

2011

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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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 this summary data are generated.

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 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 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 \(2011\): 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 \(2011\): 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 \(2011\): Domestic Sales - Medically important antimicrobial drugs and drug class](#)

[Observations Current Reporting Year \(2011\): 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 \(2011\): Domestic Sales - Medically important antimicrobial drugs and route of administration](#)

[Observations Current Reporting Year \(2011\): Domestic Sales - Antimicrobial drugs not currently medically important and route of administration](#)

[Table 5 – Domestic Sales: Medical Importance and Indication](#)

[Figure 5 – Domestic Sales: Medical Importance and Indication](#)

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 \(2011\): Domestic Sales - Medically important antimicrobial drugs and indications](#)

[Observations Current Reporting Year \(2011\): 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 \(2011\): Domestic Sales - Medically important antimicrobial drugs and dispensing status](#)

[Observations Current Reporting Year \(2011\): 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 \(2011\): Domestic Sales - Medically important antimicrobial drugs by route of administration and drug class](#)

[Observations Current Reporting Year \(2011\): Domestic Sales - Antimicrobial drugs not currently medically important by route of administration and drug class](#)

VI. Sales and Distribution Observations

In 2011, there were 24 sponsors of 135 approved new animal drug applications for antimicrobials actively marketed for use in food-producing animals ([Table 1](#), [Figure 1a](#), and [Figure 1b](#)).

In 2011, sales and distribution (domestic and export) of antimicrobials approved for use in food-producing animals was approximately 13.8 million kilograms. Domestic sales and distribution of antimicrobials approved for use in food-producing animals was approximately 13.6 million kilograms (approximately 99%), and export sales were approximately 202.3 thousand kilograms (approximately 1%) ([Table 2](#) and [Figure 2](#)). Tetracyclines accounted for 42% and ionophores for 30% of domestic sales. Tetracyclines accounted for 8% and sulfonamides for 7% of export sales. Because of confidentiality constraints, export sales and distribution data for antimicrobials approved for use in food-producing animals cannot be further reported.

A. Domestic sales and distribution of antimicrobials not currently medically important

In 2011, domestic sales and distribution of antimicrobials that are not currently medically important (NCMI) accounted for 39% of the domestic sales of all antimicrobials approved for use in food-producing animals; 78% 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](#)).

In 2011, domestic sales and distribution of NCMI antimicrobials approved for use in food-producing animals administered in feed accounted for 99% of the domestic sales of all NCMI antimicrobials for use in food-producing animals, while products by intramammary or by water administration accounted for 1% ([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 2011, 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 accounted for 71% of the domestic sales of all NCMI antimicrobials approved for use in food-producing animals. In 2011, domestic sales and distribution of NCMI antimicrobials that are approved for use in food-producing animals and are labeled solely for therapeutic indications accounted for 29% of the domestic sales of all NCMI antimicrobials approved for use in food-producing animals ([Table 5](#) and [Figure 5](#)).

In 2011, domestic sales and distribution of NCMI antimicrobials that are approved for use in food-producing animals labeled with an OTC dispensing status accounted for 39% 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](#)).

B. Domestic sales and distribution of medically important antimicrobials

In 2011, domestic sales and distribution of medically important antimicrobials accounted for 61% of the domestic sales of all antimicrobials approved for use in food-producing animals. Of these sales, tetracyclines accounted for 68%, penicillins for 11%, macrolides for 7%, sulfonamides for 5%, aminoglycosides for 3%, lincosamides for 2%, 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](#)).

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. In 2011, domestic sales and distribution of medically important antimicrobials approved for use in food-producing animals administered in feed accounted for 72% of the domestic sales of all medically important antimicrobials for use in food-producing animals, products administered by water for 21%, by means of injection for 5%, oral or topical administration for 2%, and intramammary

administration for less than 1% ([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 2011, 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 70% of the domestic sales of all medically important antimicrobials approved for use in food-producing animals. In 2011, 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 30% of the domestic sales of all medically important antimicrobials approved for use in food-producing animals ([Table 5](#) and [Figure 5](#)).

Because of confidentiality constraints, FDA cannot provide sales and distribution data for products labeled with VFD dispensing status; therefore, products labeled with either a VFD dispensing status or Rx dispensing status are combined into a single category. We can provide sales and distribution data for products approved with an OTC dispensing status. In 2011, domestic sales and distribution of medically important antimicrobials approved for use in food-producing animals labeled with solely an OTC dispensing status accounted for 97% of the domestic sales of all medically important antimicrobials for use in food-producing animals ([Table 6](#) and [Figure 6](#)).

In 2011, tetracyclines administered by feed accounted for 59% of domestic sales and distribution of medically important antimicrobials approved for use in food-producing animals, sulfas for 1%, and all other medically important antimicrobials for 12%. In 2011, tetracyclines administered by water accounted for 9% of domestic sales and distribution of medically important antimicrobials approved for use in food-producing animals, penicillins for 8%, sulfas for 2%, aminoglycosides for 2%, lincosamides for less than 1%, and all other medically important antimicrobials for less than 1%. In 2011, sulfonamides administered by all other routes of administration accounted for 2% of domestic sales and distribution of medically important antimicrobials approved for use in food-producing animals, tetracyclines for 1%, cephalosporins for less than 1%, and all other drugs for 4% ([Table 7](#) and [Figure 7](#)).

TABLE 1

**ANTIMICROBIAL DRUG CLASSES AND ACTIVE INGREDIENTS
APPROVED FOR USE IN FOOD-PRODUCING ANIMALS¹
ACTIVELY MARKETED IN 2011**

Aminocoumarins (NCMI)³

Novobiocin

Aminoglycosides (MI)²

Dihydrostreptomycin

Gentamicin

Neomycin

Spectinomycin

Streptomycin

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

Erythromycin¹

Gamithromycin⁴

Tilmicosin

Tulathromycin

Tylosin

Penicillins (MI)²

Amoxicillin

Ampicillin¹

Cloxacillin

Penicillin¹

Pleuromutilins (NCMI)³

Tiamulin

Polymyxins (MI)²

Polymyxin B¹

Polypeptides (NCMI)³

Bacitracin

Quinoxalines (NCMI)³

Carbadox

Streptogramins (MI)²

Virginiamycin

Sulfonamides (Sulfas) (MI)²

Sulfadimethoxine

Sulfamerazine

Sulfamethazine¹

Sulfaquinoxaline

Tetracyclines (MI)²

Chlortetracycline¹

Oxytetracycline¹

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).

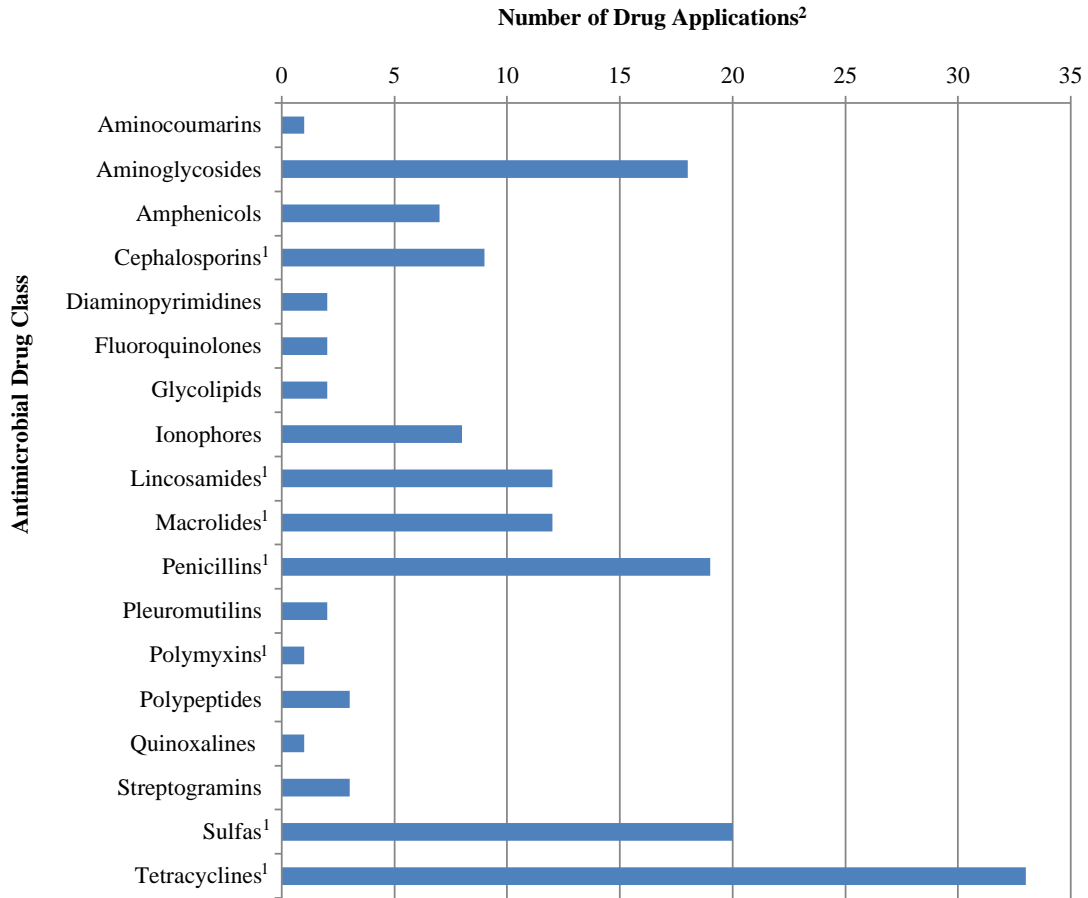
² Guidance for Industry #213 states that all antimicrobial drugs and their associated classes listed in Appendix A of FDA's Guidance for Industry #152 are considered "medically important" in human medical therapy.

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

⁴ Active ingredient not marketed in previous year (2011) for use in food-producing animals.

FIGURE 1a

**ANTIMICROBIAL DRUG CLASSES
APPROVED FOR USE IN FOOD-PRODUCING ANIMALS¹
ACTIVELY MARKETED IN 2011 (DOMESTIC SALES)
NUMBER OF DRUG APPLICATIONS²**

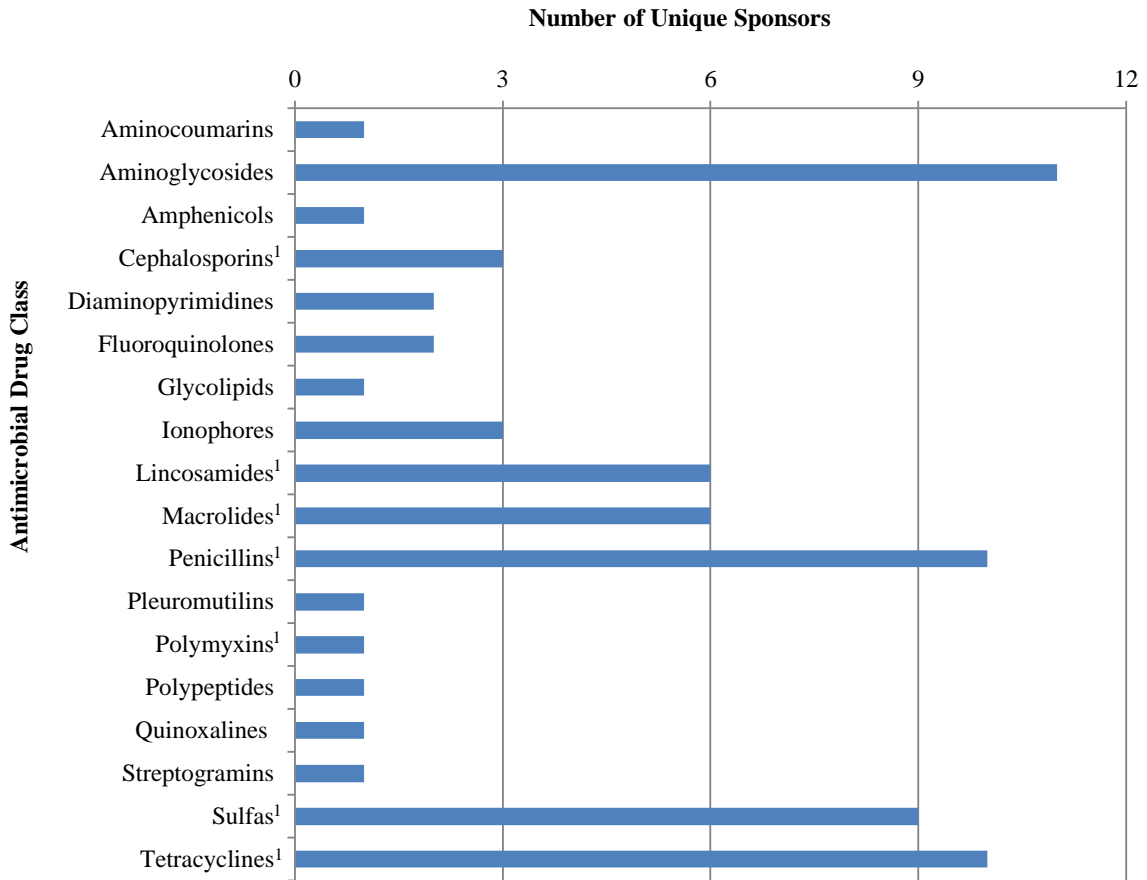


¹ Includes antimicrobial drug applications which are approved and labeled for use in both food-producing animals (e.g., cattle and swine) and nonfood-producing animals (e.g., dogs and cats).

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 2011 (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 2011
 SALES AND DISTRIBUTION DATA
 REPORTED BY DRUG CLASS

	Drug Class	Annual Totals (kg)²	% Subtotal	% Grand Total
<u>Domestic</u>	<i>Aminoglycosides</i>	214,895	2%	2%
	<i>Cephalosporins</i> ¹	26,611	<1%	<1%
	<i>Ionophores</i>	4,122,397	30%	30%
	<i>Lincosamides</i> ¹	190,101	1%	1%
	<i>Macrolides</i> ¹	582,836	4%	4%
	<i>Penicillins</i> ¹	885,304	7%	6%
	<i>Sulfas</i> ¹	383,105	3%	3%
	<i>Tetracyclines</i> ¹	5,652,855	42%	41%
	<i>NIR</i> ^{1,4}	1,510,934	11%	11%
	<i>Subtotal</i>	13,569,037	100%	99%
<u>Export</u> ³	<i>Sulfas</i>	15,005	7%	<1%
	<i>Tetracyclines</i> ¹	15,321	8%	<1%
	<i>NIRE</i> ^{1,5}	172,009	85%	1%
	<i>Subtotal</i>	202,335	100%	1%
<i>Grand Total</i>		13,771,373		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.

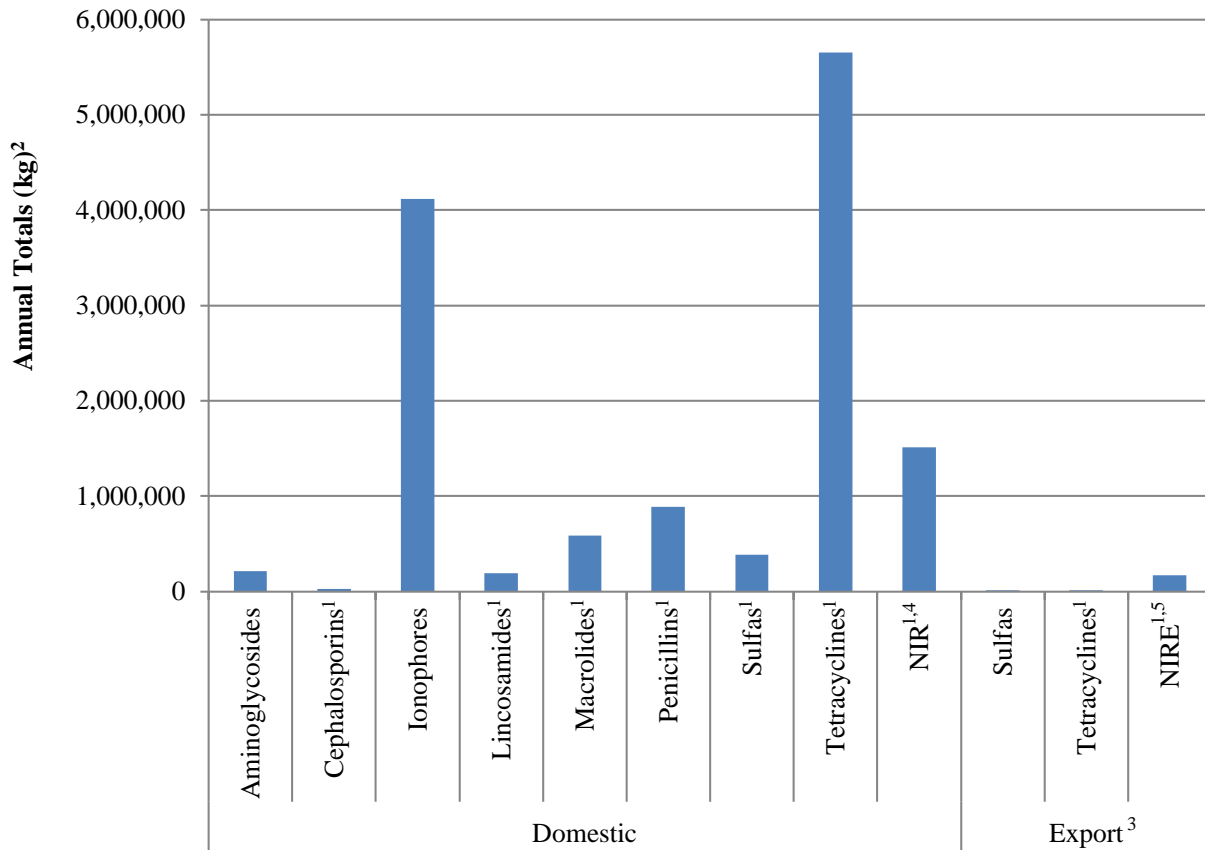
³ Only includes exports of FDA-approved, US-labeled antimicrobial drugs approved for use in food-producing animals.

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, 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, and Polypeptides.

FIGURE 2

**ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS¹
ACTIVELY MARKETED IN 2011
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, 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, and Polypeptides.

TABLE 3

ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS¹
 ACTIVELY MARKETED IN 2011
 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>	214,895	3%	2%
	<i>Cephalosporins⁴</i>	26,611	<1%	<1%
	<i>Lincosamides⁴</i>	190,101	2%	1%
	<i>Macrolides⁴</i>	582,836	7%	4%
	<i>Penicillins⁴</i>	885,304	11%	7%
	<i>Sulfas⁴</i>	383,105	5%	3%
	<i>Tetracyclines⁴</i>	5,652,855	68%	42%
	<i>NIR^{4,5}</i>	319,991	4%	2%
	<i>Subtotal</i>	8,255,697	100%	61%
<u>Not Currently Medically Important⁴</u>	<i>Ionophores</i>	4,122,397	78%	30%
	<i>NIR⁶</i>	1,190,943	22%	9%
	<i>Subtotal</i>	5,313,340	100%	39%
<i>Grand Total</i>		13,569,037		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.

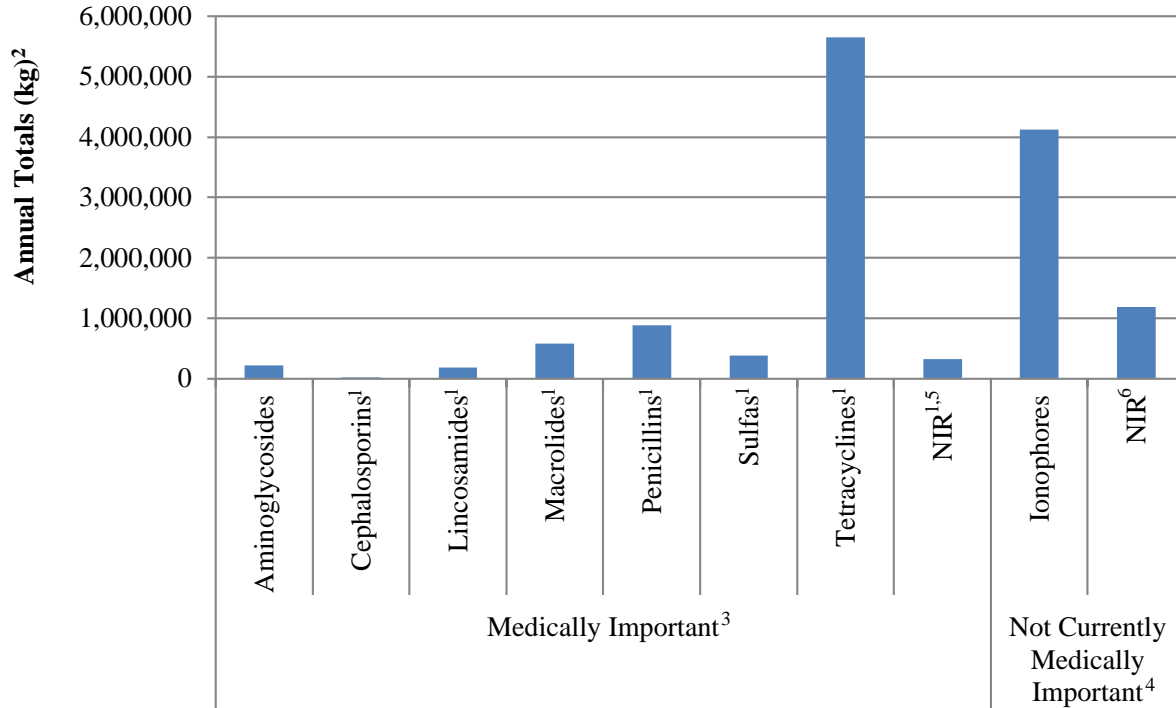
⁴ Not Currently Medically Important refers to any antimicrobial class not currently listed in Appendix A of FDA's Guidance for Industry #152.

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, Fluoroquinolones, Polymyxins, and Streptogramins.

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

FIGURE 3

**ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS¹
ACTIVELY MARKETED IN 2011
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, Fluoroquinolones, Polymyxins, and Streptogramins.
- ⁶ NIR = Not Independently Reported. Antimicrobial classes for which there were fewer than three distinct sponsors are not independently reported. These classes include the following: Aminocoumarins, Glycolipids, Pleuromutilins, Polypeptides, and Quinoxalines.

TABLE 4

ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS¹
 ACTIVELY MARKETED IN 2011
 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	5,933,440	72%	44%
	<i>Injection</i> ⁴	416,775	5%	3%
	<i>Intramammary</i>	21,023	<1%	<1%
	<i>Oral</i> ^{4,5} <i>or Topical</i> ⁴	126,775	2%	<1%
	<i>Water</i> ⁶	1,757,686	21%	13%
	<i>Subtotal</i>	8,255,697	100%	61%
<u>Not Currently Medically Important</u> ⁴	<i>Feed</i>	5,245,961	99%	39%
	<i>Intramammary or Water</i> ⁶	67,379	1%	<1%
	<i>Subtotal</i>	5,313,340	100%	39%
<i>Grand Total</i>		13,569,037		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.

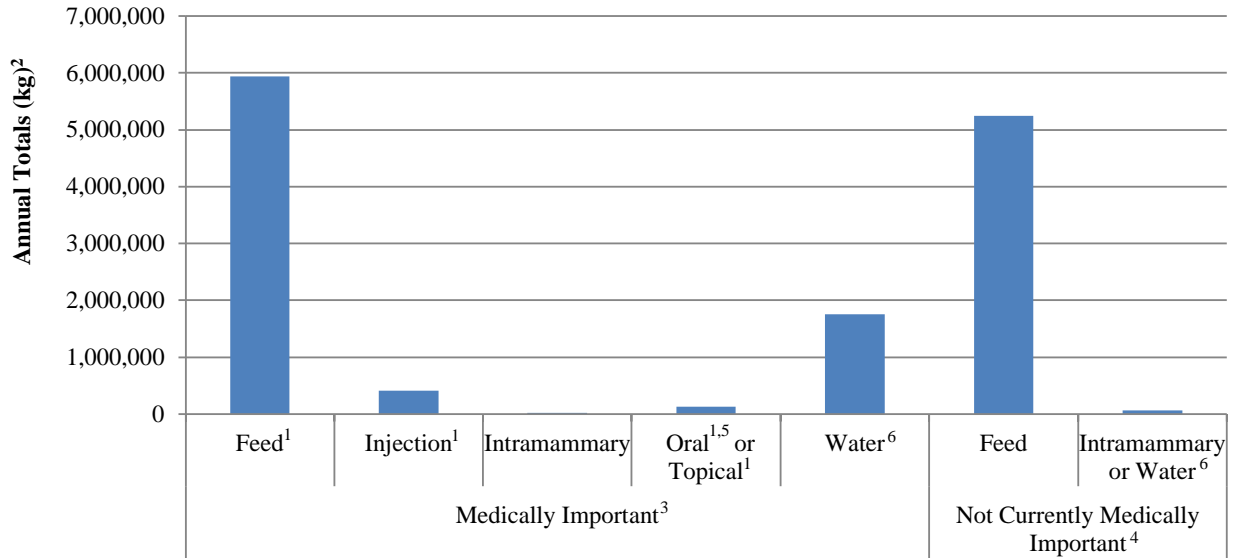
⁴ Not Currently Medically Important refers to any antimicrobial class not currently listed in Appendix A of FDA's Guidance for Industry #152.

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.

FIGURE 4

**ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS¹
ACTIVELY MARKETED IN 2011
DOMESTIC SALES AND DISTRIBUTION DATA
REPORTED BY MEDICAL IMPORTANCE AND ROUTE OF ADMINISTRATION**



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.

TABLE 5

ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS¹
ACTIVELY MARKETED IN 2011
DOMESTIC SALES AND DISTRIBUTION DATA
REPORTED BY MEDICAL IMPORTANCE AND INDICATIONS

	Indications	Annual Totals (kg)²	% Subtotal	% Grand Total
<u>Medically Important</u> ³	<i>Production⁵ or Production/Therapeutic⁶ Indications^{1,7}</i>	5,770,871	70%	43%
	<i>Therapeutic Indications Only^{1,6}</i>	2,484,827	30%	18%
	<i>Subtotal</i>	8,255,697	100%	61%
<u>Not Currently Medically Important</u> ⁴	<i>Production⁵ or Production/Therapeutic⁶ Indications⁷</i>	3,790,628	71%	28%
	<i>Therapeutic Indications Only⁶</i>	1,522,712	29%	11%
	<i>Subtotal</i>	5,313,340	100%	39%
<i>Grand Total</i>		13,569,037		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.

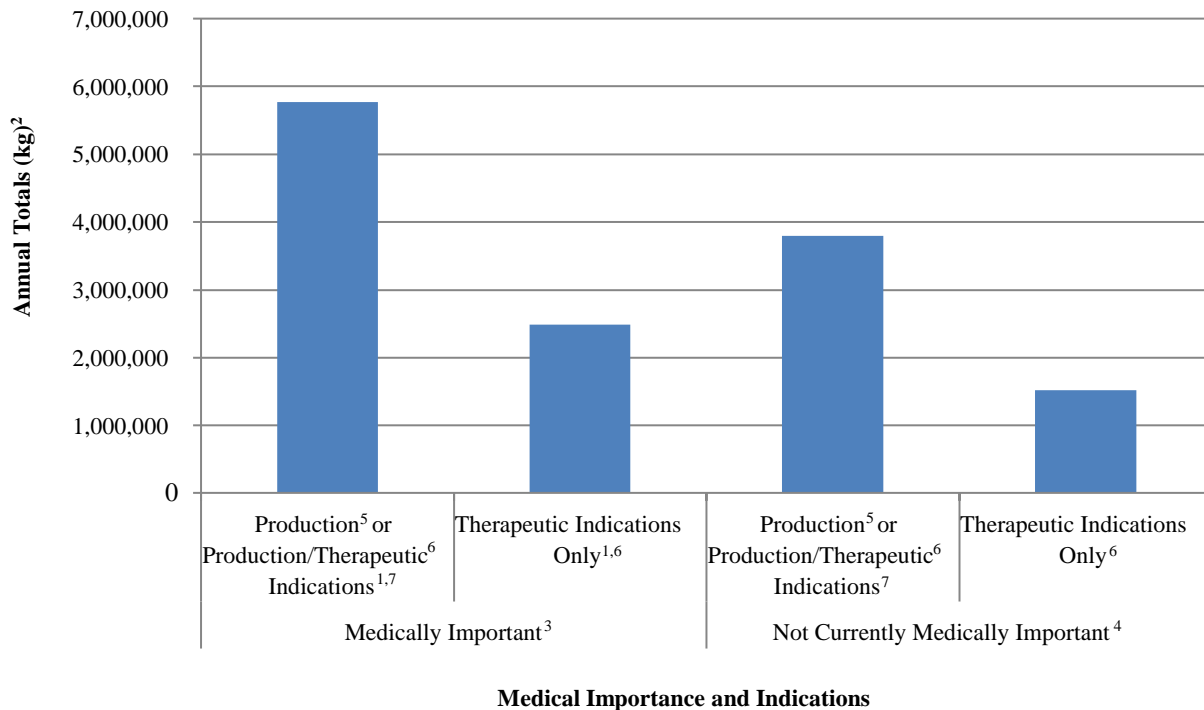
⁵ Production Indications (e.g., increased rate of weight gain or improved feed efficiency). Guidance for Industry #213 states that FDA believes that production use indications such as "increased rate of weight gain" or "improved feed efficiency" are no longer appropriate for the approved conditions of 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 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 2011
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 2011
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> ^{4,5}	8,029,437	97%	59%
	<i>RX</i> ⁶ / <i>OTC</i> ^{4,5,7}	50,205	<1%	<1%
	<i>RX</i> ⁶ or <i>VFD</i> ^{4,8,9}	176,055	2%	1%
	<i>Subtotal</i>	8,255,697	100%	61%
<u>Not Currently Medically Important</u> ⁴	<i>OTC</i> ⁵	5,313,340		39%
<i>Grand Total</i>		13,569,037		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.

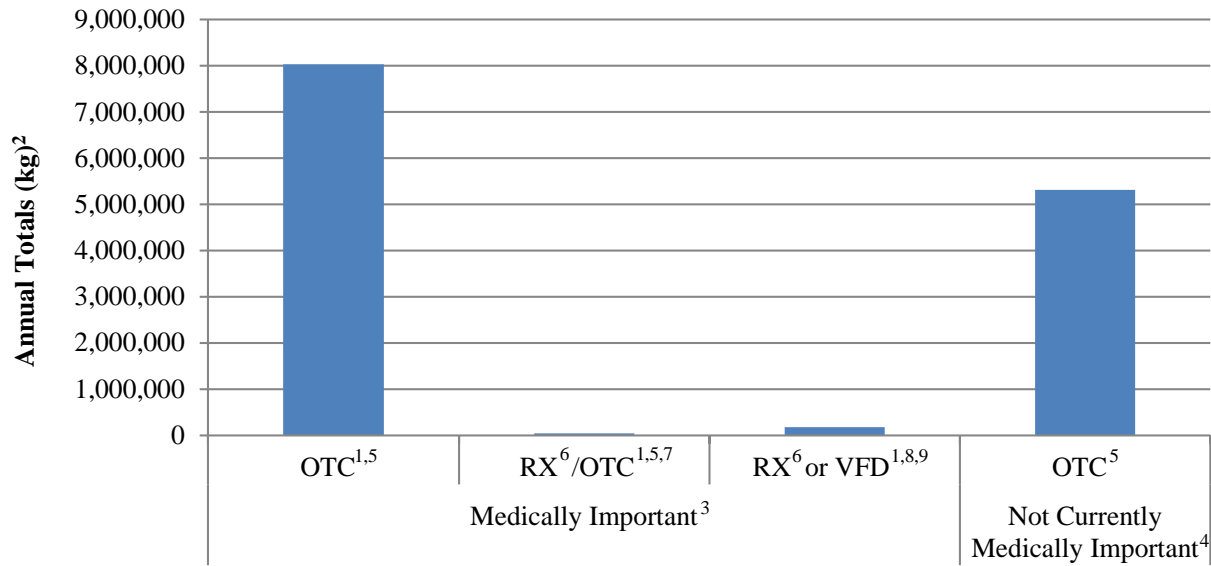
⁷ Animal drugs that were approved with both a prescription and OTC dispensing status (RX/OTC), with the approved drug being marketed with either a prescription label or an OTC label, depending upon the species and indication on the label.

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.

⁹ The "Rx or VFD" category includes four VFD products marketed by only two distinct sponsors; therefore, VFD products cannot be independently reported.

FIGURE 6

ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS¹
ACTIVELY MARKETED IN 2011
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.

TABLE 7

**ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS¹
 ACTIVELY MARKETED IN 2011
 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>	105,400	1%	<1%
		<i>Tetracyclines⁴</i>	4,848,946	59%	36%
		<i>Other Drugs⁷</i>	979,093	12%	7%
	Water	<i>Aminoglycosides</i>	162,672	2%	1%
		<i>Lincosamides</i>	66,510	<1%	<1%
		<i>Penicillins</i>	650,220	8%	5%
		<i>Sulfas</i>	145,972	2%	1%
		<i>Tetracyclines</i>	710,403	9%	5%
		<i>Other Drugs⁸</i>	21,909	<1%	<1%
		Other Routes⁵	<i>Cephalosporins¹</i>	26,611	<1%
	<i>Sulfas¹</i>		131,733	2%	<1%
	<i>Tetracyclines¹</i>		93,506	1%	<1%
	<i>Other Drugs^{1,9}</i>		312,723	4%	2%
<i>Subtotal</i>			8,255,697	100%	61%
<u>Not Currently Medically Important⁴</u>	All Routes⁶	<i>All Drugs¹⁰</i>	5,313,340		39%
<i>Grand Total</i>			13,569,037		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, Topical, 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.

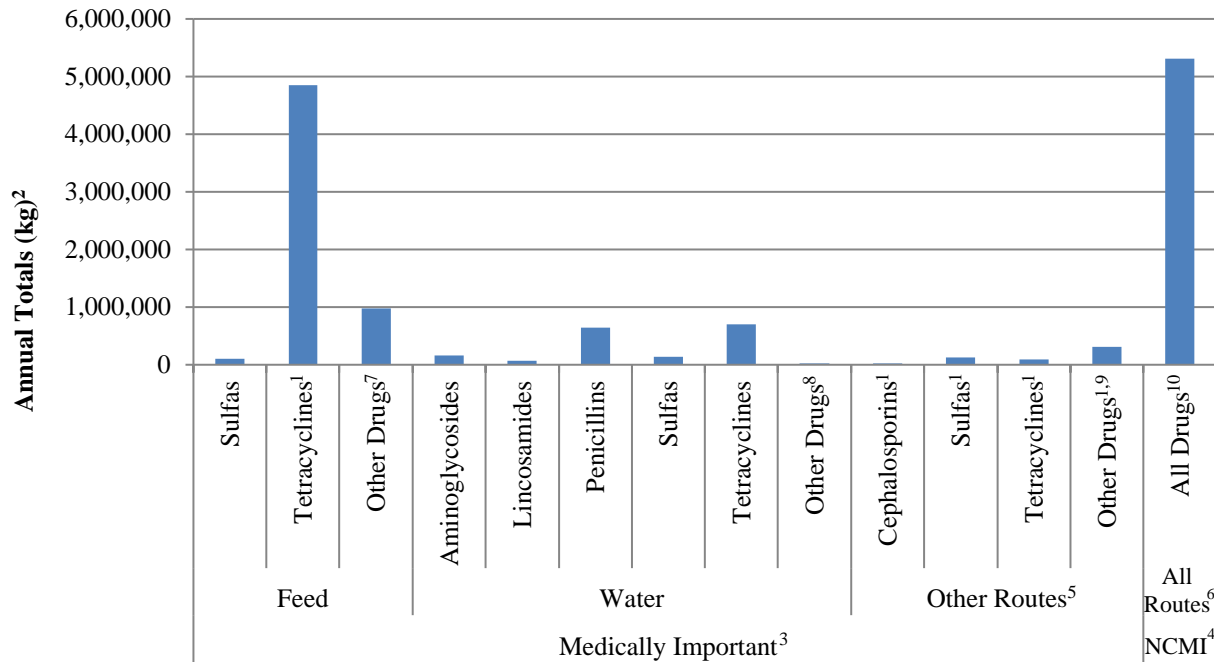
⁸ This category includes the following: Amphenicols and Macrolides.

⁹ This category includes the following: Aminoglycosides, Amphenicols, Fluoroquinolones, Lincosamides, Macrolides, Penicillins, and Polymyxins.

¹⁰ 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 2011
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, Topical, 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: Amphenicols and Macrolides.

⁹ This category includes the following: Aminoglycosides, Amphenicols, Fluoroquinolones, Lincosamides, Macrolides, Penicillins, and Polymyxins.

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

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 - “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”
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