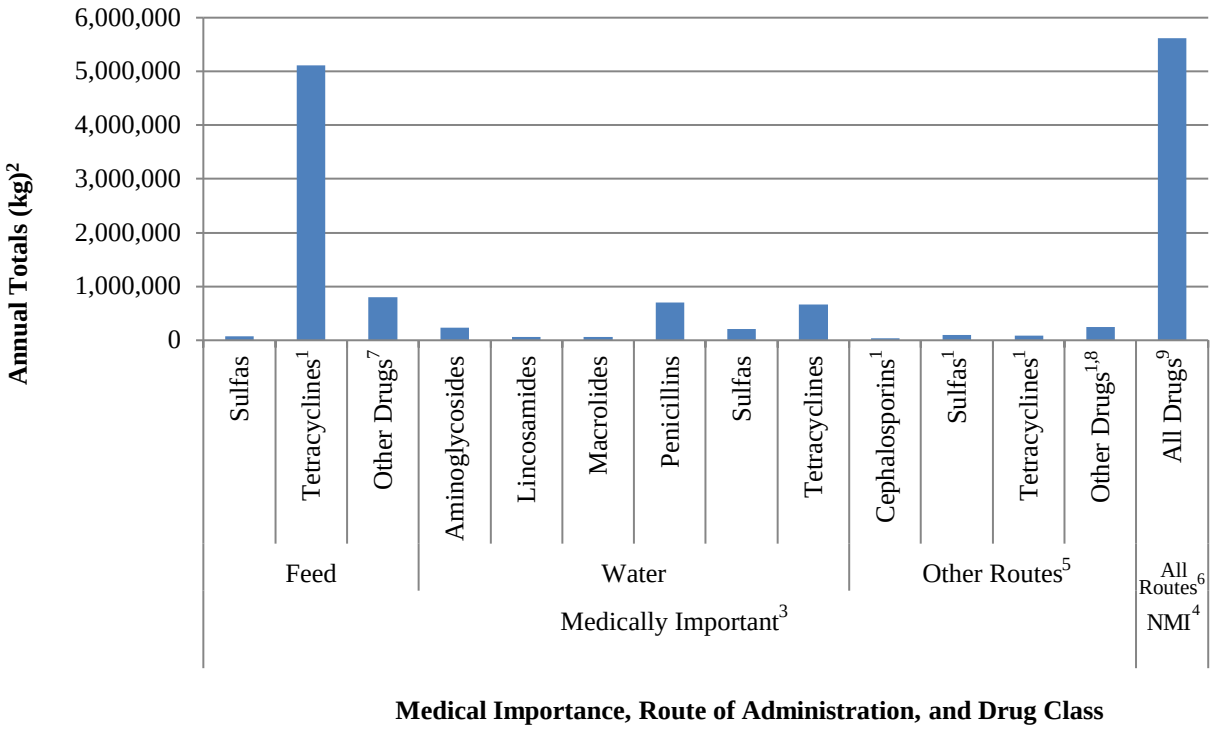
7 This category includes the following: Aminoglycosides, Amphenicols, Diaminopyrimidines, Lincosamides, Macrolides, Penicillins, and Streptogramins.

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

9 This category includes the following: Aminocoumarins, Glycolipids, Ionophores, Orthosomycins, Pleuromutilins, Polypeptides, and Quinoxalines.

FIGURE 7

ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS[1]
ACTIVELY MARKETED IN 2016
DOMESTIC SALES AND DISTRIBUTION DATA
REPORTED BY MEDICAL IMPORTANCE, ROUTE OF ADMINSTRATION, 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. 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] 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] NMI = Not Medically Important. Refers to any antimicrobial class not listed in Appendix A of FDA's Guidance for Industry #152.

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

[6] This category includes the following: Feed, Intramammary, and Water.

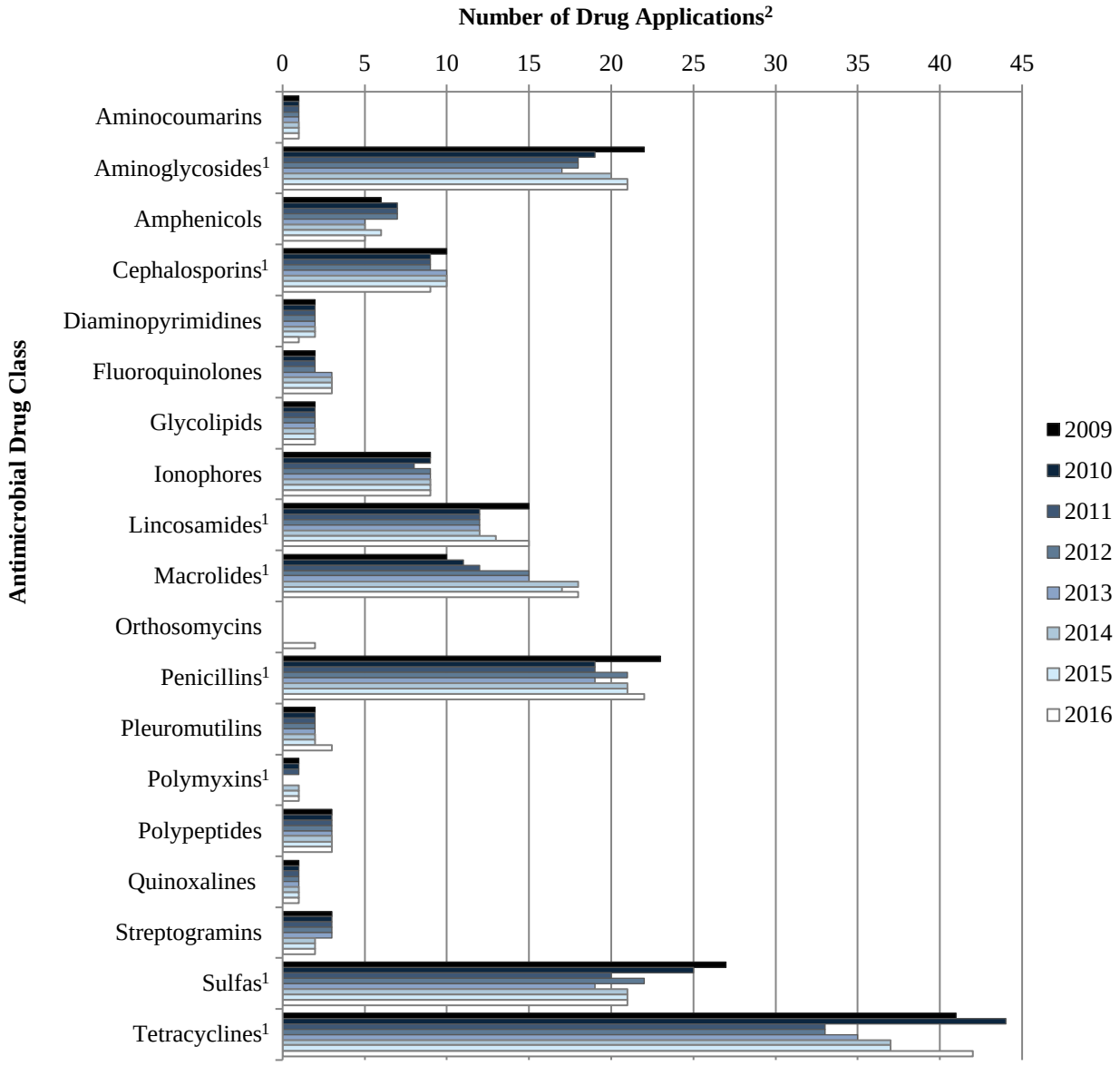
[7] This category includes the following: Aminoglycosides, Amphenicols, Diaminopyrimidines, Lincosamides, Macrolides, Penicillins, and Streptogramins.

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

[9] This category includes the following: Aminocoumarins, Glycolipids, Ionophores, Orthosomycins, Pleuromutilins, Polypeptides, and Quinoxalines.

FIGURE 8a

ANTIMICROBIAL DRUG CLASSES
APPROVED FOR USE IN FOOD-PRODUCING ANIMALS[1]
ACTIVELY MARKETED 2009-2016 (DOMESTIC SALES)
NUMBER OF DRUG APPLICATIONS[2]

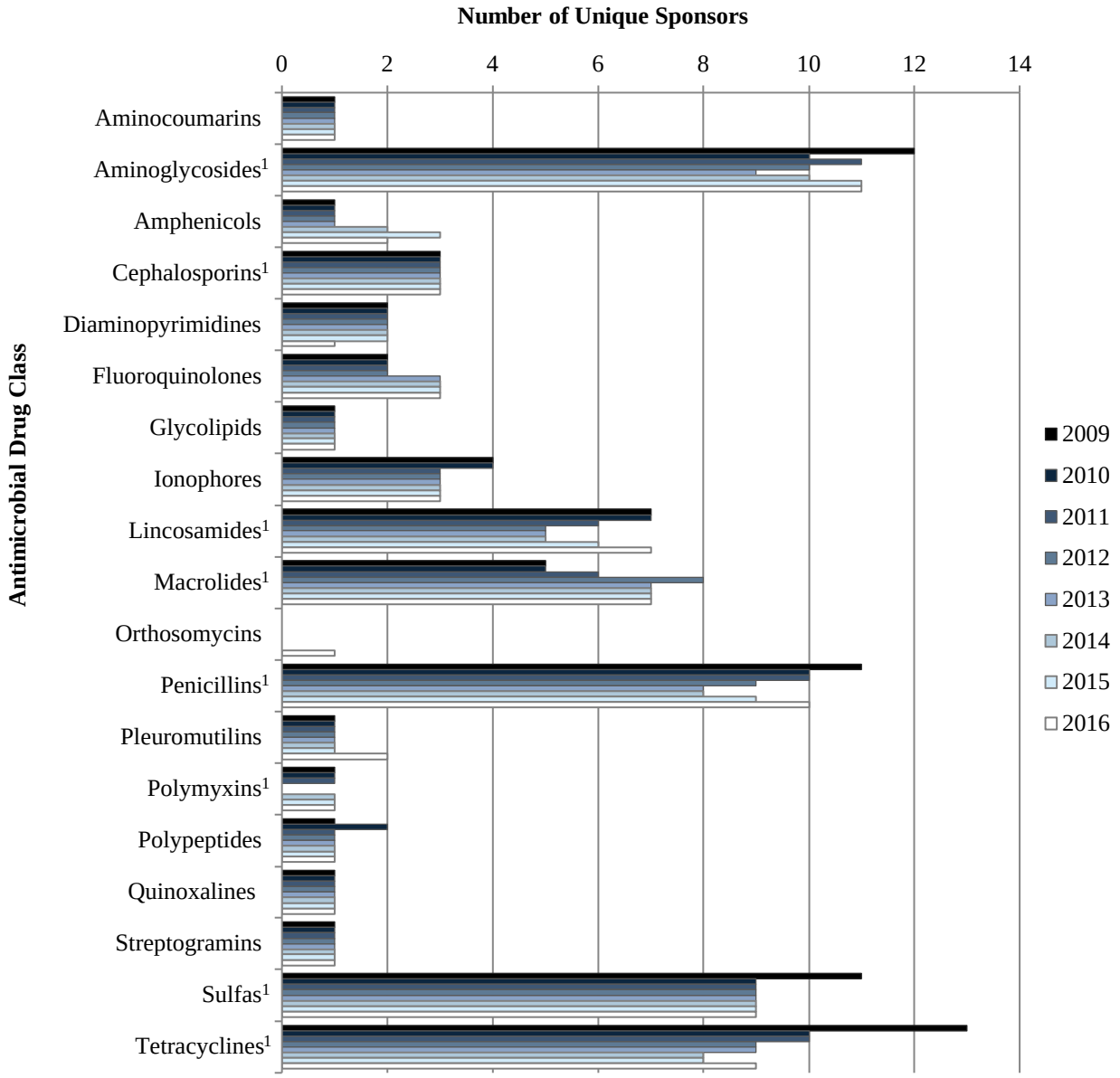


[1] Includes antimicrobial drug applications which are approved and labeled for use in both food-producing animals (e.g., cattle and swine) and nonfood-producing animals (e.g., dogs and horses).

[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 8b

ANTIMICROBIAL DRUG CLASSES
APPROVED FOR USE IN FOOD-PRODUCING ANIMALS[1]
ACTIVELY MARKETED 2009-2016 (DOMESTIC SALES)
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 9

ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS[1]
ACTIVELY MARKETED 2009-2016
SALES AND DISTRIBUTION DATA
REPORTED BY 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]	% Change 2009 - 2016	% Change 2015 - 2016
Domestic	*Aminoglycosides*[1]	223,117	211,790	214,895	277,854	267,734	304,160	344,120	319,009	43%	-7%
	Cephalosporins[1]	20,145	24,588	26,611	27,654	28,337	31,722	32,254	31,010	54%	-4%
	Fluoroquinolones	*	*	*	*	15,099	17,220	20,063	18,502	**	-8%
	Ionophores	3,739,352	3,820,004	4,122,397	4,573,795	4,434,657	4,718,650	4,740,615	4,602,971	23%	-3%
	Lincosamides[1]	93,330	154,653	190,101	218,140	236,450	233,681	182,543	142,458	53%	-22%
	Macrolides[1]	562,062	553,229	582,836	616,274	563,251	621,769	627,757	554,714	-1%	-12%
	Penicillins[1]	691,644	884,419	885,304	965,196	828,721	885,975	936,669	842,863	22%	-10%
	Sulfas[1]	505,880	517,128	383,105	493,514	383,469	452,224	380,186	369,826	-27%	-3%
	Tetracyclines[1]	5,260,995	5,602,281	5,652,855	5,954,361	6,514,779	6,604,199	6,881,530	5,866,588	12%	-15%
	NIR[1,4]	1,490,932	1,519,005	1,510,934	1,495,959	1,512,547	1,491,960	1,432,204	1,235,076	-17%	-14%
	Subtotal	***12,587,457***	***13,287,097***	***13,569,037***	***14,622,747***	***14,785,045***	***15,361,560***	***15,577,940***	***13,983,016***	***11%***	***-10%***
Export[3]	*NIRE*[1,5]	202,556	219,072	202,335	139,173	74,374	30,682	20,861	6,818	-97%	-67%
	Grand Total	***12,790,013***	***13,506,168***	***13,771,373***	***14,761,919***	***14,859,419***	***15,392,242***	***15,598,801***	***13,989,834***	***9%***	***-10%***

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

[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: Aminocoumarins, Amphenicols, Diaminopyrimidines, Glycolipids, Orthosomycins (excluding 2009 through 2015), Pleuromutilins, Polymyxins (excluding 2012 and 2013), Polypeptides, Quinoxalines, and Streptogramins.

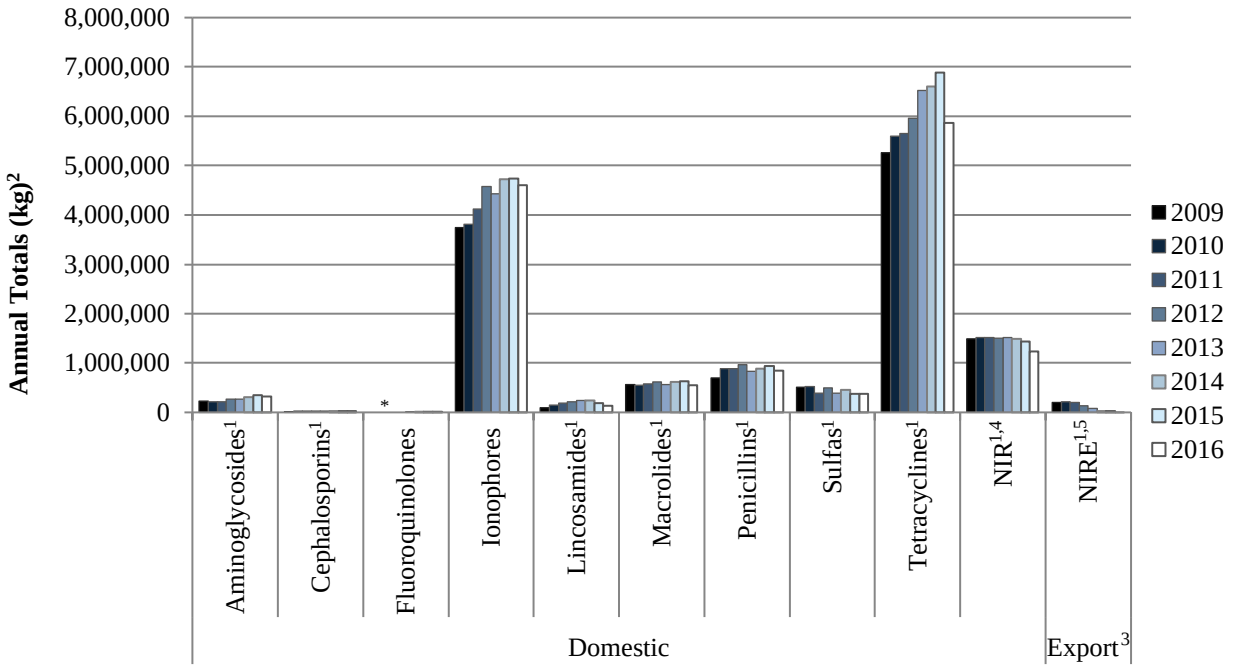
[5] NIRE = Not Independently Reported Export. Antimicrobial classes for which there were fewer than three distinct sponsors exporting products are not independently reported. These classes include the following: Aminocoumarins (excluding 2010 through 2016), Aminoglycosides (excluding 2016), Amphenicols, Cephalosporins, Diaminopyrimidines (excluding 2009), Ionophores, Lincosamides (excluding 2010, 2011, 2012, 2013, and 2015), Macrolides, Penicillins (excluding 2013), Polymyxins (excluding 2010 through 2013), Polypeptides (excluding 2012 through 2016), Sulfonamides, and Tetracyclines.

[*] 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.

FIGURE 9

ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS[1]
ACTIVELY MARKETED 2009-2016
SALES AND DISTRIBUTION DATA
REPORTED BY DRUG CLASS



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. 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.

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5 NIRE = Not Independently Reported Export. Antimicrobial classes for which there were fewer than three distinct sponsors exporting products are not independently reported. These classes include the following: Aminocoumarins (excluding 2010 through 2016), Aminoglycosides (excluding 2016), Amphenicols, Cephalosporins, Diaminopyrimidines (excluding 2009), Ionophores, Lincosamides (excluding 2010, 2011, 2012, 2013, and 2015), Macrolides, Penicillins (excluding 2013), Polymyxins (excluding 2010 through 2013), Polypeptides (excluding 2012 through 2016), Sulfonamides, and Tetracyclines.

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

TABLE 10

ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS[1]
ACTIVELY MARKETED 2009-2016
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]	% Change 2009 - 2016	% Change 2015 - 2016
Medically Important[3]	*Aminoglycosides*[1]	223,117	211,790	214,895	277,854	267,734	304,160	344,120	319,009	43%	-7%
	Cephalosporins[1]	20,145	24,588	26,611	27,654	28,337	31,722	32,254	31,010	54%	-4%
	Fluoroquinolones	*	*	*	*	15,099	17,220	20,063	18,502	**	-8%
	Lincosamides[1]	93,330	154,653	190,101	218,140	236,450	233,681	182,543	142,458	53%	-22%
	Macrolides[1]	562,062	553,229	582,836	616,274	563,251	621,769	627,757	554,714	-1%	-12%
	Penicillins[1]	691,644	884,419	885,304	965,196	828,721	885,975	936,669	842,863	22%	-10%
	Sulfas[1]	505,880	517,128	383,105	493,514	383,469	452,224	380,186	369,826	-27%	-3%
	Tetracyclines[1]	5,260,995	5,602,281	5,652,855	5,954,361	6,514,779	6,604,199	6,881,530	5,866,588	12%	-15%
	NIR[1,5]	329,391	281,221	319,991	344,428	355,452	328,389	297,822	216,771	-34%	-27%
	Subtotal	***7,686,564***	***8,229,309***	***8,255,697***	***8,897,420***	***9,193,293***	***9,479,339***	***9,702,943***	***8,361,740***	***9%***	***-14%***
Not Medically Important[4]	*Ionophores*	3,739,352	3,820,004	4,122,397	4,573,795	4,434,657	4,718,650	4,740,615	4,602,971	23%	-3%
	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	-12%	-10%
	Subtotal	***4,900,893***	***5,057,788***	***5,313,340***	***5,725,327***	***5,591,752***	***5,882,221***	***5,874,997***	***5,621,276***	***15%***	***-4%***
	Grand Total	***12,587,457***	***13,287,097***	***13,569,037***	***14,622,747***	***14,785,045***	***15,361,560***	***15,577,940***	***13,983,016***	***11%***	***-10%***

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

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

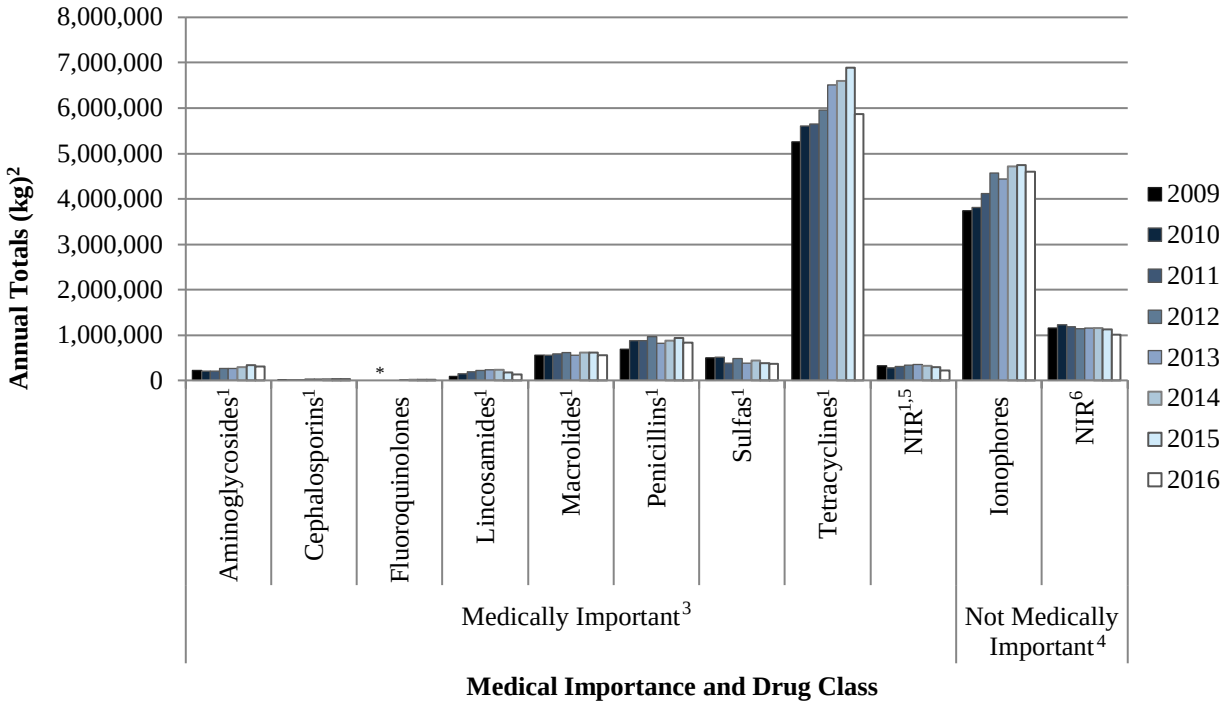
6 NIR = Not Independently Reported. Antimicrobial classes for which there were fewer than three distinct sponsors are not independently reported. These classes include the following: Aminocoumarins, Glycolipids, Orthosomycins (excluding 2009 through 2015), Pleuromutilins, Polypeptides, and Quinoxalines.

* 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.

FIGURE 10

ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS[1]
ACTIVELY MARKETED 2009-2016
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. 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.

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TABLE 11a

ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS[1]
ACTIVELY MARKETED 2009-2016
DOMESTIC SALES AND DISTRIBUTION DATA
REPORTED BY MEDICAL IMPORTANCE AND ROUTE OF ADMINISTRATION

	Route	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]	% Change 2009 - 2016	% Change 2015 - 2016
Medically Important[3]	*Feed[1]*	5,687,084	5,957,748	5,933,440	6,250,770	6,833,526	6,981,097	7,139,853	5,987,751	5%	-16%
	Injection[1]	388,518	421,272	416,775	393,422	352,693	341,790	353,297	348,239	-10%	-1%
	Intramammary	23,409	24,692	21,023	25,979	9,875	11,450	16,049	16,172	-31%	1%
	Oral[1,5] or Topical[1,8]	120,506	109,839	126,775	113,409	97,952	104,082	121,288	90,464	-25%	-25%
	Water[6]	1,467,048	1,715,757	1,757,686	2,113,840	1,899,248	2,040,920	2,071,492	1,919,115	31%	-7%
	Subtotal	***7,686,564***	***8,229,309***	***8,255,697***	***8,897,420***	***9,193,293***	***9,479,339***	***9,701,978***	***8,361,740***	***9%***	***-14%***
Not Medically Important[4]	*All Routes[7]*	4,900,893	5,057,788	5,313,340	5,725,327	5,591,752	5,882,221	5,874,997	5,621,276	15%	-4%
	Grand Total	***12,587,457***	***13,287,097***	***13,569,037***	***14,622,747***	***14,785,045***	***15,361,560***	***15,576,975***	***13,983,016***	***11%***	***-10%***

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).

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

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

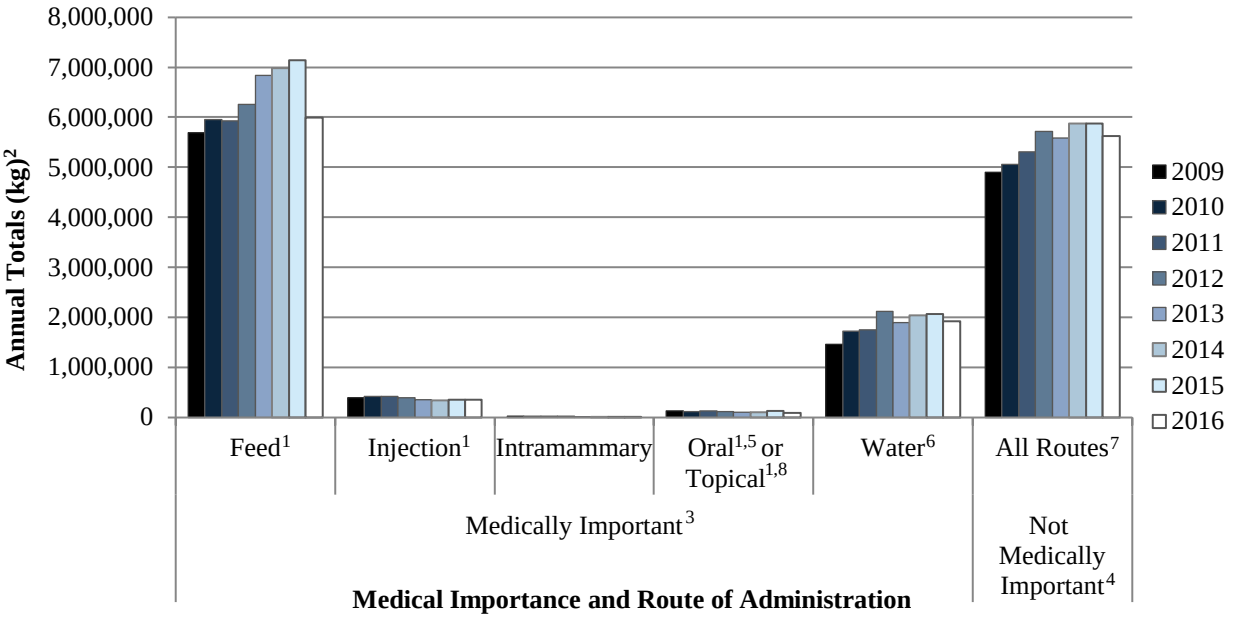
6 Water includes when the drug is administered either through drinking water, as a drench, through the immersion of fish, or as a syrup or dusting for honey bees.

7 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.

8 No Topical sales and distribution in 2012 and 2013.

FIGURE 11a

ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS[1]
ACTIVELY MARKETED 2009-2016
DOMESTIC SALES AND DISTRIBUTION DATA
REPORTED BY MEDICAL IMPORTANCE AND ROUTE OF ADMINISTRATION



[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).

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[5] Orally administered, excluding administration by means of feed and water.

[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.

[7] 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.

[8] No Topical sales and distribution in 2012 and 2013.

TABLE 11b

ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS[1]
ACTIVELY MARKETED 2009-2016
PERCENTAGE OF DOMESTIC SALES AND DISTRIBUTION
MEDICALLY IMPORTANT[2] ONLY
REPORTED BY ROUTE OF ADMINISTRATION

	Route	2009 % Sales and Distribution	2010 % Sales and Distribution	2011 % Sales and Distribution	2012 % Sales and Distribution	2013 % Sales and Distribution	2014 % Sales and Distribution	2015 % Sales and Distribution	2016 % Sales and Distribution
Medically Important[2]	*Feed*[1]	74%	72%	72%	70%	74%	74%	74%	72%
	Injection[1]	5%	5%	5%	4%	4%	4%	4%	4%
	Intramammary	<1%	<1%	<1%	<1%	<1%	<1%	<1%	<1%
	Oral[1,3] *or Topical*[1,5]	2%	1%	2%	1%	1%	1%	1%	1%
	Water[4]	19%	21%	21%	24%	21%	22%	21%	23%
	Subtotal	***100%***	***100%***	***100%***	***100%***	***100%***	***100%***	***100%***	***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 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.

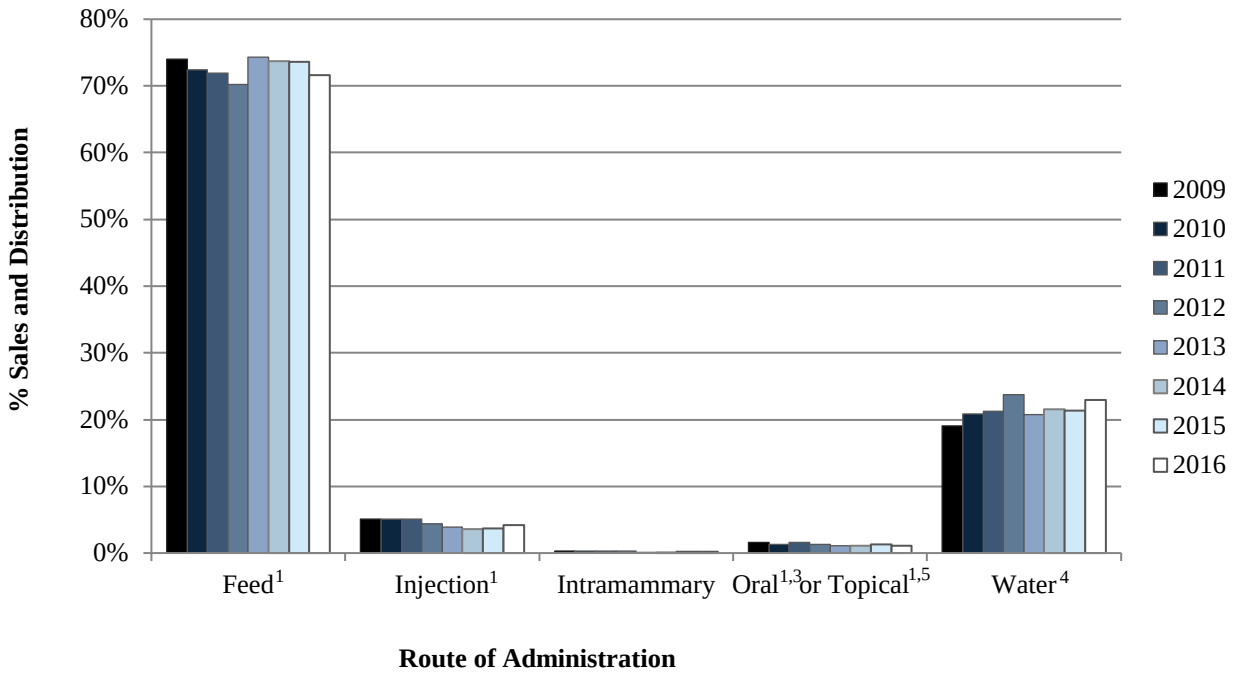
3 Orally administered, excluding administration by means of feed and water.

4 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.

5 No Topical sales and distribution in 2012 and 2013.

FIGURE 11b

ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS[1]
ACTIVELY MARKETED 2009-2016
PERCENTAGE OF DOMESTIC SALES AND DISTRIBUTION
MEDICALLY IMPORTANT[2] ONLY
REPORTED BY ROUTE OF ADMINISTRATION



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

4 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.

5 No Topical sales and distribution in 2012 and 2013.

TABLE 12a

ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS[1]
ACTIVELY MARKETED 2009-2016
DOMESTIC SALES AND DISTRIBUTION DATA
REPORTED BY MEDICAL IMPORTANCE AND INDICATIONS

	Indications	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]	% Change 2009 - 2016	% Change 2015 - 2016
Medically Important[3]	*Production[5] or Production/Therapeutic[6] Indications[1,7]*	5,563,029	5,828,079	5,770,871	6,073,485	6,664,835	6,790,996	6,917,639	5,776,055	4%	-17%
	Therapeutic Indications Only[1,6]	2,123,536	2,401,230	2,484,827	2,823,935	2,528,458	2,688,343	2,784,339	2,585,685	22%	-7%
	Subtotal	***7,686,564***	***8,229,309***	***8,255,697***	***8,897,420***	***9,193,293***	***9,479,339***	***9,701,978***	***8,361,740***	***9%***	***-14%***
Not Medically Important[4]	*Production[5] or Production/Therapeutic[6] Indications[7]*	3,562,501	3,622,315	3,790,628	3,972,057	3,900,298	4,259,148	4,329,598	4,301,555	21%	-1%
	Therapeutic Indications Only[6]	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%	-15%
	Subtotal	***4,900,893***	***5,057,788***	***5,313,340***	***5,725,327***	***5,591,752***	***5,882,221***	***5,874,997***	***5,621,276***	***15%***	***-4%***
	Grand Total	***12,587,457***	***13,287,097***	***13,569,037***	***14,622,747***	***14,785,045***	***15,361,560***	***15,576,975***	***13,983,016***	***11%***	***-10%***

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

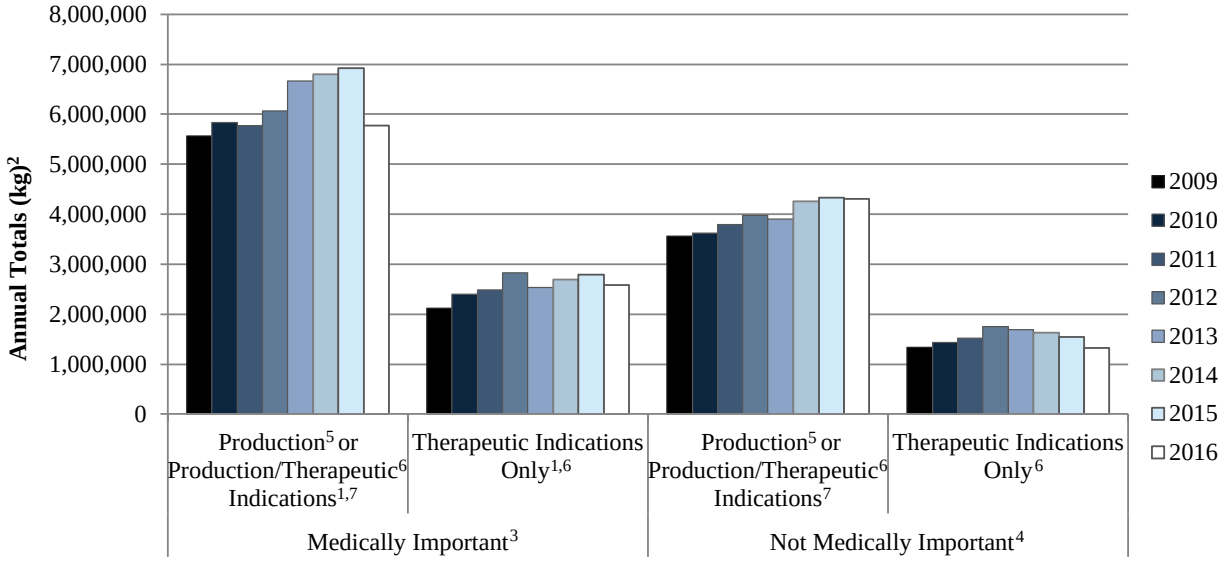
5 As part of the implementation of Guidance for Industry (GFI) #213, production indications (e.g., increased rate of weight gain or improved feed efficiency) of some of the medically important antimicrobial products affected by GFI #213 started to be removed from product labeling during 2016. Sales and distribution data for each product are reported to FDA broken out for each month of the calendar year; thus, the sales data in this summary report reflect the indication(s) on the labeling of each product as reported to FDA for any particular month. The implementation of GFI #213 was completed in January 2017; all remaining affected products removed production indications from their labeling at that time. The 2017 Summary Report will reflect the full removal of production indications from the labeling of all medically important antimicrobials affected by GFI #213.

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

7 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 12a

ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS[1]
ACTIVELY MARKETED 2009-2016
DOMESTIC SALES AND DISTRIBUTION DATA
REPORTED BY MEDICAL IMPORTANCE AND 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. 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 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 Not Medically Important refers to any antimicrobial class not listed in Appendix A of FDA's Guidance for Industry #152.

5 As part of the implementation of Guidance for Industry (GFI) #213, production indications e.g., increased rate of weight gain or improved feed efficiency) of some of the medically important antimicrobial products affected by GFI #213 started to be removed from product labeling during 2016. Sales and distribution data for each product are reported to FDA broken out for each month of the calendar year; thus, the sales data in this summary report reflect the indication(s) on the labeling of each product as reported to FDA for any particular month. The implementation of GFI #213 was completed in January 2017; all remaining affected products removed production indications from their labeling at that time. The 2017 Summary Report will reflect the full removal of production indications from the labeling of all medically important antimicrobials affected by GFI #213.

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

7 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 12b

ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS[1]
ACTIVELY MARKETED 2009-2016
PERCENTAGE OF DOMESTIC SALES AND DISTRIBUTION
MEDICALLY IMPORTANT[2] ONLY
REPORTED BY INDICATIONS

Indications	2009 % Sales and Distribution	2010 % Sales and Distribution	2011 % Sales and Distribution	2012 % Sales and Distribution	2013 % Sales and Distribution	2014 % Sales and Distribution	2015 % Sales and Distribution	2016 % Sales and Distribution
Production[3] or Production/Therapeutic[4] Indications[1,5]	72%	71%	70%	68%	72%	72%	71%	69%
Therapeutic Indications Only[1,4]	28%	29%	30%	32%	28%	28%	29%	31%
Subtotal	***100%***	***100%***	***100%***	***100%***	***100%***	***100%***	***100%***	***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 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.

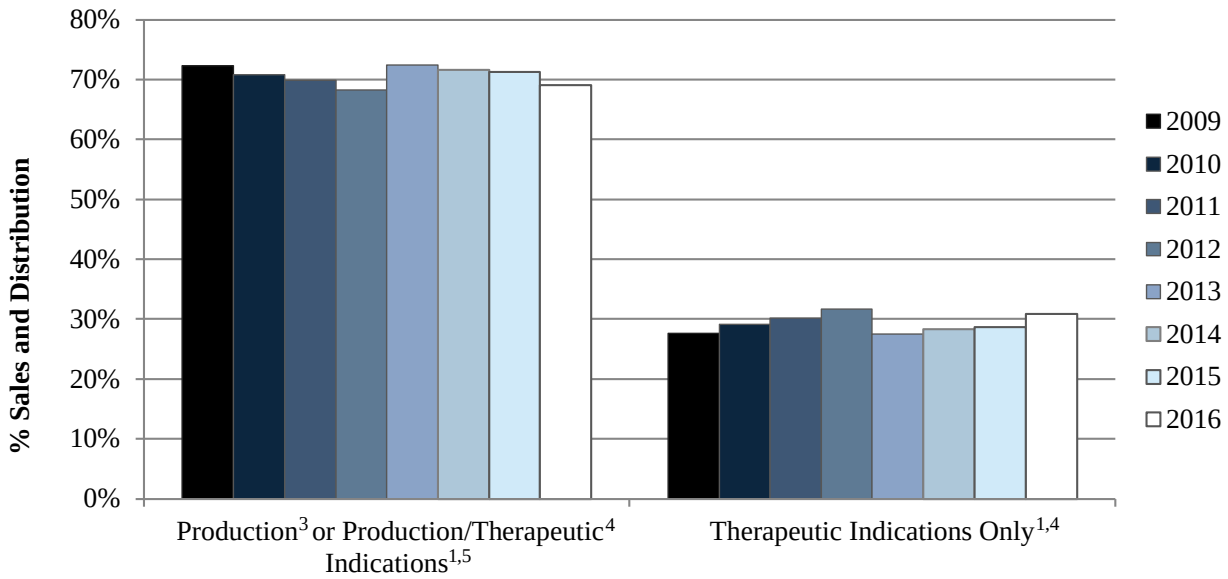
3 As part of the implementation of Guidance for Industry (GFI) #213, production indications (e.g., increased rate of weight gain or improved feed efficiency) of some of the medically important antimicrobial products affected by GFI #213 started to be removed from product labeling during 2016. Sales and distribution data for each product are reported to FDA broken out for each month of the calendar year; thus, the sales data in this summary report reflect the indication(s) on the labeling of each product as reported to FDA for any particular month. The implementation of GFI #213 was completed in January 2017; all remaining affected products removed production indications from their labeling at that time. The 2017 Summary Report will reflect the full removal of production indications from the labeling of all medically important antimicrobials affected by GFI #213.

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

5 From 2009 to 2014 there were fewer than three distinct sponsors marketing antimicrobial animal drugs with only production indications (i.e., with no therapeutic indications). To protect confidential business information these data cannot be independently reported and are, therefore, combined with the data for drugs with both production and therapeutic (production/therapeutic) indications. In 2015 and 2016, there were no products that only have production claims.

FIGURE 12b

ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS[1]
ACTIVELY MARKETED 2009-2016
PERCENTAGE OF DOMESTIC SALES AND DISTRIBUTION
MEDICALLY IMPORTANT[2] ONLY
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] 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] As part of the implementation of Guidance for Industry (GFI) #213, production indications of some of the medically important antimicrobial products affected by GFI #213 started to be removed from product labeling during 2016. Sales and distribution data for each product are reported to FDA broken out for each month of the calendar year; thus, the sales data in this summary report reflect the indication(s) on the labeling of each product as reported to FDA for any particular month. The implementation of GFI #213 was completed in January 2017; all remaining affected products removed production indications from their labeling at that time. The 2017 Summary Report will reflect the full removal of production indications from the labeling of all medically important antimicrobials affected by GFI #213.

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

[5] From 2009 to 2014 there were fewer than three distinct sponsors marketing antimicrobial animal drugs with only production indications (i.e., with no therapeutic indications). To protect confidential business information these data cannot be independently reported and are, therefore, combined with the data for drugs with both production and therapeutic (production/therapeutic) indications. In 2015 and 2016, there were no products that only have production claims.

TABLE 13a

ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS[1]
ACTIVELY MARKETED 2009-2016
DOMESTIC SALES AND DISTRIBUTION DATA
REPORTED BY MEDICAL IMPORTANCE AND DISPENSING STATUS

	Dispensing Status	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]	% Change 2009 - 2016	% Change 2015 - 2016
Medically Important[3]	*OTC[1,5,11]*	7,506,644	8,050,340	8,029,437	8,642,153	8,964,750	9,219,892	9,421,337	8,005,726	7%	-15%
	RX[6]/OTC[1,5,7]	44,117	47,901	50,205	54,968	54,942	48,489	56,363	60,705	38%	8%
	RX[6] or VFD[1,8,9]	135,803	131,068	176,055	200,298	173,600	210,958	224,279	295,309	117%	32%
	Subtotal	***7,686,564***	***8,229,309***	***8,255,697***	***8,897,420***	***9,193,293***	***9,479,339***	***9,701,978***	***8,361,740***	***9%***	***-14%***
Not Medically Important[4]	*All Dispensing Statuses[10]*	4,900,893	5,057,788	5,313,340	5,725,327	5,591,752	5,882,221	5,874,997	5,621,276	15%	-4%
	Grand Total	***12,587,457***	***13,287,097***	***13,569,037***	***14,622,747***	***14,785,045***	***15,361,560***	***15,576,975***	***13,983,016***	***11%***	***-10%***

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

[5] OTC = Over-The-Counter. Approved animal drugs that are available without a prescription or veterinary feed directive.

[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.

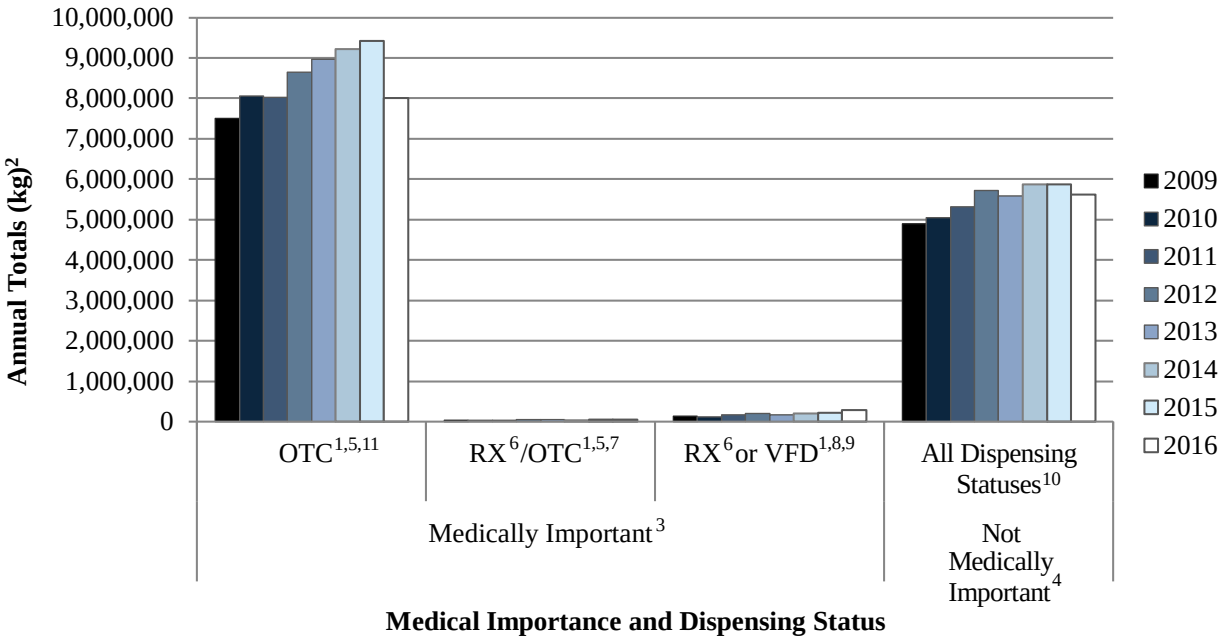
[9] The "Rx or VFD" category includes four VFD products marketed by only two distinct sponsors; therefore, VFD products cannot be independently reported (excluding 2013 through 2016).

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

[11] As part of the implementation of Guidance for Industry (GFI) #213, the dispensing status of some of the medically important antimicrobial products affected by GFI #213 started to change from OTC to either Rx or VFD during 2016. Sales and distribution data for each product are reported to FDA broken out for each month of the calendar year; thus, the sales data in this summary report reflect the dispensing status of each product as reported to FDA for any particular month. The implementation of GFI #213 was completed in January 2017; all remaining affected products transitioned from OTC to either Rx or VFD marketing status at that time. The 2017 Summary Report will reflect the full transition of all medically important antimicrobials affected by GFI #213 from OTC to either Rx or VFD.

FIGURE 13a

ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS[1]
ACTIVELY MARKETED 2009-2016
DOMESTIC SALES AND DISTRIBUTION DATA
REPORTED BY MEDICAL IMPORTANCE AND 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 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 Not Medically Important refers to any antimicrobial class not listed in Appendix A of FDA's Guidance for Industry #152.

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

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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.

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

11 As part of the implementation of Guidance for Industry (GFI) #213, the dispensing status of some of the medically important antimicrobial products affected by GFI #213 started to change from OTC to either Rx or VFD during 2016. Sales and distribution data for each product are reported to FDA broken out for each month of the calendar year; thus, the sales data in this summary report reflect the dispensing status of each product as reported to FDA for any particular month. The implementation of GFI #213 was completed in January 2017; all remaining affected products transitioned from OTC to either Rx or VFD marketing status at that time. The 2017 Summary Report will reflect the full transition of all medically important antimicrobials affected by GFI #213 from OTC to either Rx or VFD.

TABLE 13b

ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS[1]
ACTIVELY MARKETED 2009-2016
PERCENTAGE OF DOMESTIC SALES AND DISTRIBUTION
MEDICALLY IMPORTANT[2] ONLY
REPORTED BY DISPENSING STATUS

Dispensing Status	2009 % Sales and Distribution	2010 % Sales and Distribution	2011 % Sales and Distribution	2012 % Sales and Distribution	2013 % Sales and Distribution	2014 % Sales and Distribution	2015 % Sales and Distribution	2016 % Sales and Distribution
OTC[1,3,8]	98%	98%	97%	97%	98%	97%	97%	96%
RX[4]/OTC[1,3,5]	0.57%	0.58%	0.61%	0.62%	0.60%	0.51%	0.58%	0.73%
RX[4] or VFD[1,6,7]	2%	2%	2%	2%	2%	2%	2%	4%
Subtotal	***100%***	***100%***	***100%***	***100%***	***100%***	***100%***	***100%***	***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 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 OTC = Over-The-Counter. Approved animal drugs that are available without a prescription or veterinary feed directive.

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

5 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.

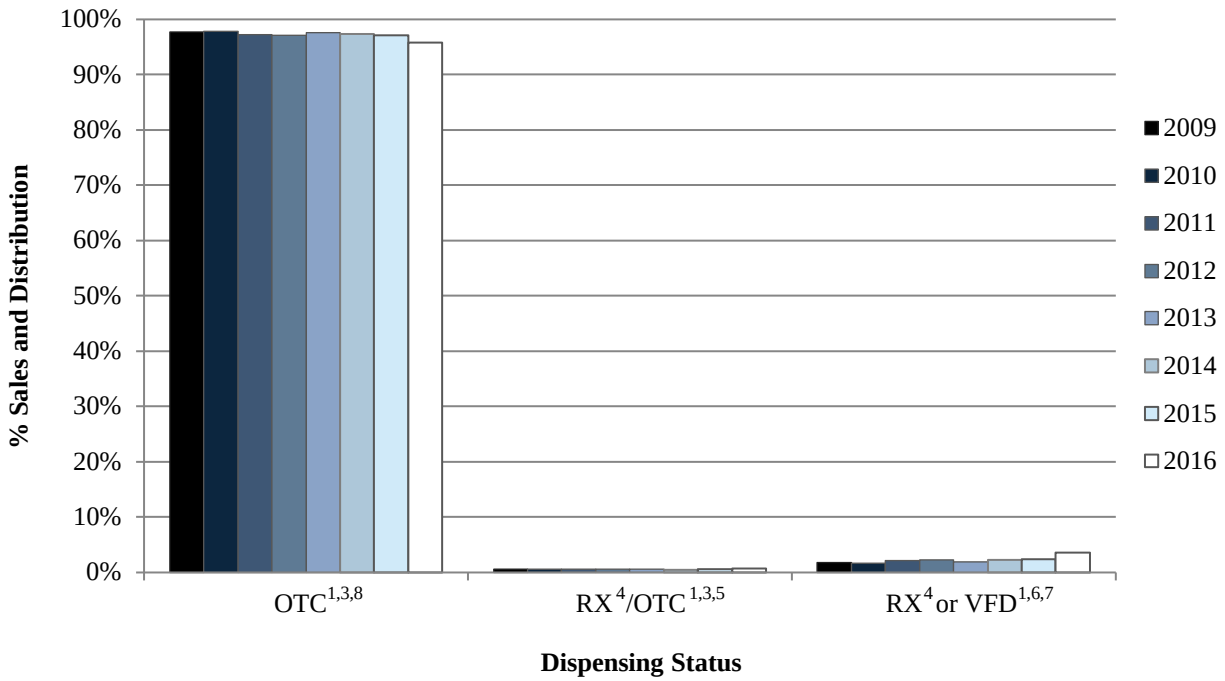
6 VFD = Veterinary Feed Directive. Approved animal drugs that are intended for use in or on animal feed and must be used under the professional supervision of a licensed veterinarian.

7 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 2016).

8 As part of the implementation of Guidance for Industry (GFI) #213, the dispensing status of some of the medically important antimicrobial products affected by GFI #213 started to change from OTC to either Rx or VFD during 2016. Sales and distribution data for each product are reported to FDA broken out for each month of the calendar year; thus, the sales data in this summary report reflect the dispensing status of each product as reported to FDA for any particular month. The implementation of GFI #213 was completed in January 2017; all remaining affected products transitioned from OTC to either Rx or VFD marketing status at that time. The 2017 Summary Report will reflect the full transition of all medically important antimicrobials affected by GFI #213 from OTC to either Rx or VFD.

FIGURE 13b

ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS[1]
ACTIVELY MARKETED 2009-2016
PERCENTAGE OF DOMESTIC SALES AND DISTRIBUTION
MEDICALLY IMPORTANT[2] ONLY
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 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.

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7 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 2016).

8 As part of the implementation of Guidance for Industry (GFI) #213, the dispensing status of some of the medically important antimicrobial products affected by GFI #213 started to change from OTC to either Rx or VFD during 2016. Sales and distribution data for each product are reported to FDA broken out for each month of the calendar year; thus, the sales data in this summary report reflect the dispensing status of each product as reported to FDA for any particular month. The implementation of GFI #213 was completed in January 2017; all remaining affected products transitioned from OTC to either Rx or VFD marketing status at that time. The 2017 Summary Report will reflect the full transition of all medically important antimicrobials affected by GFI #213 from OTC to either Rx or VFD.

TABLE 14

ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS[1]
ACTIVELY MARKETED 2009-2016
DOMESTIC SALES AND DISTRIBUTION DATA
REPORTED BY MEDICAL IMPORTANCE, ROUTE OF ADMINSTRATION, AND DRUG CLASS

	Route	Drug Class	2009 Annual Total (kg)[2]	2010 Annual Total (kg)[2]	2011 Annual Total (kg)[2]	2012 Annual Total (kg)[2]	2013 Annual Total (kg)[2]	2014 Annual Total (kg)[2]	2015 Annual Total (kg)[2]	2016 Annual Total (kg)[2]	% Change 2009 - 2016	% Change 2015 - 2016
Medically Important[3]	**Feed**	*Sulfas*	113,658	109,983	105,400	90,972	90,723	103,243	98,831	77,217	-32%	-22%
		Tetracyclines[1]	4,594,714	4,921,071	4,848,946	5,085,178	5,699,364	5,811,961	6,033,388	5,114,433	11%	-15%
		Other Drugs[7]	978,711	926,695	979,093	1,074,620	1,043,439	1,065,893	1,007,634	796,102	-19%	-21%
	Water	*Aminoglycosides*	140,652	153,907	162,672	195,043	198,247	198,505	223,139	233,668	66%	5%
		Lincosamides	25,033	41,186	66,510	72,187	88,709	100,057	90,086	57,085	128%	-37%
		Penicillins	448,166	630,946	650,220	753,510	672,131	740,929	793,018	700,779	56%	-12%
		Sulfas	265,873	289,529	145,972	283,909	192,995	239,582	154,529	199,201	-25%	29%
		Tetracyclines	574,408	582,660	710,403	782,959	719,529	712,026	762,411	663,602	16%	-13%
		Other Drugs[8]	12,916	17,529	21,909	26,233	27,637	49,822	49,374	64,780	402%	31%
	Other Routes[5]	*Cephalosporins[1]*	20,145	24,588	26,611	27,654	28,337	31,722	32,254	31,010	54%	-4%
		Fluoroquinolones	*	*	*	*	15,099	17,220	20,063	18,502	**	-8%
		Tetracyclines[1]	91,874	98,551	93,506	86,224	95,887	80,211	85,732	88,553	-4%	3%
		Other Drugs[1,9]	420,414	432,665	444,456	418,933	321,196	328,168	352,485	316,809	-25%	-10%
		Subtotal	***7,686,564***	***8,229,309***	***8,255,697***	***8,897,420***	***9,193,293***	***9,479,339***	***9,702,943***	***8,361,740***	***9%***	***-14%***
Not Medically Important[4]	**All Routes[6]**	*All Drugs[10]*	4,900,893	5,057,788	5,313,340	5,725,327	5,591,752	5,882,221	5,874,997	5,621,276	15%	-4%
		Grand Total	***12,587,457***	***13,287,097***	***13,569,037***	***14,622,747***	***14,785,045***	***15,361,560***	***15,577,940***	***13,983,016***	***11%***	***-10%***

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

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

6 This category includes the following: Feed, Intramammary, and Water.

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

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

9 This category includes the following: Aminoglycosides, Amphenicols, Lincosamides, Macrolides, Penicillins, and Polymyxins (excluding 2012 and 2013), and Sulfonamides.

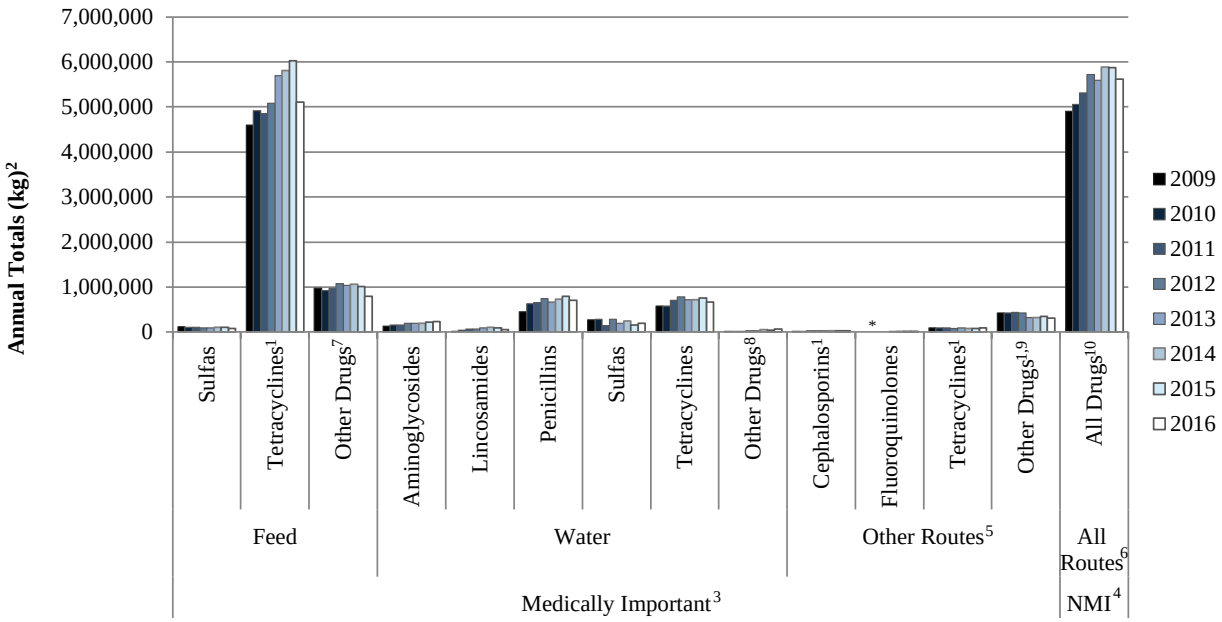
10 This category includes the following: Aminocoumarins, Glycolipids, Ionophores, Orthosomycins (excluding 2009 through 2015), Pleuromutilins, Polypeptides, and Quinoxalines.

* 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.

FIGURE 14

ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS[1]
ACTIVELY MARKETED 2009-2016
DOMESTIC SALES AND DISTRIBUTION DATA
REPORTED BY MEDICAL IMPORTANCE, ROUTE OF ADMINSTRATION, AND DRUG CLASS



Medical Importance, Route of Administration, and Drug Class (2009 - 2016)

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

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

[6] This category includes the following: Feed, Intramammary, and Water.

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

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

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

[10] This category includes the following: Aminocoumarins, Glycolipids, Ionophores, Orthosomycins (excluding 2009 through 2015), Pleuromutilins, Polypeptides, and Quinoxalines.

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

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

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