

2013

SUMMARY REPORT

On

Antimicrobials Sold or Distributed for Use in Food-Producing Animals



Food and Drug Administration
Department of Health and Human Services
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TABLE OF CONTENTS

Overview 6

I. Background 6

II. Scope of Reporting 7

III. Protecting Confidential Information 7

IV. Use of the Summary Information 8

V. Description of Tables and Figures 9

VI. Sales and Distribution Observations 16

A. Current Reporting Year (2013) 16

1. Domestic sales and distribution of antimicrobials not currently medically important .. 16

2. Domestic sales and distribution of medically important antimicrobials..... 17

B. Multi-Year Trends (2009-2013) 18

1. Domestic sales and distribution of antimicrobials not currently medically important .. 18

2. Domestic sales and distribution of medically important antimicrobials..... 19

Tables and Figures:

Current Reporting Year Sales and Distribution Information

Table 1 - Antimicrobial Drug Classes and Active Ingredients Approved for Use in Food-Producing Animals Actively Marketed in 2013 22

Figure 1a - Antimicrobial Drug Classes Approved for Use in Food-Producing Animals Actively Marketed in 2013 (Domestic Sales) Number of Drug Applications 23

Figure 1b - Antimicrobial Drug Classes Approved for Use in Food-Producing Animals Actively Marketed in 2013 (Domestic Sales) Number of Unique Sponsors 24

Table 2 - Antimicrobial Drugs Approved for Use in Food-Producing Animals Actively Marketed in 2013 Sales and Distribution Data Reported by Drug Class 25

Figure 2 - Antimicrobial Drugs Approved for Use in Food-Producing Animals Actively Marketed in 2013 Sales and Distribution Data Reported by Drug Class 26

Table 3 - Antimicrobial Drugs Approved for Use in Food-Producing Animals Actively Marketed in 2013 Domestic Sales and Distribution Data Reported by Medical Importance and Drug Class	27
Figure 3 - Antimicrobial Drugs Approved for Use in Food-Producing Animals Actively Marketed in 2013 Domestic Sales and Distribution Data Reported by Medical Importance and Drug Class	28
Table 4 - Antimicrobial Drugs Approved for Use in Food-Producing Animals Actively Marketed in 2013 Domestic Sales And Distribution Data Reported by Medical Importance and Route of Administration	29
Figure 4 - Antimicrobial Drugs Approved for use in Food-Producing Animals, Actively Marketed in 2013 Domestic Sales and Distribution Data Reported by Medical Importance and Route of Administration	30
Table 5 - Antimicrobial Drugs Approved for Use in Food-Producing Animals Actively Marketed in 2013 Domestic Sales and Distribution Data Reported by Medical Importance and Indications	31
Figure 5 - Antimicrobial Drugs Approved for Use in Food-Producing Animals Actively Marketed in 2013 Domestic Sales and Distribution Data Reported by Medical Importance and Indications.....	32
Table 6 - Antimicrobial Drugs Approved for Use in Food-Producing Animals Actively Marketed in 2013 Domestic Sales and Distribution Data Reported by Medical Importance and Dispensing Status	33
Figure 6 - Antimicrobial Drugs Approved for Use in Food-Producing Animals Actively Marketed in 2013 Domestic Sales and Distribution Data Reported by Medical Importance and Dispensing Status	34
Table 7 - Antimicrobial Drugs Approved for Use in Food-Producing Animals Actively Marketed in 2013 Domestic Sales and Distribution Data Reported by Medical Importance, Route of Administration, and Drug Class	35
Figure 7 - Antimicrobial Drugs Approved for Use in Food-Producing Animals Actively Marketed in 2013 Domestic Sales and Distribution Data Reported by Medical Importance, Route of Administration, and Drug Class	36

Multi-Year Trends of Sales and Distribution Information

Figure 8a - Antimicrobial Drug Classes Approved for Use in Food-Producing Animals Actively Marketed 2009-2013 (Domestic Sales) Number of Drug Applications	37
Figure 8b - Antimicrobial Drug Classes Approved for Use in Food-Producing Animals Actively Marketed 2009-2013 (Domestic Sales) Number of Unique Sponsors	38

Table 9 - Antimicrobial Drugs Approved for Use In Food-Producing Animals Actively Marketed 2009-2013 Sales and Distribution Data Reported by Drug Class	39
Figure 9 - Antimicrobial Drugs Approved for Use in Food-Producing Animals Actively Marketed 2009-2013 Sales and Distribution Data Reported by Drug Class	40
Table 10 - Antimicrobial Drugs Approved for Use in Food-Producing Animals Actively Marketed 2009-2013 Domestic Sales and Distribution Data Reported by Medical Importance and Drug Class	41
Figure 10 - Antimicrobial Drugs Approved for Use in Food-Producing Animals Actively Marketed 2009-2013 Domestic Sales and Distribution Data Reported by Medical Importance and Drug Class	42
Table 11a - Antimicrobial Drugs Approved for Use in Food-Producing Animals Actively Marketed 2009-2013 Domestic Sales and Distribution Data Reported by Medical Importance and Route of Administration	43
Figure 11a - Antimicrobial Drugs Approved for Use in Food-Producing Animals Actively Marketed 2009-2013 Domestic Sales and Distribution Data Reported by Medical Importance and Route of Administration.....	44
Table 11b - Antimicrobial Drugs Approved for Use in Food-Producing Animals Actively Marketed 2009-2013 Percentage of Domestic Sales and Distribution Medically Important Only Reported by Route of Administration	45
Figure 11b - Antimicrobial Drugs Approved for Use in Food-Producing Animals Actively Marketed 2009-2013 Percentage of Domestic Sales and Distribution Medically Important Only Reported by Route of Administration.....	46
Table 12a - Antimicrobial Drugs Approved for Use in Food-Producing Animals Actively Marketed 2009-2013 Domestic Sales and Distribution Data Reported by Medical Importance and Indications.....	47
Figure 12a - Antimicrobial Drugs Approved for Use in Food-Producing Animals Actively Marketed 2009-2013 Domestic Sales and Distribution Data Reported by Medical Importance and Indications	48
Table 12b - Antimicrobial Drugs Approved for Use in Food-Producing Animals Actively Marketed 2009-2013 Percentage of Domestic Sales and Distribution Medically Important Only Reported by Indications	49
Figure 12b - Antimicrobial Drugs Approved for Use in Food-Producing Animals Actively Marketed 2009-2013 Percentage of Domestic Sales and Distribution Medically Important Only Reported by Indications	50
Table 13a - Antimicrobial Drugs Approved for Use in Food-Producing Animals Actively Marketed 2009-2013 Domestic Sales and Distribution Data Reported by Medical Importance and Dispensing Status	51
Figure 13a - Antimicrobial Drugs Approved for Use in Food-Producing Animals Actively Marketed 2009-2013 Domestic Sales and Distribution Data Reported by Medical Importance and Dispensing Status.....	52

Table 13b - Antimicrobial Drugs Approved for Use in Food-Producing Animals Actively Marketed 2009-2013 Percentage of Domestic Sales and Distribution Medically Important Only Reported by Dispensing Status	53
Figure 13b - Antimicrobial Drugs Approved for Use in Food-Producing Animals Actively Marketed 2009-2013 Percentage of Domestic Sales and Distribution Medically Important Only Reported by Dispensing Status.....	54
Table 14 - Antimicrobial Drugs Approved for Use in Food-Producing Animals Actively Marketed 2009-2013 Domestic Sales and Distribution Data Reported by Medical Importance, Route of Administration, and Drug Class	55
Figure 14 - Antimicrobial Drugs Approved for Use in Food-Producing Animals Actively Marketed 2009-2013 Domestic Sales and Distribution Data Reported by Medical Importance, Route of Administration, and Drug Class	56
REFERENCES	57

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 summary report presents the sales and distribution data for the 2013 calendar year for antimicrobial drugs approved for use in food-producing animals. This 2013 summary report also includes multiple years of domestic sales and distribution data of actively marketed antimicrobial drugs by medical importance, route of administration, and drug class, as well as observations on the changes in the sales and distribution of the subject drugs for the periods 2009 through 2013 and 2012 through 2013.

Several observed trends include:

1. Domestic sales and distribution of antimicrobials approved for use in food-producing animals increased by 17% from 2009 through 2013, and increased by 1% from 2012 through 2013.
2. Domestic sales and distribution of medically important antimicrobials approved for use in food-producing animals increased by 20% from 2009 through 2013, and increased by 3% from 2012 through 2013.
3. 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 72% to 68% from 2009 through 2012, but then increased from 68% to 72% from 2012 through 2013. 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.
4. 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) did not appreciably change from 2009 through 2013, including from 2012 through 2013, remaining relatively steady at 98%.

For more discussion of trends, see [Section VI.B. Multi-Year Trends \(2009-2013\)](#) 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).

Under section 512(l)(3) of the Act [21 U.S.C. 360b(l)(3)], each report submitted to the FDA must specify the amount of each antimicrobial active ingredient (1) by container size, strength, and dosage form; (2) by quantities distributed domestically and quantities exported; and (3) by dosage form, including, for each such dosage form, a listing of the target animals, indications, and production classes that are specified on

the approved label of the product. Sponsors of antimicrobial drug applications that are approved and labeled for use in more than one food-producing animal species are not required to report sales and distribution information for each individual animal species listed on a product's approved label. Only total product sales information is required. Each year's report provides monthly sales and distribution data for the preceding calendar year and 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)], FDA is directed to make annual summaries of the information reported by animal drug sponsors publicly available by antimicrobial class.

II. Scope of Reporting

This summary report includes sales and distribution data of antimicrobial drugs that are specifically approved for antibacterial uses or are known to have antibacterial properties. 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." However, sponsors are not required to provide a breakdown of sales by individual target animal species. They report sales totals reflecting combined data for all species listed on the approved label; therefore, this summary report does not include summaries of sales by individual animal species.

Some antimicrobial drug applications include approved products that are labeled for use in both food-producing animal species (e.g., cattle and swine) and nonfood-producing animal species (e.g., dogs and cats). As noted above, because product sales and distribution information is not provided to FDA broken out by species, this summary report does not include information indicating what proportion of antimicrobial drugs was sold for use in food-producing animals and what proportion was sold for use in nonfood-producing animals.

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, 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.

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 will be further discussed later, 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. Because of all these variations, assumptions cannot be made about actual product use.

Readers might want to compare the information in this summary report with information published elsewhere regarding sales and distribution of antimicrobial drugs for use in humans. However, before making comparisons between human and animal drug sales and distribution data, 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 population compared to the much larger number of animals in each of the many animal populations.
- The differences in physical characteristics of humans compared to various animal species (e.g., weight and physiology).
- 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 definitive conclusions from any direct comparisons between the quantity of antimicrobial drugs sold for use in humans and the quantity sold for use in animals. 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.

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 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” (<http://www.accessdata.fda.gov/scripts/animaldrugsatfda/>) 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 currently 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 cats). 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, sulfamethazine, 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, 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.

[Observations Current Reporting Year \(2013\): Actively marketed antimicrobial drug sponsors and applications](#)

Table 2 – Domestic/Export Sales and Antimicrobial Drug Class

Figure 2 – Domestic/Export Sales and Antimicrobial Drug Class

Table 2 and Figure 2 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.

[Observations Current Reporting Year \(2013\): Actively marketed antimicrobial drugs](#)

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

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

Table 3 and Figure 3 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.

[Observations Current Reporting Year \(2013\): Domestic Sales - Medically important antimicrobial drugs and drug class](#)

[Observations Current Reporting Year \(2013\): Domestic Sales - Antimicrobial drugs not currently medically important and drug class](#)

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.

[Observations Current Reporting Year \(2013\): Domestic Sales - Medically important antimicrobial drugs and route of administration](#)

[Observations Current Reporting Year \(2013\): Domestic Sales - Antimicrobial drugs not currently medically important and route of administration](#)

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.

[Observations Current Reporting Year \(2013\): Domestic Sales - Medically important antimicrobial drugs and indications](#)

[Observations Current Reporting Year \(2013\): Domestic Sales - Antimicrobial drugs not currently medically important and indications](#)

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).

[Observations Current Reporting Year \(2013\): Domestic Sales - Medically important antimicrobial drugs and dispensing status](#)

[Observations Current Reporting Year \(2013\): Domestic Sales - Antimicrobial drugs not currently medically important and dispensing status](#)

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.

[Observations Current Reporting Year \(2013\): Domestic Sales - Medically important antimicrobial drugs by route of administration and drug class](#)

[Observations Current Reporting Year \(2013\): Domestic Sales - Antimicrobial drugs not currently 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.

[Multi-Year Trends \(2009-2013\): Domestic Sales - Actively marketed antimicrobial drug sponsors and applications](#)

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).

[Multi-Year Trends \(2009-2013\): Domestic Sales - Actively marketed antimicrobial drugs](#)

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).

[Multi-Year Trends \(2009-2013\): Medically important antimicrobial drugs and drug class](#)

[Multi-Year Trends \(2009-2013\): Antimicrobial drugs not currently medically important and drug class](#)

[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.

[Multi-Year Trends \(2009-2013\): Domestic Sales - Medically important antimicrobials and route of administration](#)

[Multi-Year Trends \(2009-2013\): Domestic Sales - Antimicrobials not currently medically important and route of administration](#)

[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.

[Multi-Year Trends \(2009-2013\): Domestic Sales - Medically important antimicrobials and indications](#)

[Multi-Year Trends \(2009-2013\): Domestic Sales - Antimicrobials not currently medically important and indications](#)

[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).

[Multi-Year Trends \(2009-2013\): Domestic Sales - Medically important antimicrobials and dispensing status](#)

[Multi-Year Trends \(2009-2013\): Domestic Sales - Antimicrobials not currently medically important and dispensing status](#)

[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).

[Multi-Year Trends \(2009-2013\): Domestic Sales - Medically important antimicrobials by route of administration and drug class](#)

[Multi-Year Trends \(2009-2013\): Domestic Sales - Antimicrobials not currently medically important by route of administration and drug class](#)

VI. Sales and Distribution Observations

A. Current Reporting Year (2013)

In 2013, there were 21 sponsors of 141 approved new animal drug applications for antimicrobials actively marketed for use in food-producing animals ([Table 1](#), [Figure 1a](#), and [Figure 1b](#)).

In 2013, sales and distribution (domestic and export) of antimicrobials approved for use in food-producing animals was approximately 14.9 million kilograms. Domestic sales and distribution of antimicrobials approved for use in food-producing animals was approximately 14.8 million kilograms (approximately 99%), and export sales and distribution was approximately 77 thousand kilograms (< 1%) ([Table 2](#) and [Figure 2](#)). Tetracyclines accounted for 44% and ionophores for 30% of domestic sales. 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 currently medically important

In 2013, domestic sales and distribution of antimicrobials that are not currently medically important (NCMI) accounted for 38% of the domestic sales of all antimicrobials approved for use in food-producing animals; 79% of these were ionophores. Because of confidentiality constraints, sales and distribution data for other drug classes of NCMI antimicrobials approved for use in food-producing animals cannot be further reported ([Table 3](#) and [Figure 3](#)).

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

In 2013, domestic sales and distribution of NCMI antimicrobials that are approved for use in food-producing animals and are labeled solely for production indications accounted for 1% of the domestic sales of all NCMI antimicrobials approved for use in food-producing animals. In 2013, domestic sales and distribution of NCMI 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 NCMI antimicrobials approved for use in food-producing animals. Domestic sales and distribution of NCMI antimicrobials that are approved for use in food-producing animals and labeled solely for therapeutic indications accounted for 30% of domestic sales of all NCMI antimicrobials approved for use in food-producing animals ([Table 5](#) and [Figure 5](#)).

In 2013, domestic sales and distribution of NCMI antimicrobials that are approved for use in food-producing animals labeled with an OTC dispensing status accounted for 38% of the domestic sales of all antimicrobials for use in food-producing animals (100% of NCMI antimicrobials that are approved for use in food-producing animals). There are no NCMI antimicrobials that are approved for use in food-producing animals labeled with an Rx or VFD dispensing status ([Table 6](#) and [Figure 6](#)).

Because of confidentiality constraints, sales and distribution data for NCMI 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 2013, domestic sales and distribution of medically important antimicrobials accounted for 62% of the domestic sales of all antimicrobials approved for use in food-producing animals. Of these sales, tetracyclines accounted for 71%, penicillins for 9%, macrolides for 6%, sulfonamides for 4%, aminoglycosides for 3%, lincosamides for 3%, 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 3](#) and [Figure 3](#)).

In 2013, domestic sales and distribution of medically important antimicrobials approved for use in food-producing animals administered in feed accounted for 74% of the domestic sales of all medically important antimicrobials for use in food-producing animals, while products administered by water accounted for 21%. Domestic sales and distribution of products administered by means of injection, intramammary, and oral, accounted for approximately 6% of the domestic sales of all medically important antimicrobials for use in food-producing animals. In 2013, there were no sales and distribution of medically important antimicrobials approved for use in food-producing animals administered topically ([Table 4](#) and [Figure 4](#)).

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. In 2013, domestic sales and distribution of medically important antimicrobials that are approved for use in food-producing animals and are labeled solely for production indications or for both production and therapeutic indications accounted for 72% of the domestic sales of all medically important antimicrobials approved for use in food-producing animals. In 2013, 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 28% of the domestic sales of all medically important antimicrobials approved for use in food-producing animals ([Table 5](#) and [Figure 5](#)).

In 2013, domestic sales and distribution of medically important antimicrobials approved for use in food-producing animals labeled with solely an OTC dispensing status accounted for 98% of the domestic sales of all medically important antimicrobials for use in food-producing animals. In 2013, 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 2% of the domestic sales of all medically important antimicrobials for use in food-producing animals ([Table 6](#) and [Figure 6](#)).

In 2013, tetracyclines administered by feed accounted for 62% of domestic sales and distribution of medically important antimicrobials approved for use in food-producing animals, sulfas for less than 1%, and all other medically important antimicrobials for 11%. In 2013, 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 7%, sulfas for 2%, aminoglycosides for 2%, lincosamides for less than 1%, and macrolides for less than 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 and drug class ([Table 7](#) and [Figure 7](#)).

B. Multi-Year Trends (2009-2013)

This 2013 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 2013, and from 2012 through 2013.

From 2009 through 2013, the number of animal drug sponsors of approved new animal drug applications for antimicrobials actively marketed for use in food-producing animals declined from 25 to 21. The number of approved new animal drug applications for antimicrobials actively marketed for use in food-producing animals declined from 157 to 141 ([Figure 8a](#) and [Figure 8b](#)).

From 2009 through 2013, sales and distribution (domestic and export) of antimicrobials approved for use in food-producing animals increased by 15%, and increased by 1% from 2012 through 2013. From 2009 through 2013, domestic sales and distribution of antimicrobials approved for use in food-producing animals increased by 17%, and increased by 1% from 2012 through 2013. From 2009 through 2013, export sales and distribution of antimicrobials approved for use in food-producing animals decreased by 62%, and decreased by 44% from 2012 through 2013; however, it should be noted that export sales are a small fraction 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 currently medically important

From 2009 through 2013, domestic sales and distribution of antimicrobials approved for use in food-producing animals that are not currently medically important (NCMI) increased by 14%, but decreased 2% from 2012 through 2013. The increase of 14% from 2009 through 2013 reflects a 19% increase in sales and distribution of ionophores. Because of confidentiality constraints, FDA cannot provide sales and distribution data separately for NCMI antimicrobial drug products broken out by other drug classes ([Table 10](#) and [Figure 10](#)).

Because of confidentiality constraints, sales and distribution data for NCMI 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 2013, the percentage of domestic

sales and distribution of NCMI 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 9%, but decreased by 2% from 2012 through 2013. From 2009 through 2013, the percentage of domestic sales and distribution of NCMI antimicrobials that are approved for use in food-producing animals and are labeled solely for therapeutic indications increased by 26%, but decreased by 4% from 2012 through 2013 ([Table 12a](#) and [Figure 12a](#)).

From 2009 through 2013, the percentage of domestic sales and distribution of NCMI that are approved for use in food-producing animals labeled with an OTC dispensing status increased by 14%, but decreased by 2% from 2012 through 2013. There are no NCMI antimicrobials that are approved for use in food-producing animals labeled with an Rx or VFD dispensing status ([Table 13a](#) and [Figure 13a](#)).

Because of confidentiality constraints, sales and distribution data for NCMI 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 2013, domestic sales and distribution of medically important antimicrobials approved for use in food-producing animals increased by 20%, and increased by 3% from 2012 through 2013 ([Table 10](#) and [Figure 10](#)). From 2009 through 2013, domestic sales and distribution of medically important antimicrobials administered by water increased from 19% to 21% of the domestic sales of all medically important antimicrobials approved for use in food-producing animals, while sales of products administered by feed remained unchanged at 74% ([Table 11b](#) and [Figure 11b](#)). Also during this same period, domestic sales of medically important antimicrobials labeled solely for therapeutic indications remained unchanged at 28% 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 class¹

From 2009 through 2013, domestic sales and distribution of tetracycline products approved for use in food-producing animals increased by 24%, and increased by 9% from 2012 through 2013 ([Table 10](#) and [Figure 10](#)). The increase of 24% from 2009 through 2013 reflects a 24% increase in sales and distribution of tetracyclines administered by feed, a 25% increase for tetracyclines administered by water, and a 4% increase 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 35 ([Figure 8a](#)), and the number of unique sponsors of these products decreased from 13 to 9 ([Figure 8b](#)).

¹ With the exception of aminoglycosides, 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 cats).

From 2009 through 2013, domestic sales and distribution of penicillin products approved for use in food-producing animals increased by 20%, but decreased by 14% from 2012 through 2013 ([Table 10](#) and [Figure 10](#)). The increase of 20% from 2009 through 2013 reflects a 50% 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 19 ([Figure 8a](#)), and the number of unique drug sponsors of these products decreased from 11 to 8 ([Figure 8b](#)).

From 2009 through 2013, domestic sales and distribution of macrolide products approved for use in food-producing animals increased by less than 1%, but decreased by 9% from 2012 through 2013 ([Table 10](#) and [Figure 10](#)). The overall increase in sales and distribution of macrolides of less than 1% from 2009 through 2013, and decrease by 9% from 2012 through 2013, 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 15 ([Figure 8a](#)), and the number of unique drug sponsors of these products increased from 5 to 8 ([Figure 8b](#)).

From 2009 through 2013, domestic sales and distribution of sulfonamide (sulfa) products approved for use in food-producing animals decreased by 24%, and decreased by 22% from 2012 through 2013 ([Table 10](#) and [Figure 10](#)). The decrease of 24% from 2009 through 2013 reflects a 20% decrease in sales and distribution of sulfas administered by feed, and a 27% 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 2013, domestic sales and distribution of aminoglycoside products approved for use in food-producing animals increased by 21%, and decreased by 1% from 2012 through 2013 ([Table 10](#) and [Figure 10](#)). The increase of 21% from 2009 through 2013 reflects a 46% 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 16 ([Figure 8a](#)), and the number of unique drug sponsors of these products decreased from 12 to 8 ([Figure 8b](#)).

From 2009 through 2013, domestic sales and distribution of lincosamide products approved for use in food-producing animals increased by 153%, and increased 8% from 2012 through 2013 ([Table 9](#) and [Figure 9](#)). The increase of 153% from 2009 through 2013 reflects a 254% 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 12 ([Figure 8a](#)), and the number of unique drug sponsors of these products decreased from 7 to 5 ([Figure 8b](#)).

From 2009 through 2013, domestic sales and distribution of cephalosporin products approved for use in food-producing animals increased by 41%, and increased by 2% from 2012 through 2013 ([Table 10](#) and [Figure 10](#)). The overall increase in sales and distribution of cephalosporins of 41% from 2009 through 2013, and increase of 2% from 2012 through 2013, cannot be further reported by routes of administration because of confidentiality constraints ([Table 14](#) and [Figure 14](#)). From 2009 through 2012, the number of actively marketed cephalosporin products for use in food-producing animals decreased from 10 to 9, and returned to 10 in 2013 ([Figure 8a](#)). From 2009 through 2013, 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 2013, 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 21%, while products administered by feed remained unchanged at 74%. 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 2013, 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 remained unchanged at 72%. 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 remained unchanged at 28% ([Table 12b](#) and [Figure 12b](#)).

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 2013, 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 remained unchanged at approximately 98%. ([Table 13b](#) and [Figure 13b](#)).

TABLE 1

**ANTIMICROBIAL DRUG CLASSES AND ACTIVE INGREDIENTS
APPROVED FOR USE IN FOOD-PRODUCING ANIMALS¹
ACTIVELY MARKETED IN 2013**

Aminocoumarins (NCMI)³

Novobiocin

Aminoglycosides (MI)²

Gentamicin

Neomycin

Spectinomycin

Amphenicols (MI)²

Florfenicol

Cephalosporins (MI)²

Ceftiofur¹

Cephapirin

Diaminopyrimidines (MI)²

Ormetoprim

Fluoroquinolones (MI)²

Danofloxacin

Enrofloxacin

Glycolipids (NCMI)³

Bambermycins

Ionophores (NCMI)³

Laidlomycin

Lasalocid

Monensin

Narasin

Salinomycin

Lincosamides (MI)²

Lincomycin¹

Pirlimycin

Macrolides (MI)²

Erythromycin

Gamithromycin

Tildipirosin

Tilmicosin

Tulathromycin

Tylosin

Tylvalosin

Penicillins (MI)²

Amoxicillin

Ampicillin¹

Cloxacillin

Penicillin¹

Pleuromutilins (NCMI)³

Tiamulin

Polypeptides (NCMI)³

Bacitracin

Quinoxalines (NCMI)³

Carbadox

Streptogramins (MI)²

Virginiamycin

Sulfonamides (Sulfas) (MI)²

Sulfadimethoxine

Sulfamethazine¹

Tetracyclines (MI)²

Chlortetracycline¹

Oxytetracycline

Tetracycline

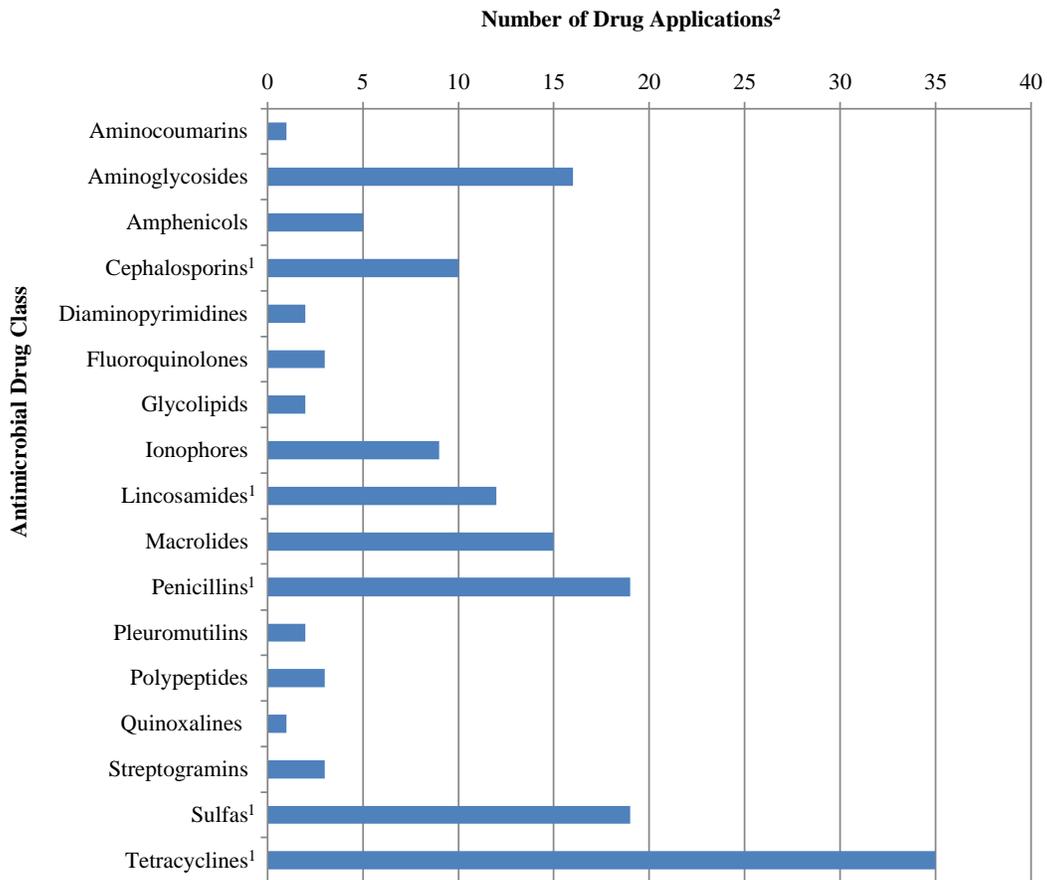
¹ Includes antimicrobial drug applications which are approved and labeled for use in both food-producing animals (e.g., cattle and swine) and nonfood-producing animals (e.g., dogs and cats).

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

FIGURE 1a

**ANTIMICROBIAL DRUG CLASSES
APPROVED FOR USE IN FOOD-PRODUCING ANIMALS¹
ACTIVELY MARKETED IN 2013 (DOMESTIC SALES)
NUMBER OF DRUG APPLICATIONS²**

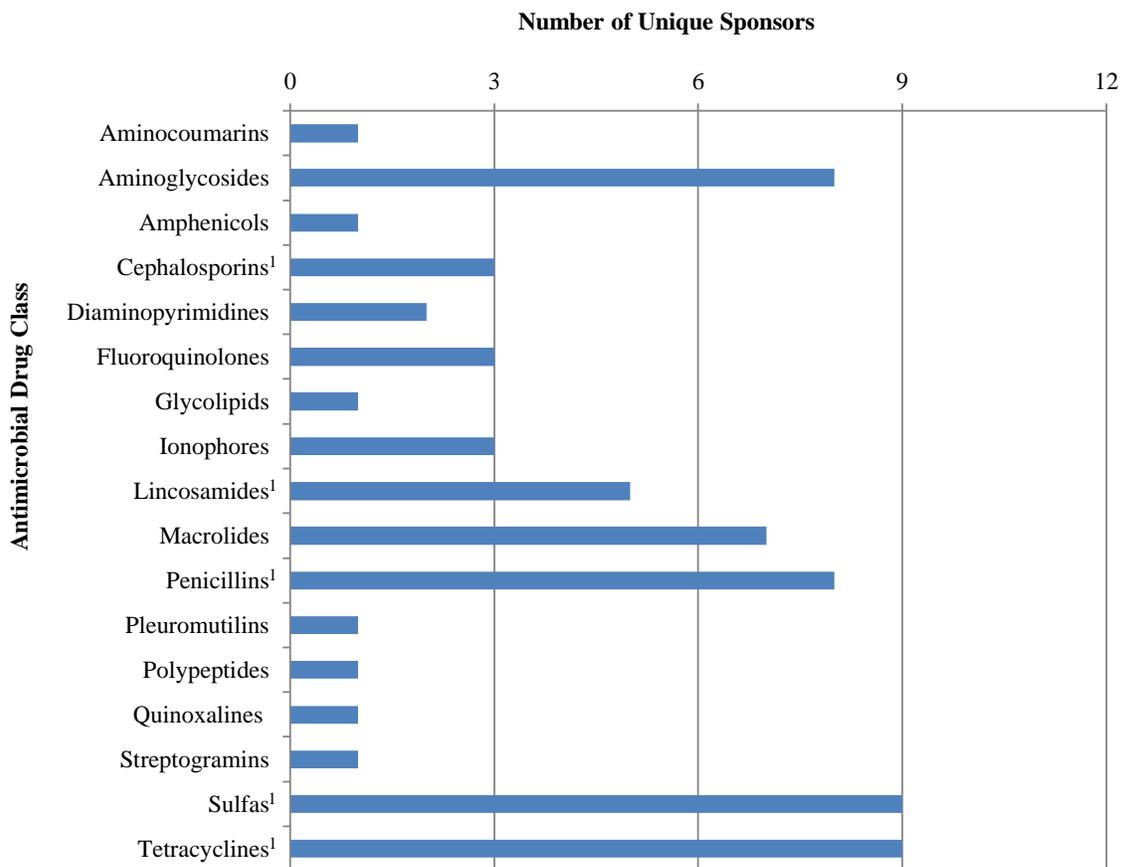


¹ Includes antimicrobial drug applications which are approved and labeled for use in both food-producing animals (e.g., cattle and swine) and nonfood-producing animals (e.g., dogs and cats).

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

FIGURE 1b

**ANTIMICROBIAL DRUG CLASSES
APPROVED FOR USE IN FOOD-PRODUCING ANIMALS¹
ACTIVELY MARKETED IN 2013 (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 cats).

TABLE 2

ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS¹
 ACTIVELY MARKETED IN 2013
 SALES AND DISTRIBUTION DATA
 REPORTED BY DRUG CLASS

	Drug Class	Annual Totals (kg)²	% Subtotal	% Grand Total
<u>Domestic</u>	Aminoglycosides	270,342	2%	2%
	Cephalosporins ¹	28,337	<1%	<1%
	Fluoroquinolones	15,099	<1%	<1%
	Ionophores	4,434,657	30%	30%
	Lincosamides ¹	236,450	2%	2%
	Macrolides	563,251	4%	4%
	Penicillins ¹	828,721	6%	6%
	Sulfas ¹	384,371	3%	3%
	Tetracyclines ¹	6,514,779	44%	44%
	NIR ⁴	1,512,547	10%	10%
	<i>Subtotal</i>	<i>14,788,555</i>	<i>100%</i>	<i>99%</i>
<u>Export³</u>	NIRE ^{1,5}	70,385	91%	<1%
	Tetracyclines	6,927	9%	<1%
	<i>Subtotal</i>	<i>77,312</i>	<i>100%</i>	<i><1%</i>
<i>Grand Total</i>		<i>14,865,867</i>		<i>100%</i>

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 cats).

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.

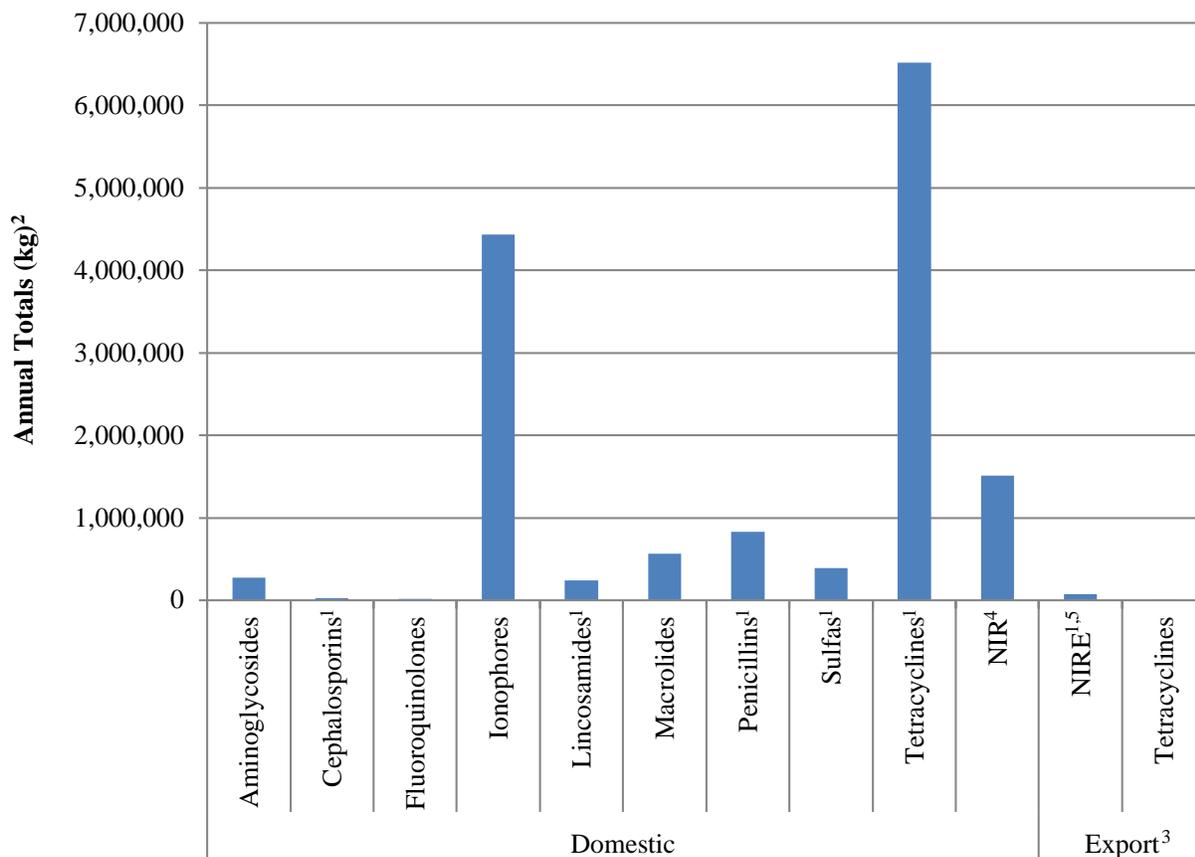
³ Only includes exports of FDA-approved, US-labeled antimicrobial drugs approved for use in food-producing animals.

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, Pleuromutilins, 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: Aminoglycosides, Amphenicols, Cephalosporins, Diaminopyrimidines, Ionophores, Macrolides, Penicillins, Sulfas.

FIGURE 2

**ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS¹
ACTIVELY MARKETED IN 2013
SALES AND DISTRIBUTION DATA
REPORTED BY DRUG CLASS**



Domestic/Export³ 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 cats).
- 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, Pleuromutilins, 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: Aminoglycosides, Amphenicols, Cephalosporins, Diaminopyrimidines, Ionophores, Macrolides, Penicillins, Sulfas.

TABLE 3

ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS¹
 ACTIVELY MARKETED IN 2013
 DOMESTIC SALES AND DISTRIBUTION DATA
 REPORTED BY MEDICAL IMPORTANCE AND DRUG CLASS

	Drug Class	Annual Totals (kg)²	% Subtotal	% Grand Total
<u>Medically Important³</u>	<i>Aminoglycosides</i>	270,342	3%	2%
	<i>Cephalosporins⁴</i>	28,337	<1%	<1%
	<i>Fluoroquinolones</i>	15,099	<1%	<1%
	<i>Lincosamides⁴</i>	236,450	3%	2%
	<i>Macrolides</i>	563,251	6%	4%
	<i>Penicillins⁴</i>	828,721	9%	6%
	<i>Sulfas⁴</i>	384,371	4%	3%
	<i>Tetracyclines⁴</i>	6,514,779	71%	44%
	<i>NIR⁵</i>	355,452	4%	2%
	<i>Subtotal</i>	9,196,803	100%	62%
<u>Not Currently Medically Important⁴</u>	<i>Ionophores</i>	4,434,657	79%	30%
	<i>NIR⁶</i>	1,157,095	21%	8%
		<i>Subtotal</i>	5,591,752	100%
<i>Grand Total</i>		14,788,555		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 cats).

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.

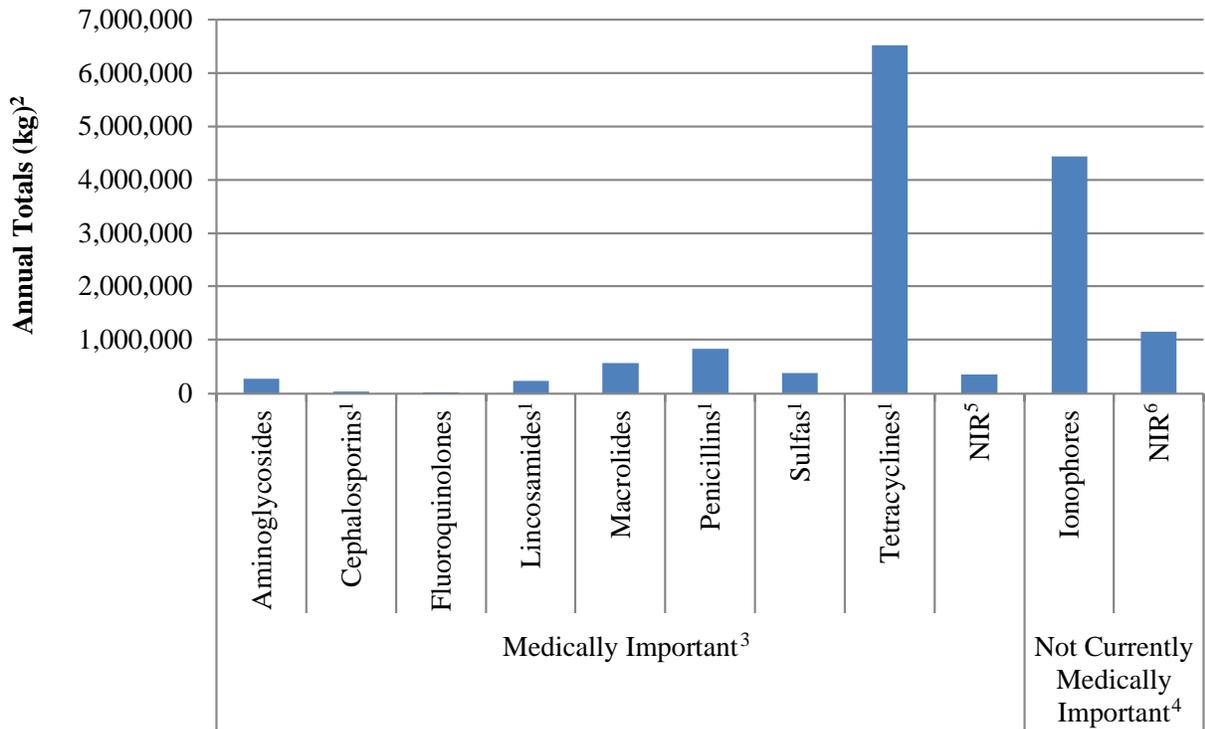
⁴ Not Currently Medically Important refers to any antimicrobial class not currently listed in Appendix A of FDA's Guidance for Industry #152.

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, 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, Pleuromutilins, Polypeptides, and Quinoxalines.

FIGURE 3

ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS¹
ACTIVELY MARKETED IN 2013
DOMESTIC SALES AND DISTRIBUTION DATA
REPORTED BY MEDICAL IMPORTANCE AND DRUG CLASS



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 cats).
- 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 Currently Medically Important refers to any antimicrobial class not currently 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, 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, Pleuromutilins, Polypeptides, and Quinoxalines.

TABLE 4

ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS¹
 ACTIVELY MARKETED IN 2013
 DOMESTIC SALES AND DISTRIBUTION DATA
 REPORTED BY MEDICAL IMPORTANCE AND ROUTE OF ADMINISTRATION

	Route	Annual Totals (kg) ²	% Subtotal	% Grand Total
<u>Medically Important</u> ³	<i>Feed</i> ⁴	6,828,506	74%	46%
	<i>Injection</i> ⁴	352,693	4%	2%
	<i>Intramammary</i>	9,875	<1%	<1%
	<i>Oral</i> ^{4,5}	98,854	1%	<1%
	<i>Water</i> ⁶	1,906,875	21%	13%
	<i>Subtotal</i>	9,196,803	100%	62%
<u>Not Currently Medically Important</u> ⁴	<i>All Routes</i> ⁷	5,591,752		38%
<i>Grand Total</i>		14,788,555		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 cats).

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

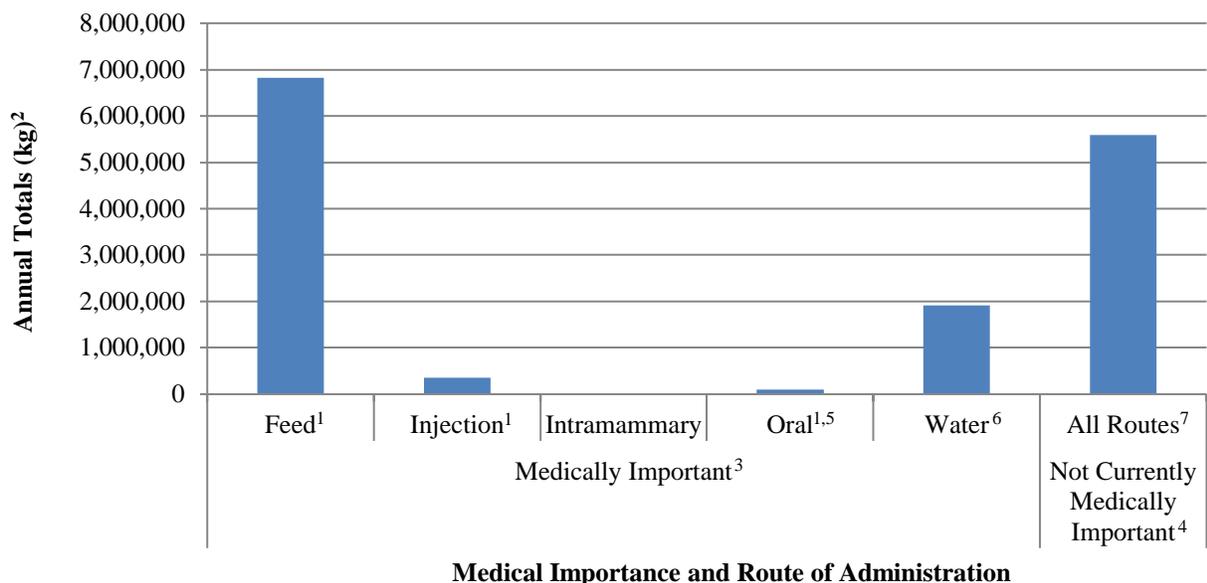
⁵ Orally administered, excluding administration by means of feed and water.

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

⁷ This category includes the following: Feed, Water, and Intramammary. In order to protect confidential business information, the routes of administration for the "not currently medically important" antimicrobial drugs are not separately presented.

FIGURE 4

**ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS¹
ACTIVELY MARKETED IN 2013
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 cats).
- 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 Currently Medically Important refers to any antimicrobial class not currently 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, or through the immersion of fish.
- ⁷ This category includes the following: Feed, Water, and Intramammary. In order to protect confidential business information, the routes of administration for the "not currently medically important" antimicrobial drugs are not separately presented.

TABLE 5

ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS¹
 ACTIVELY MARKETED IN 2013
 DOMESTIC SALES AND DISTRIBUTION DATA
 REPORTED BY MEDICAL IMPORTANCE AND INDICATIONS

	Indications	Annual Totals (kg)²	% Subtotal	% Grand Total
<u>Medically Important³</u>	<i>Production⁵ or Production/Therapeutic⁶ Indications^{1,7}</i>	6,664,835	72%	45%
	<i>Therapeutic Indications Only^{1,6}</i>	2,531,968	28%	17%
	<i>Subtotal</i>	9,196,803	100%	62%
<u>Not Currently Medically Important⁴</u>	<i>Production Indications Only⁵</i>	60,184	1%	<1%
	<i>Production/Therapeutic⁶ Indications</i>	3,840,115	69%	26%
	<i>Therapeutic Indications Only⁶</i>	1,691,454	30%	11%
	<i>Subtotal</i>	5,591,752	100%	38%
<i>Grand Total</i>		14,788,555		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 cats).

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

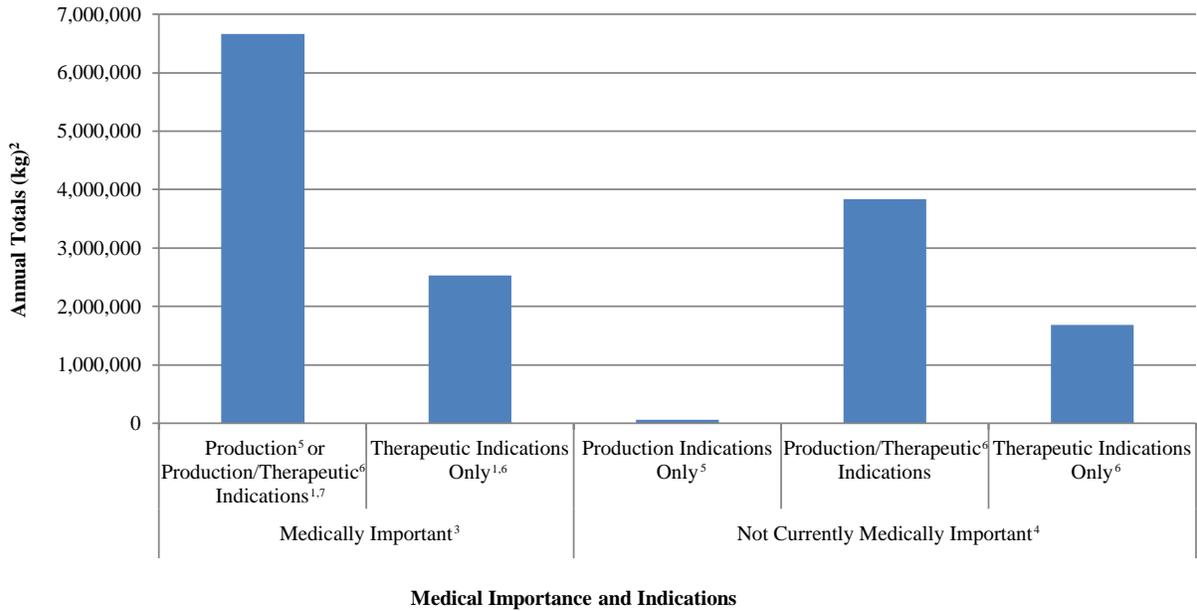
⁵ Production Indications (e.g., increased rate of weight gain or improved feed efficiency). Guidance for Industry #213 states that FDA believes that production use indications such as "increased rate of weight gain" or "improved feed efficiency" are no longer appropriate for the approved conditions of use for medically important antimicrobial drugs. It also states that FDA will be working with affected drug sponsors who wish to voluntarily withdraw approved production uses of their medically important antimicrobial new animal drugs and combination new animal drug products.

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

⁷ There were fewer than three distinct sponsors marketing medically important 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 5

**ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS¹
ACTIVELY MARKETED IN 2013
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 cats).
- 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 Currently Medically Important refers to any antimicrobial class not currently 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). Guidance for Industry #213 states that FDA believes that production use indications such as “increased rate of weight gain” or “improved feed efficiency” are no longer appropriate for the approved conditions of use for medically important antimicrobial drugs. It also states that FDA will be working with affected drug sponsors who wish to voluntarily withdraw approved production uses of their medically important antimicrobial new animal drugs and combination new animal drug products.
- ⁶ Therapeutic Indications (e.g., treatment, control, or prevention of a specific disease).
- ⁷ There were fewer than three distinct sponsors marketing antimicrobial animal drugs with only production indications (i.e., with no therapeutic indications). To protect confidential business information these data cannot be independently reported and are, therefore, combined with the data for drugs with both production and therapeutic (production/therapeutic) indications.

TABLE 6

ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS¹
 ACTIVELY MARKETED IN 2013
 DOMESTIC SALES AND DISTRIBUTION DATA
 REPORTED BY MEDICAL IMPORTANCE AND DISPENSING STATUS

	Dispensing Status	Annual Totals (kg)²	% Subtotal	% Grand Total
<u>Medically Important</u> ³	<i>OTC</i> ^{L,5}	8,968,260	98%	61%
	<i>RX</i> ^{L,6}	128,038	1%	<1%
	<i>RX</i> ⁶ / <i>OTC</i> ^{L,5,7}	54,942	<1%	<1%
	<i>VFD</i> ⁸	45,562	<1%	<1%
	<i>Subtotal</i>	9,196,803	100%	62%
<u>Not Currently Medically Important</u> ⁴	<i>OTC</i> ⁵	5,591,752		38%
<i>Grand Total</i>		14,788,555		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 cats).

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 Currently Medically Important refers to any antimicrobial class not currently 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.

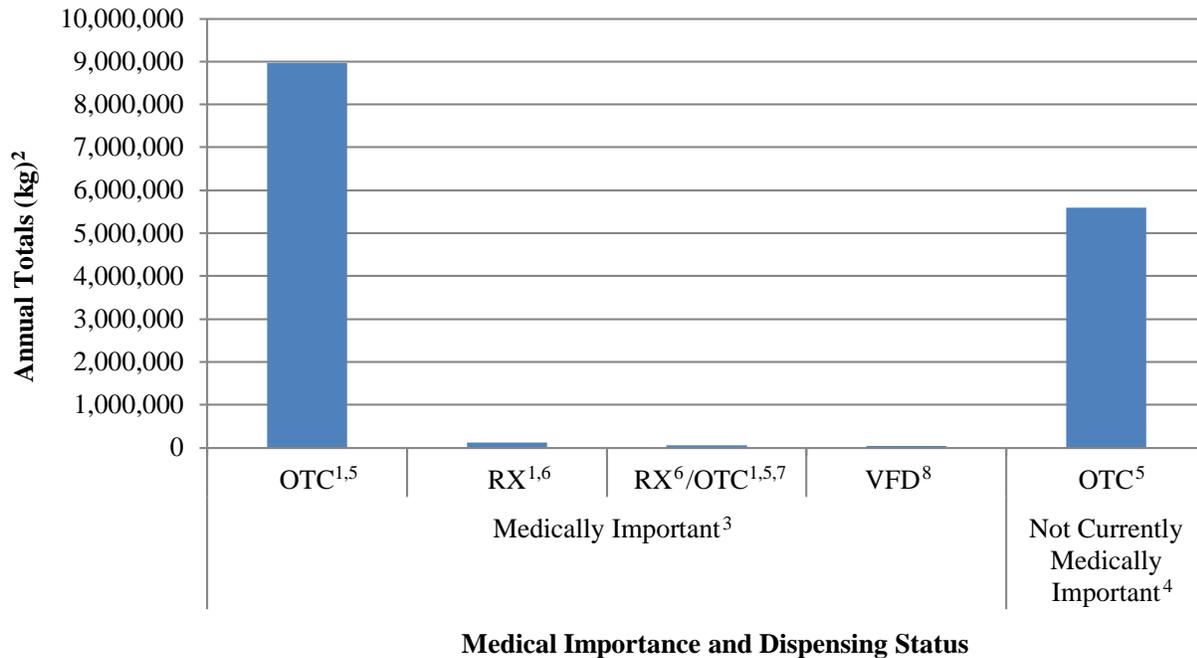
⁶ Rx = Prescription. Approved animal drugs that require a prescription from a licensed veterinarian.

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.

FIGURE 6

ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS¹
ACTIVELY MARKETED IN 2013
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 cats).
- 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 Currently Medically Important refers to any antimicrobial class not currently 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.

TABLE 7

**ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS¹
 ACTIVELY MARKETED IN 2013
 DOMESTIC SALES AND DISTRIBUTION DATA
 REPORTED BY MEDICAL IMPORTANCE, ROUTE OF ADMINISTRATION, AND DRUG CLASS**

	Route	Drug Class	Annual Total (kg)²	% Subtotal	% Grand Total
<u>Medically Important³</u>	Feed	<i>Sulfas</i>	90,723	<1%	<1%
		<i>Tetracyclines⁴</i>	5,699,364	62%	39%
		<i>Other Drugs⁷</i>	1,038,419	11%	7%
	Water	<i>Aminoglycosides</i>	205,874	2%	1%
		<i>Lincosamides</i>	88,709	<1%	<1%
		<i>Macrolides</i>	27,637	<1%	<1%
		<i>Penicillins</i>	672,131	7%	5%
		<i>Sulfas</i>	192,995	2%	1%
		<i>Tetracyclines</i>	719,529	8%	5%
		<i>Cephalosporins⁴</i>	28,337	<1%	<1%
	Other Routes⁵	<i>Sulfas⁴</i>	100,653	1%	<1%
		<i>Tetracyclines</i>	95,887	1%	<1%
		<i>Other Drugs^{4,8}</i>	236,544	3%	2%
		<i>Subtotal</i>	9,196,803	100%	62%
<u>Not Currently Medically Important⁴</u>	All Routes⁶	<i>All Drugs⁹</i>	5,591,752		38%
		<i>Grand Total</i>	14,788,555		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 cats).

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

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

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

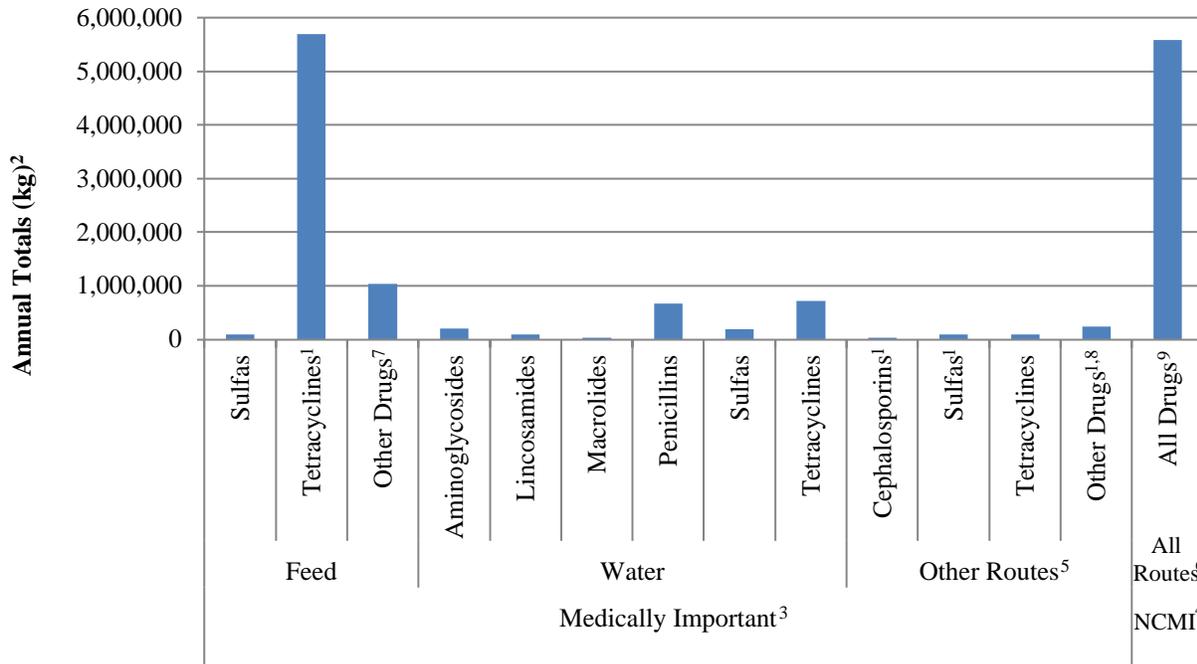
⁷ This category includes the following: Aminoglycosides, Amphenicols, Diaminopyrimidines, Lincosamides, Macrolides, Penicillins, and Streptogramins.

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

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

FIGURE 7

ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS¹
ACTIVELY MARKETED IN 2013
DOMESTIC SALES AND DISTRIBUTION DATA
REPORTED BY MEDICAL IMPORTANCE, ROUTE OF ADMINISTRATION, AND DRUG CLASS

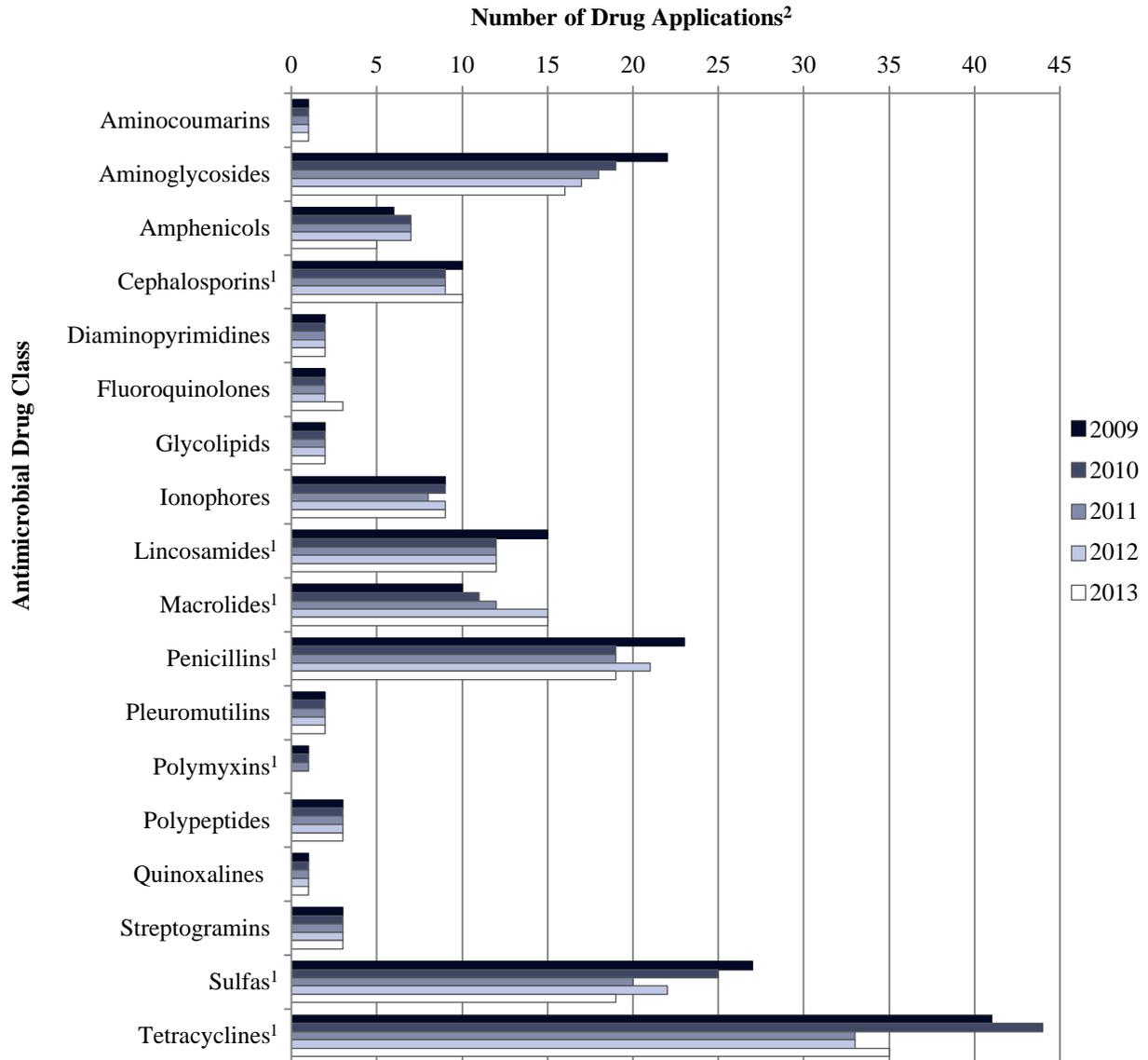


Medical Importance, Route of Administration, and Drug Class

- 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 cats).
- 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 NCMI = Not Currently Medically Important. Refers to any antimicrobial class not currently listed in Appendix A of FDA's Guidance for Industry #152.
- ⁵ This category includes the following: Injection, Intramammary, and Oral (excluding administration by means of feed or water).
- ⁶ This category includes the following: Feed, Injection, 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, and Penicillins.
- ⁹ This category includes the following: Aminocoumarins, Glycolipids, Ionophores, Pleuromutilins, Polypeptides, and Quinoxalines.

FIGURE 8a

**ANTIMICROBIAL DRUG CLASSES
APPROVED FOR USE IN FOOD-PRODUCING ANIMALS¹
ACTIVELY MARKETED 2009-2013 (DOMESTIC SALES)
NUMBER OF DRUG APPLICATIONS²**

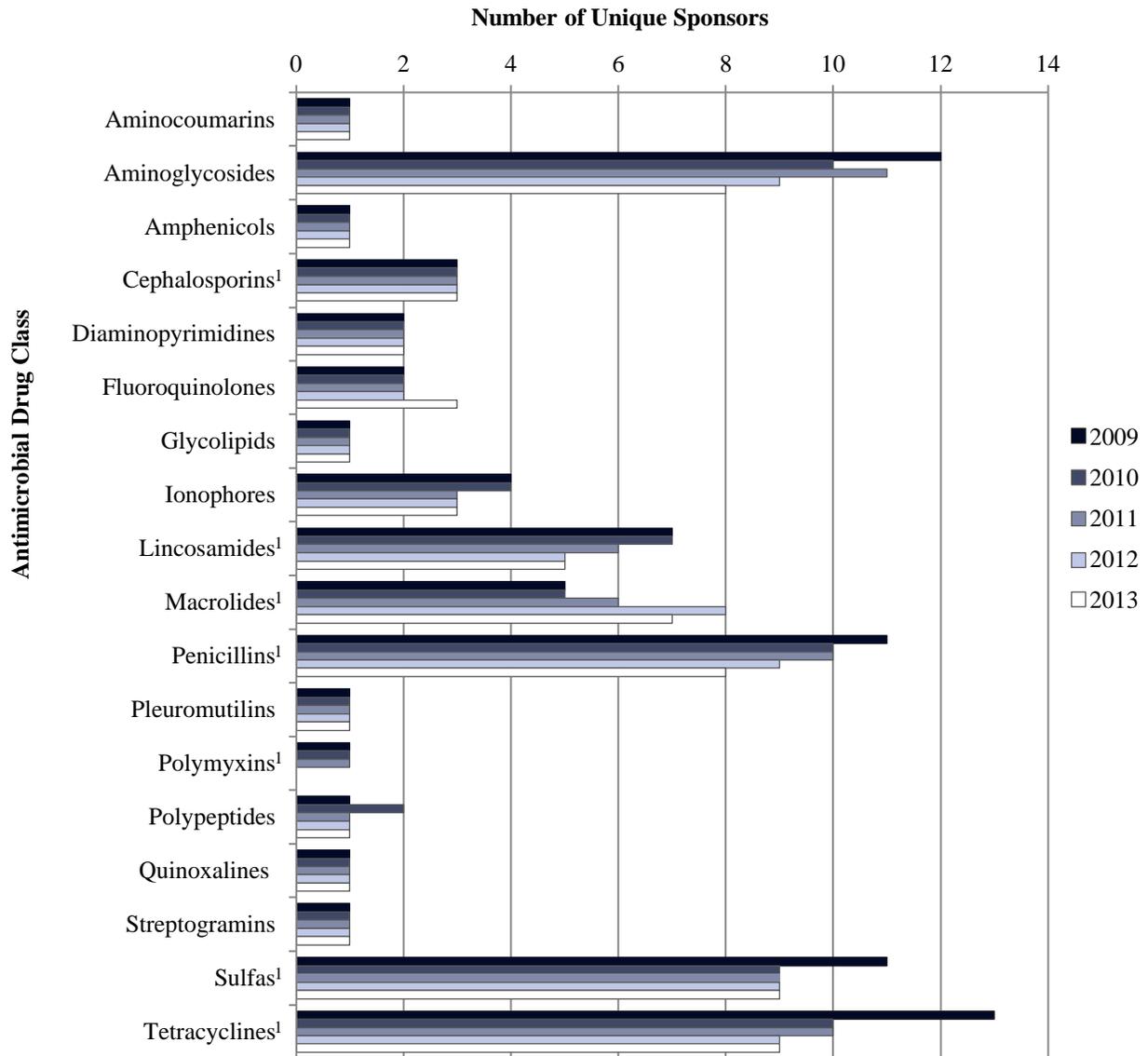


¹ Includes antimicrobial drug applications which are approved and labeled for use in both food-producing animals (e.g., cattle and swine) and nonfood-producing animals (e.g., dogs and cats).

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 ANIMALS¹
ACTIVELY MARKETED 2009-2013 (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 cats).

TABLE 9

**ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS¹
 ACTIVELY MARKETED 2009-2013
 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	% Change 2009 - 2013	% Change 2012 - 2013
<u>Domestic</u>	<i>Aminoglycosides</i>	223,117	211,790	214,895	273,536	270,342	21%	-1%
	<i>Cephalosporins^L</i>	20,145	24,588	26,611	27,654	28,337	41%	2%
	<i>Ionophores</i>	3,739,352	3,820,004	4,122,397	4,573,795	4,434,657	19%	-3%
	<i>Lincosamides^L</i>	93,330	154,653	190,101	218,140	236,450	153%	8%
	<i>Macrolides^L</i>	562,062	553,229	582,836	616,274	563,251	0%	-9%
	<i>Penicillins^L</i>	691,644	884,419	885,304	965,196	828,721	20%	-14%
	<i>Sulfas^L</i>	505,880	517,128	383,105	493,514	384,371	-24%	-22%
	<i>Tetracyclines^L</i>	5,260,995	5,602,281	5,652,855	5,954,361	6,514,779	24%	9%
	<i>NIR^{L,4}</i>	1,490,932	1,519,005	1,510,934	1,495,959	1,527,646	2%	2%
	<i>Subtotal</i>	12,587,457	13,287,097	13,569,037	14,618,428	14,788,555	17%	1%
<u>Export³</u>	<i>NIRE^{L,5}</i>	202,556	219,072	202,335	139,173	77,312	-62%	-44%
	<i>Grand Total</i>	12,790,013	13,506,168	13,771,373	14,757,601	14,865,867	15%	1%

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 cats).

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.

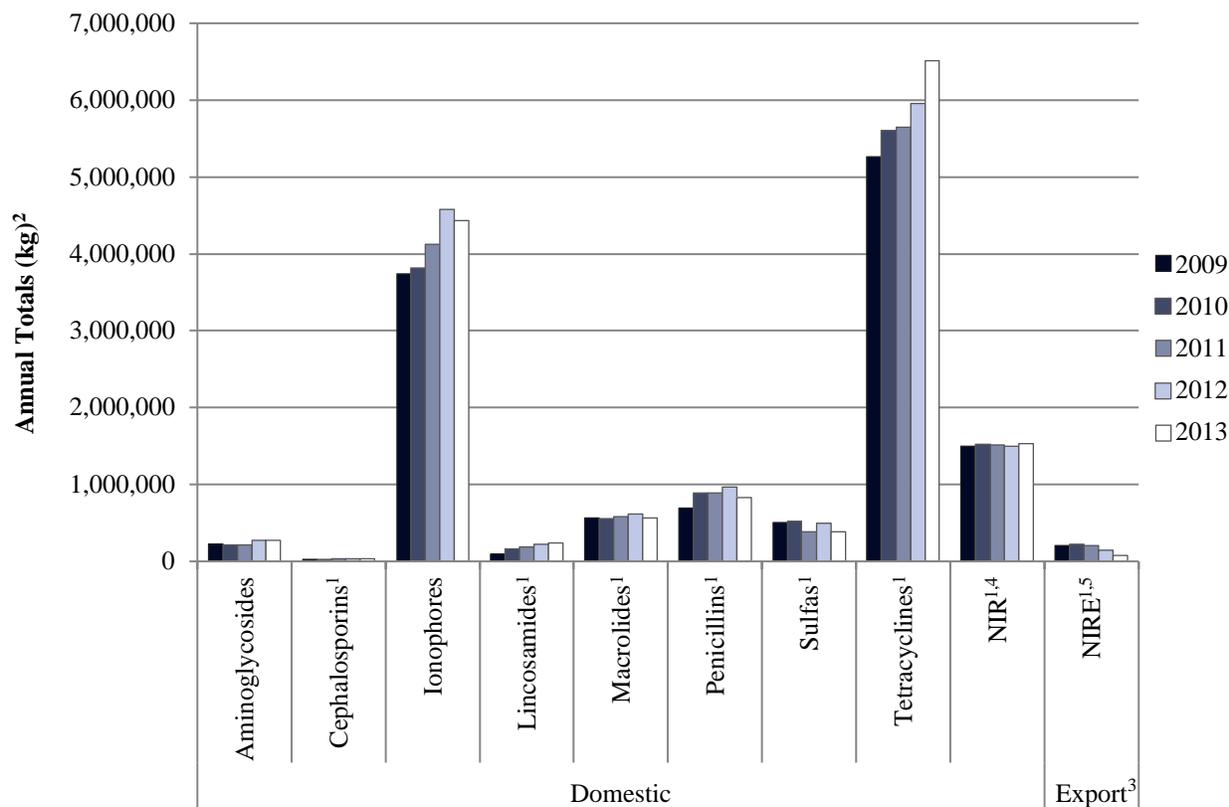
³ Only includes exports of FDA-approved, US-labeled antimicrobial drugs approved for use in food-producing animals.

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, Fluoroquinolones, Glycolipids, 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, 2011, 2012, and 2013), Aminoglycosides, Amphenicols, Cephalosporins, Diaminopyrimidines (excluding 2009), Ionophores, Lincosamides (excluding 2010, 2011, 2012, and 2013), Macrolides, Penicillins, Polymyxins (excluding 2010, 2011, 2012, and 2013), Polypeptides (excluding 2012 and 2013), Sulfonamides, and Tetracyclines.

FIGURE 9

**ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS¹
 ACTIVELY MARKETED 2009-2013
 SALES AND DISTRIBUTION DATA
 REPORTED BY DRUG CLASS**



Domestic/Export³ 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 cats).
- 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, Fluoroquinolones, Glycolipids, 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, 2011, 2012, and 2013), Aminoglycosides, Amphenicols, Cephalosporins, Diaminopyrimidines (excluding 2009), Ionophores, Lincosamides (excluding 2010, 2011, 2012, and 2013), Macrolides, Penicillins, Polymyxins (excluding 2010, 2011, 2012, and 2013), Polypeptides (excluding 2012 and 2013), Sulfonamides, and Tetracyclines.

TABLE 10

**ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS¹
 ACTIVELY MARKETED 2009-2013
 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	% Change 2009 - 2013	% Change 2012 - 2013
<u>Medically Important³</u>	<i>Aminoglycosides</i>	223,117	211,790	214,895	273,536	270,342	21%	-1%
	<i>Cephalosporins⁴</i>	20,145	24,588	26,611	27,654	28,337	41%	2%
	<i>Lincosamides⁴</i>	93,330	154,653	190,101	218,140	236,450	153%	8%
	<i>Macrolides⁴</i>	562,062	553,229	582,836	616,274	563,251	<1%	-9%
	<i>Penicillins⁴</i>	691,644	884,419	885,304	965,196	828,721	20%	-14%
	<i>Sulfas⁴</i>	505,880	517,128	383,105	493,514	384,371	-24%	-22%
	<i>Tetracyclines⁴</i>	5,260,995	5,602,281	5,652,855	5,954,361	6,514,779	24%	9%
	<i>NIR⁵</i>	329,391	281,221	319,991	344,428	370,551	12%	8%
	<i>Subtotal</i>	7,686,564	8,229,309	8,255,697	8,893,101	9,196,803	20%	3%
<u>Not Currently Medically Important⁴</u>	<i>Ionophores</i>	3,739,352	3,820,004	4,122,397	4,573,795	4,434,657	19%	-3%
	<i>NIR⁶</i>	1,161,541	1,237,784	1,190,943	1,151,532	1,157,095	<1%	0%
		<i>Subtotal</i>	4,900,893	5,057,788	5,313,340	5,725,327	5,591,752	14%
	<i>Grand Total</i>	12,587,457	13,287,097	13,569,037	14,618,428	14,788,555	17%	1%

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 cats).

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.

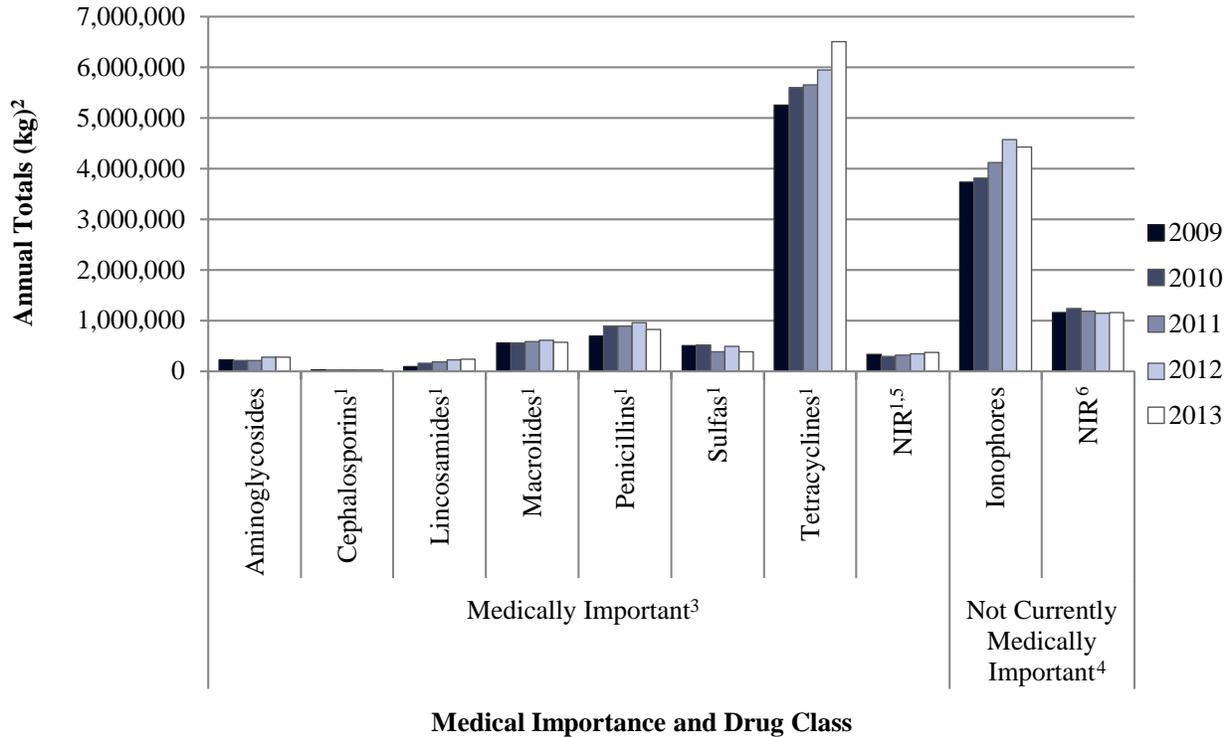
⁴ Not Currently Medically Important refers to any antimicrobial class not currently listed in Appendix A of FDA's Guidance for Industry #152.

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, Fluoroquinolones, 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, Pleuromutilins, Polypeptides, and Quinoxalines.

FIGURE 10

**ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS¹
ACTIVELY MARKETED 2009-2013
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 cats).
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 Currently Medically Important refers to any antimicrobial class not currently 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, Fluoroquinolones, 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, Pleuromutilins, Polypeptides, and Quinoxalines.

TABLE 11a

**ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS¹
ACTIVELY MARKETED 2009-2013
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	% Change 2009 - 2013	% Change 2012 - 2013
<u>Medically Important³</u>	<i>Feed⁴</i>	5,687,084	5,957,748	5,933,440	6,246,451	6,828,506	20%	9%
	<i>Injection⁴</i>	388,518	421,272	416,775	393,422	352,693	-9%	-10%
	<i>Intramammary</i>	23,409	24,692	21,023	25,979	9,875	-58%	-62%
	<i>Oral^{4,5} or Topical^{4,8}</i>	120,506	109,839	126,775	113,409	98,854	-18%	-13%
	<i>Water⁶</i>	1,467,048	1,715,757	1,757,686	2,113,840	1,906,875	30%	-10%
	<i>Subtotal</i>	7,686,564	8,229,309	8,255,697	8,893,101	9,196,803	20%	3%
<u>Not Currently Medically Important⁴</u>	<i>All Routes⁷</i>	4,900,893	5,057,788	5,313,340	5,725,327	5,591,752	14%	-2%
	<i>Grand Total</i>	12,587,457	13,287,097	13,569,037	14,618,428	14,788,555	17%	1%

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 cats).

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

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

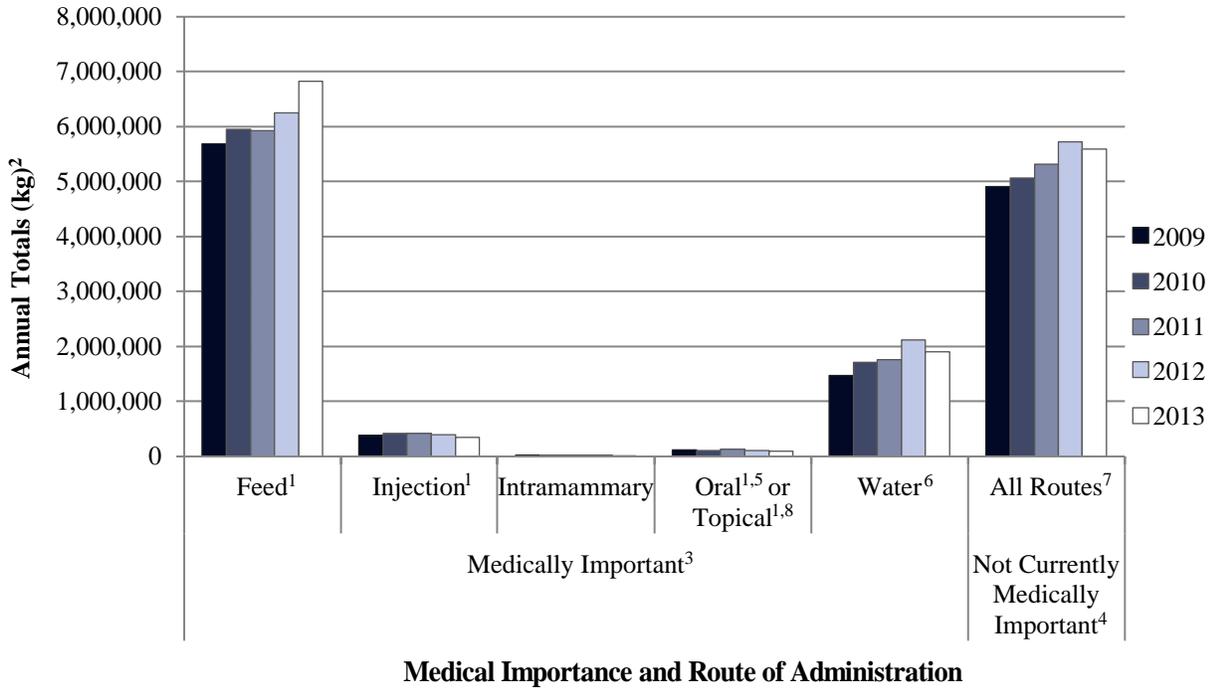
⁶ Water includes when the drug is administered either through drinking water, as a drench, or through the immersion of fish.

⁷ This category includes the following: Feed, Water, and Intramammary. In order to protect confidential business information, the routes of administration for the Not Currently 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 ANIMALS¹
 ACTIVELY MARKETED 2009-2013
 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 cats).

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 Currently Medically Important refers to any antimicrobial class not currently 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, or through the immersion of fish.

⁷ This category includes the following: Feed, Water, and Intramammary. In order to protect confidential business information, the routes of administration for the Not Currently 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 ANIMALS¹
ACTIVELY MARKETED 2009-2013
PERCENTAGE OF DOMESTIC SALES AND DISTRIBUTION
MEDICALLY IMPORTANT² 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
<i>Feed¹</i>	74%	72%	72%	70%	74%
<i>Injection¹</i>	5%	5%	5%	4%	4%
<i>Intramammary</i>	<1%	<1%	<1%	<1%	<1%
<i>Oral^{1,3} or Topical^{1,5}</i>	2%	1%	2%	1%	1%
<i>Water⁴</i>	19%	21%	21%	24%	21%
<i>Total</i>	<i>100%</i>	<i>100%</i>	<i>100%</i>	<i>100%</i>	<i>100%</i>

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 cats).

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.

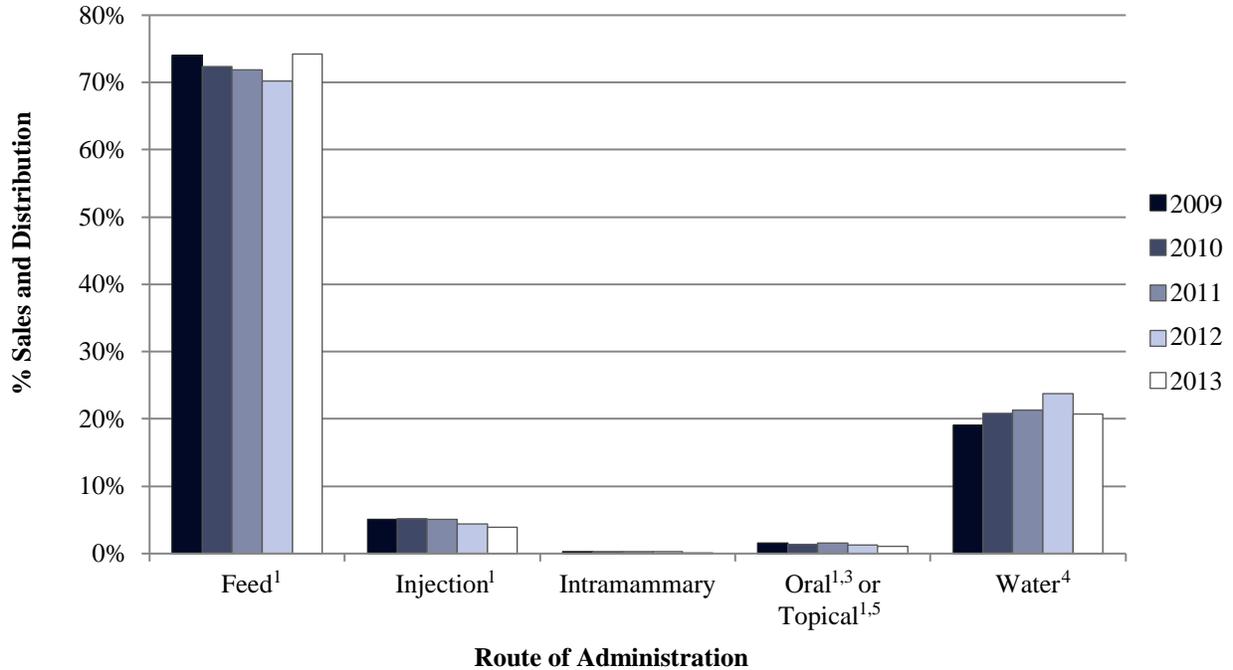
³ Orally administered, excluding administration by means of feed and water.

⁴ Water includes when the drug is administered either through drinking water, as a drench, or through the immersion of fish.

⁵ No Topical sales and distribution in 2012 and 2013.

FIGURE 11b

ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS¹
ACTIVELY MARKETED 2009-2013
PERCENTAGE OF DOMESTIC SALES AND DISTRIBUTION
MEDICALLY IMPORTANT² 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 cats).

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, or through the immersion of fish.

⁵ No Topical sales and distribution in 2012 and 2013.

TABLE 12a

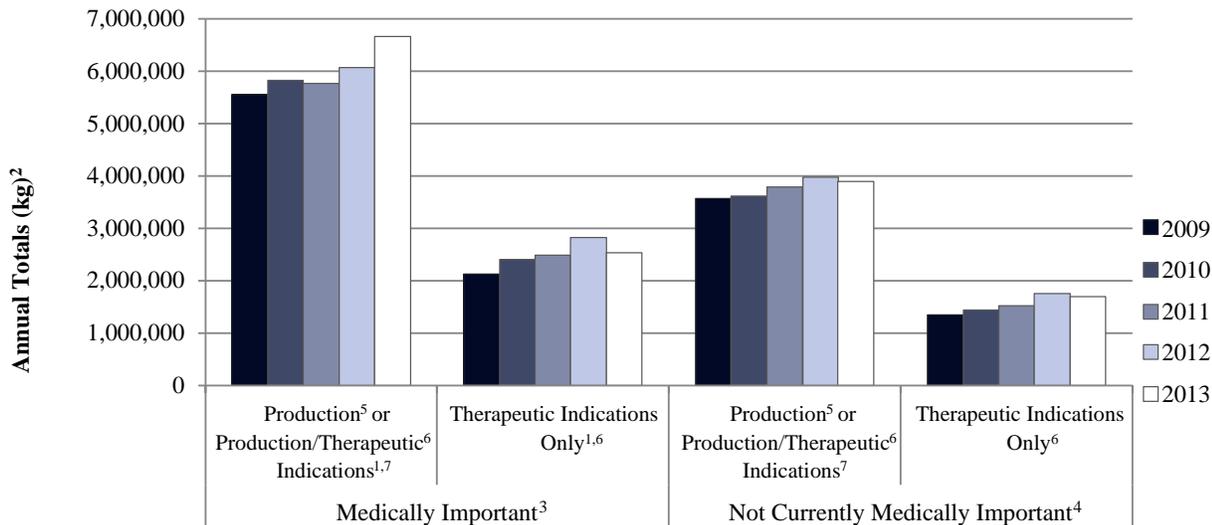
ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS¹
ACTIVELY MARKETED 2009-2013
DOMESTIC SALES AND DISTRIBUTION DATA
REPORTED BY MEDICAL IMPORTANCE AND INDICATIONS

	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	% Change 2009 - 2013	% Change 2012 - 2013
Medically Important ³	<i>Production⁵ or Production/Therapeutic⁶ Indications^{1,7}</i>	5,563,029	5,828,079	5,770,871	6,073,485	6,664,835	20%	10%
	<i>Therapeutic Indications Only^{1,6}</i>	2,123,536	2,401,230	2,484,827	2,819,616	2,531,968	19%	-10%
	Subtotal	7,686,564	8,229,309	8,255,697	8,893,101	9,196,803	20%	3%
Not Currently Medically Important ⁴	<i>Production⁵ or Production/Therapeutic⁶ Indications²</i>	3,562,501	3,622,315	3,790,628	3,972,057	3,900,298	9%	-2%
	<i>Therapeutic Indications Only⁶</i>	1,338,391	1,435,473	1,522,712	1,753,270	1,691,454	26%	-4%
	Subtotal	4,900,893	5,057,788	5,313,340	5,725,327	5,591,752	14%	-2%
	Grand Total	12,587,457	13,287,097	13,569,037	14,618,428	14,788,555	17%	1%

- 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 cats).
- 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 Currently Medically Important refers to any antimicrobial class not currently 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). Guidance for Industry #213 states that FDA believes that production use indications such as "increased rate of weight gain" or "improved feed efficiency" are no longer appropriate for the approved conditions of use for medically important antimicrobial drugs. It also states that FDA will be working with affected drug sponsors who wish to voluntarily withdraw approved production uses of their medically important antimicrobial new animal drugs and combination new animal drug products.
- ⁶ Therapeutic Indications (e.g., treatment, control, or prevention of a specific disease).
- ⁷ There were fewer than three distinct sponsors (excluding 2012 and 2013 for the NCMI 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 ANIMALS¹
 ACTIVELY MARKETED 2009-2013
 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 cats).
- 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 Currently Medically Important refers to any antimicrobial class not currently 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). Guidance for Industry #213 states that FDA believes that production use indications such as “increased rate of weight gain” or “improved feed efficiency” are no longer appropriate for the approved conditions of use for medically important antimicrobial drugs. It also states that FDA will be working with affected drug sponsors who wish to voluntarily withdraw approved production uses of their medically important antimicrobial new animal drugs and combination new animal drug products.
- ⁶ Therapeutic Indications (e.g., treatment, control, or prevention of a specific disease).
- ⁷ There were fewer than three distinct sponsors (excluding 2012 and 2013 for the NCMI 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 ANIMALS¹
ACTIVELY MARKETED 2009-2013
PERCENTAGE OF DOMESTIC SALES AND DISTRIBUTION
MEDICALLY IMPORTANT² 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
<i>Production³ or Production/Therapeutic⁴ Indications^{1,5}</i>	72%	71%	70%	68%	72%
<i>Therapeutic Indications Only^{1,4}</i>	28%	29%	30%	32%	28%
Total	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 cats).

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.

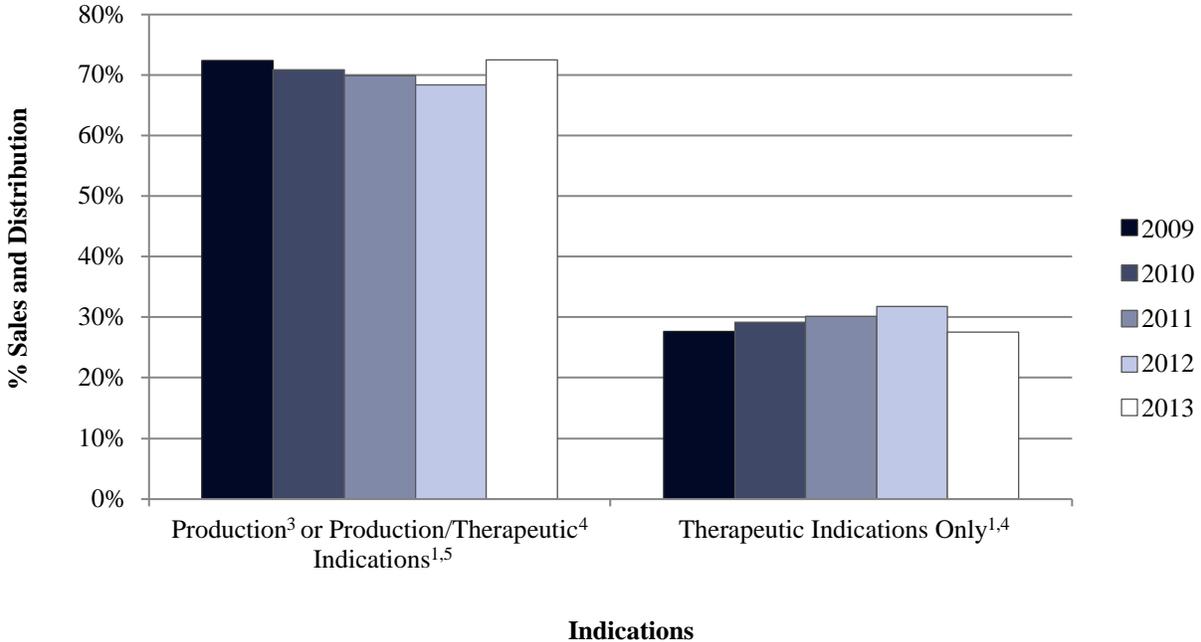
³ Production Indications (e.g., increased rate of weight gain or improved feed efficiency). Guidance for Industry #213 states that FDA believes that production use indications such as "increased rate of weight gain" or "improved feed efficiency" are no longer appropriate for the approved conditions of use for medically important antimicrobial drugs. It also states that FDA will be working with affected drug sponsors who wish to voluntarily withdraw approved production uses of their medically important antimicrobial new animal drugs and combination new animal drug products.

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

⁵ There were fewer than three distinct sponsors (excluding 2012 and 2013 for the NCMI category) marketing antimicrobial animal drugs with only production indications (i.e., with no therapeutic indications). To protect confidential business information these data cannot be independently reported and are, therefore, combined with the data for drugs with both production and therapeutic (production/therapeutic) indications.

FIGURE 12b

ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS¹
ACTIVELY MARKETED 2009-2013
PERCENTAGE OF DOMESTIC SALES AND DISTRIBUTION
MEDICALLY IMPORTANT² 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 cats).
- 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 Production Indications (e.g., increased rate of weight gain or improved feed efficiency). Guidance for Industry #213 states that FDA believes that production use indications such as “increased rate of weight gain” or “improved feed efficiency” are no longer appropriate for the approved conditions of use for medically important antimicrobial drugs. It also states that FDA will be working with affected drug sponsors who wish to voluntarily withdraw approved production uses of their medically important antimicrobial new animal drugs and combination new animal drug products.
- ⁴ Therapeutic Indications (e.g., treatment, control, or prevention of a specific disease).
- ⁵ There were fewer than three distinct sponsors (excluding 2012 and 2013 for the NCMI category) marketing antimicrobial animal drugs with only production indications (i.e., with no therapeutic indications). To protect confidential business information these data cannot be independently reported and are, therefore, combined with the data for drugs with both production and therapeutic (production/therapeutic) indications.

TABLE 13a

ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS¹
ACTIVELY MARKETED 2009-2013
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	% Change 2009 - 2013	% Change 2012 - 2013
Medically Important³	<i>OTC^{L,5}</i>	7,506,644	8,050,340	8,029,437	8,637,835	8,968,260	19%	4%
	<i>RX⁶/OTC^{L,5,7}</i>	44,117	47,901	50,205	54,968	54,942	25%	<1%
	<i>RX⁶ or VFD^{L,8,9}</i>	135,803	131,068	176,055	200,298	173,600	28%	-13%
	Subtotal	7,686,564	8,229,309	8,255,697	8,893,101	9,196,803	20%	3%
Not Currently Medically Important⁴	<i>OTC⁵</i>	4,900,893	5,057,788	5,313,340	5,725,327	5,591,752	14%	-2%
	Grand Total	12,587,457	13,287,097	13,569,037	14,618,428	14,788,555	17%	1%

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 cats).

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 Currently Medically Important refers to any antimicrobial class not currently 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.

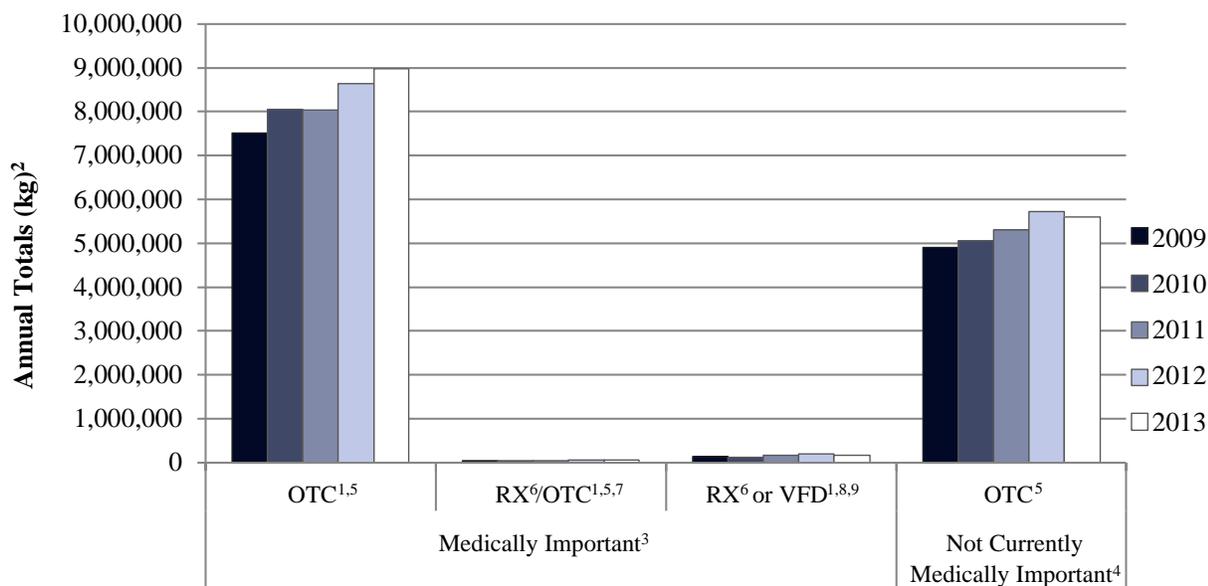
⁷ Animal drugs that were approved with both a prescription and OTC dispensing status (RX/OTC), with the approved drug being marketed with either a prescription label or an OTC label, depending upon the species and indication on the label.

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).

FIGURE 13a

ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS¹
ACTIVELY MARKETED 2009-2013
DOMESTIC SALES AND DISTRIBUTION DATA
REPORTED BY MEDICAL IMPORTANCE AND DISPENSING STATUS



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 cats).
- 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 Currently Medically Important refers to any antimicrobial class not currently 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).

TABLE 13b

ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS¹
ACTIVELY MARKETED 2009-2013
PERCENTAGE OF DOMESTIC SALES AND DISTRIBUTION
MEDICALLY IMPORTANT² 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
<i>OTC</i> ^{L.3}	98%	98%	97%	97%	98%
<i>RX</i> ⁴ / <i>OTC</i> ^{L.3.5}	<1%	<1%	<1%	<1%	<1%
<i>RX</i> ⁴ or <i>VFD</i> ^{L.6.7}	2%	2%	2%	2%	2%
Total	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 cats).

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.

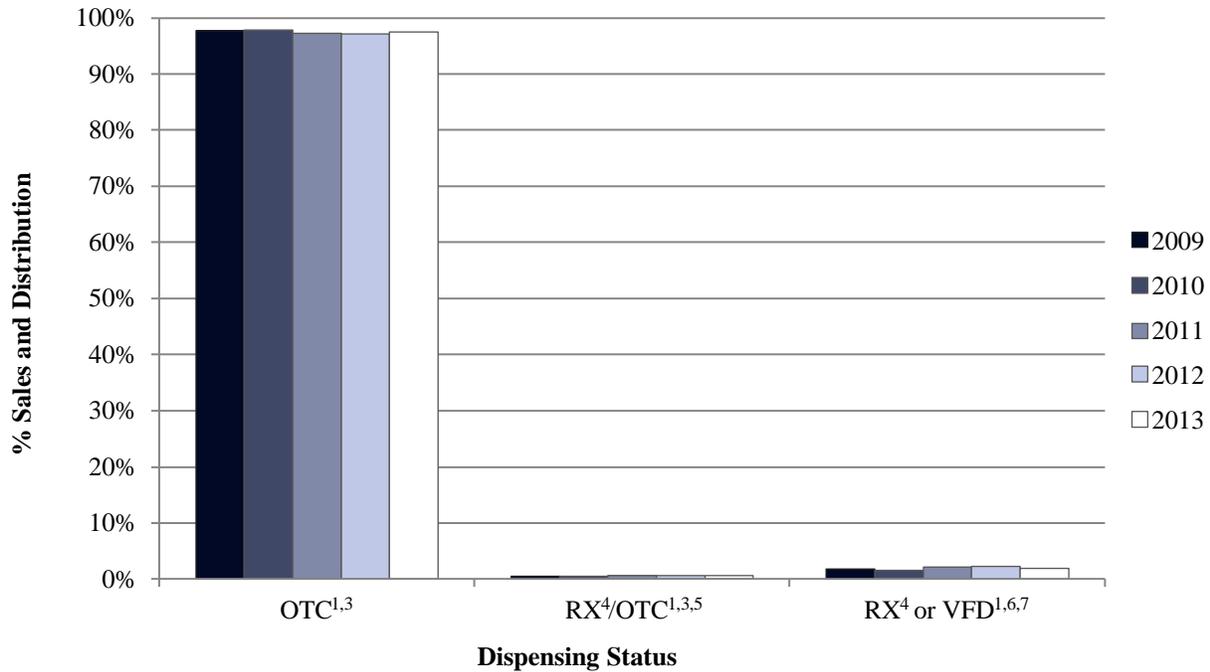
⁵ Animal drugs that were approved with both a prescription and OTC dispensing status (RX/OTC), with the approved drug being marketed with either a prescription label or an OTC label, depending upon the species and indication on the label.

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).

FIGURE 13b

ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS¹
ACTIVELY MARKETED 2009-2013
PERCENTAGE OF DOMESTIC SALES AND DISTRIBUTION
MEDICALLY IMPORTANT² 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 cats).
- 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).

TABLE 14

**ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS¹
 ACTIVELY MARKETED 2009-2013
 DOMESTIC SALES AND DISTRIBUTION DATA
 REPORTED BY MEDICAL IMPORTANCE, ROUTE OF ADMINISTRATION, 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	% Change 2009 - 2013	% Change 2012 - 2013
Medically Important³	Feed	<i>Sulfas</i>	113,658	109,983	105,400	90,972	90,723	-20%	<1%
		<i>Tetracyclines⁴</i>	4,594,714	4,921,071	4,848,946	5,085,178	5,699,364	24%	12%
		<i>Other Drugs⁷</i>	978,711	926,695	979,093	1,070,301	1,038,419	6%	-3%
	Water	<i>Aminoglycosides</i>	140,652	153,907	162,672	195,043	205,874	46%	6%
		<i>Lincosamides</i>	25,033	41,186	66,510	72,187	88,709	254%	23%
		<i>Penicillins</i>	448,166	630,946	650,220	753,510	672,131	50%	-11%
		<i>Sulfas</i>	265,873	289,529	145,972	283,909	192,995	-27%	-32%
		<i>Tetracyclines</i>	574,408	582,660	710,403	782,959	719,529	25%	-8%
		<i>Other Drugs⁸</i>	12,916	17,529	21,909	26,233	27,637	114%	5%
		Other Routes⁵	<i>Cephalosporins⁴</i>	20,145	24,588	26,611	27,654	28,337	41%
	<i>Sulfas⁴</i>	126,349	117,617	131,733	118,633	100,653	-20%	-15%	
	<i>Tetracyclines⁴</i>	91,874	98,551	93,506	86,224	95,887	4%	11%	
	<i>Other Drugs^{4,9}</i>	294,065	315,048	312,723	300,300	236,544	-20%	-21%	
	Subtotal	7,686,564	8,229,309	8,255,697	8,893,101	9,196,803	20%	3%	
Not Currently Medically Important⁴	All Routes⁶	<i>All Drugs¹⁰</i>	4,900,893	5,057,788	5,313,340	5,725,327	5,591,752	14%	-2%
		Grand Total	12,587,457	13,287,097	13,569,037	14,618,428	14,788,555	17%	1%

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 cats).

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 Currently Medically Important refers to any antimicrobial class not currently 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.

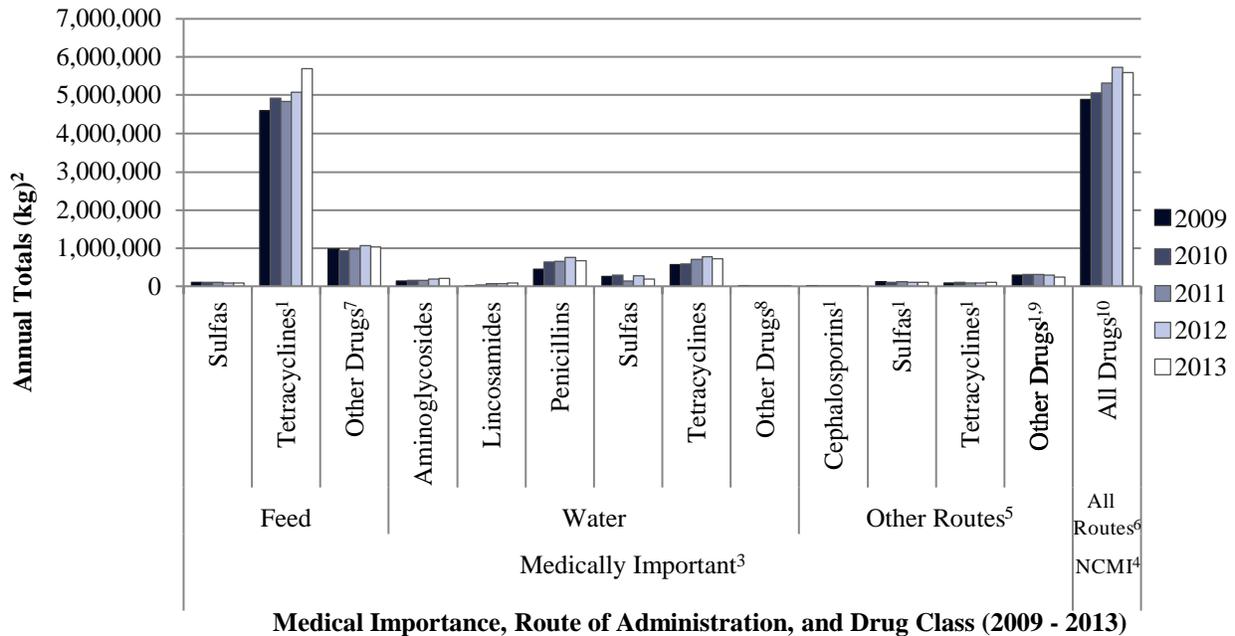
⁸ This category includes the following: Amphenicols (excluding 2013) and Macrolides.

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

¹⁰ This category includes the following: Aminocoumarins, Glycolipids, Ionophores, Pleuromutilins, Polypeptides, and Quinoxalines.

FIGURE 14

**ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS¹
ACTIVELY MARKETED 2009-2013
DOMESTIC SALES AND DISTRIBUTION DATA
REPORTED BY MEDICAL IMPORTANCE, ROUTE OF ADMINISTRATION, 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 cats).
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 NCMI = Not Currently Medically Important. Refers to any antimicrobial class not currently 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 Macrolides.
⁹ This category includes the following: Aminoglycosides, Amphenicols, Fluoroquinolones, Lincosamides, Macrolides, Penicillins, and Polymyxins (excluding 2012 and 2013).
¹⁰ This category includes the following: Aminocoumarins, Glycolipids, Ionophores, Pleuromutilins, Polypeptides, and Quinoxalines.

REFERENCES

- **FDA Webpage on Antimicrobial Resistance**
 - <http://www.fda.gov/newsevents/publichealthfocus/ucm235649.htm>
- **FDA/CVM Webpage on Antimicrobial Resistance**
 - <http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/default.htm>
- **FDA/CVM Webpage on the National Antimicrobial Resistance Monitoring System (NARMS)**
 - <http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/NationalAntimicrobialResistanceMonitoringSystem/default.htm>
- **FDA/CVM Webpage on Judicious Use of Antimicrobials**
 - <http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/JudiciousUseofAntimicrobials/default.htm>
- **FDA/CDER Webpage on Antimicrobial Resistance**
 - <http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm135344.htm>
- **FDA Guidance for Industry #152**
 - “Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern”
 - <http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm052519.pdf>
- **FDA Guidance for Industry #209**
 - “The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals”
 - <http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM216936.pdf>
- **FDA Guidance for Industry #213**
 - “New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209”
 - <http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM299624.pdf>