



# Characterizing US Animal Drug Consumption by Sales

Farm Foundation &  
USDA, Economic Research Service  
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# Sales of Drugs for Food-Producing Animals

- **US Congress** - Section 105 of the Animal Drug User Fee Amendments of **2008**
- First summary on 2009 sales published on **December, 2010**

Public Law 110–316  
110th Congress

## An Act

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the animal drug user fee program, to establish a program of fees relating to generic new animal drugs, to make certain technical corrections to the Food and Drug Administration Amendments Act of 2007, and for other purposes.

Aug. 14, 2008  
[H.R. 6432]

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

### SECTION 1. TABLE OF CONTENTS.

The table of contents of this Act is as follows:

- Sec. 1. Table of contents.
- Sec. 2. References in Act.

TITLE I—ANIMAL DRUG USER FEE AMENDMENTS

# FDA-Approved Animal Drug Products



- Ingredient(s)
- Dispensing Status
- Route of Administration
- Species
- Indication(s)
- Dosing Information
- Duration of Use

# Congressional Limitations to the Public



(E) The Secretary shall make summaries of the information reported under this paragraph publicly available, except that-

(i) the summary data shall be reported by antimicrobial class, and no class with fewer than 3 distinct sponsors of approved applications shall be independently reported; and

(ii) the data shall be reported in a manner consistent with protecting both national security and confidential business information.



# Original 2009 Sales Report

**2009**

**SUMMARY REPORT**

on

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

Food and Drug Administration  
Department of Health and Human Services

Section 105 of the Animal Drug Use Fee Amendment of 2008 (ADUFA) (110 P.L. 364, 122 Stat. 3509) amended section 511 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b) to require that sponsors of applications for new animal drug containing an antimicrobial active ingredient submit a annual report to the Food and Drug Administration 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 effectiveness (including drug resistance), efficacy, and safety of antibiotics approved for use in both humans and food-producing animals (21 CFR 314.800).

Each report submitted to the FDA must specify: (1) the amount of each antimicrobial active ingredient by container size, strength, and dosage form; (2) quantities distributed domestically and quantities exported; and (3) a listing of the target animals, indications, and production classes that are specified on the approved label of the product. Sponsors of antimicrobial drug products that are approved and labeled for more than one food-producing animal species are not required to report sales and distribution information for each individual animal species. Only total product sales information is required. The first report must be submitted not later than March 31, 2010, and each year's report will provide assembly sales and distribution data for the preceding calendar year. These reports are separate from periodic drug experience reports that are required under 21 CFR 314.800(x).

Section 105 of ADUFA also directs the FDA to make annual summaries of the reported information publicly available. In accordance with statutory requirements designed to protect confidential business information, annual sales and distribution data will be summarized by drug class and only those antimicrobial classes with three or more distinct sponsors of approved and actively marketed animal drug products are independently reported. Antimicrobial classes with fewer than three distinct sponsors are reported collectively as "Not Independently Reported" (NIR) if the product was marketed domestically or "Not Independently Reported Export" (NIRE) if the product was exported. The number of distinct sponsors in a particular antimicrobial class is determined by two criteria: (1) the sponsor must be named in 21 CFR 310.600 as the holder of an approved application for an animal drug product in that particular class 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.

FDA's annual summary report for 2009 is presented in Table 1. The annual totals provided in Table 1 reflect all approved uses of all dosage forms (e.g., injectable, oral, medicated feed) of the identified classes of actively marketed drugs in food-producing animals. Table 2 lists the 17 antimicrobial drug classes represented in the report. As referenced, this table also lists the specific drugs in each class for which there are approved animal drug products. However, the fact that an animal drug product is approved does not necessarily mean that it was actively marketed during this particular annual reporting period. This summary report includes antimicrobial drugs that are specifically approved for antibacterial uses or are known to have antibacterial properties. Anti-fungal and anti-viral 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 products actively marketed for these purposes in food-producing animals.

**Table 1. Antimicrobial Drugs Approved for Use in Food-Producing Animals: 2009 Sales and Distribution Data Reported by Drug Class**

	Antimicrobial Class	Annual Totals (kg <sup>1</sup> )
Domestic	Aminoglycosides	339,678
	Cephalosporins	41,328
	Ionophores	3,743,627
	Lincoamides	115,837
	Macrolides	861,985
	Penicillins	610,514
	Sulfas	517,873
	Tetracyclines	4,611,892
	NIR <sup>2</sup>	2,227,366
	Tetracyclines	515,819
Export	NIRE <sup>3</sup>	1,115,726

<sup>1</sup> kg = kilogram of active ingredient. Antimicrobials which were reported in international units (IU) (i.e., Penicillins and Polypeptides) were converted to kg.

<sup>2</sup> NIR = Not Independently Reported. Antimicrobial classes for which there were less than three distinct sponsors actively marketing products domestically were not independently reported. These classes include: Amoxicillins, Amphipolins, Diaminopyridines, Fluoroquinolones, Glycolides, Pleuromulins, Polypeptides, Quinolones, and Streptogramins.

<sup>3</sup> NIRE = Not Independently Reported Export. Antimicrobial classes for which there were less than three distinct sponsors exporting products were not independently reported. These classes include: Amoxicillins, Aminoglycosides, Amphipolins, Cephalosporins, Diaminopyridines, Fluoroquinolones, Glycolides, Ionophores, Lincoamides, Macrolides, Penicillins, Pleuromulins, Polypeptides, Quinolones, Streptogramins and Sulfas.

**Table 2. Antimicrobial Drugs and Drug Classes Approved for Use in Food-Producing Animals**

Aminocoumarins Neovicin	Macrolides Carbamazepine Erythronin Tetracycline Tiamulin Tylosin
Aminoglycosides Apramycin Chlorthalidone Biotin Centron Isoniazid Neomycin Spectinomycin Streptomycin	Penicillins Amoxicillin Ampicillin Cloxacillin Hidradin Penicillin
Amphotericin B Furazolidone	Pleuromulins Toumin
Cephalosporins Ceftiofur Ceftiofur Ceftiofur	Polypeptides Bactracin Polymixin B
Diaminopyridines Cimetidine	Quinolones Caradox
Fluoroquinolones Lanoprost Enrofloxacin	Streptogramins Virginiamycin
Glycolides Bartamycin	Sulfas Sulfadiazine Sulfamonomethoxine Sulfamethoxazole Sulfathiazole Sulfisoxazole Sulfasalazine
Ionophores Lasidion Lasidion Marsilan Narsin Salmeterol Sulfoxon Lincoamides Lincocin	Tetracyclines Chlorthalidone Oxytetracycline Tetracycline

**Table 1. Antimicrobial Drugs Approved for Use in Food-Producing Animals:  
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	<b>Antimicrobial Class</b>	<b>Annual Totals (kg<sup>1</sup>)</b>
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	<i>NIR<sup>2</sup></i>	2,227,366
<b>Export</b>	<i>Tetracyclines</i>	515,819
	<i>NIRE<sup>3</sup></i>	1,115,728

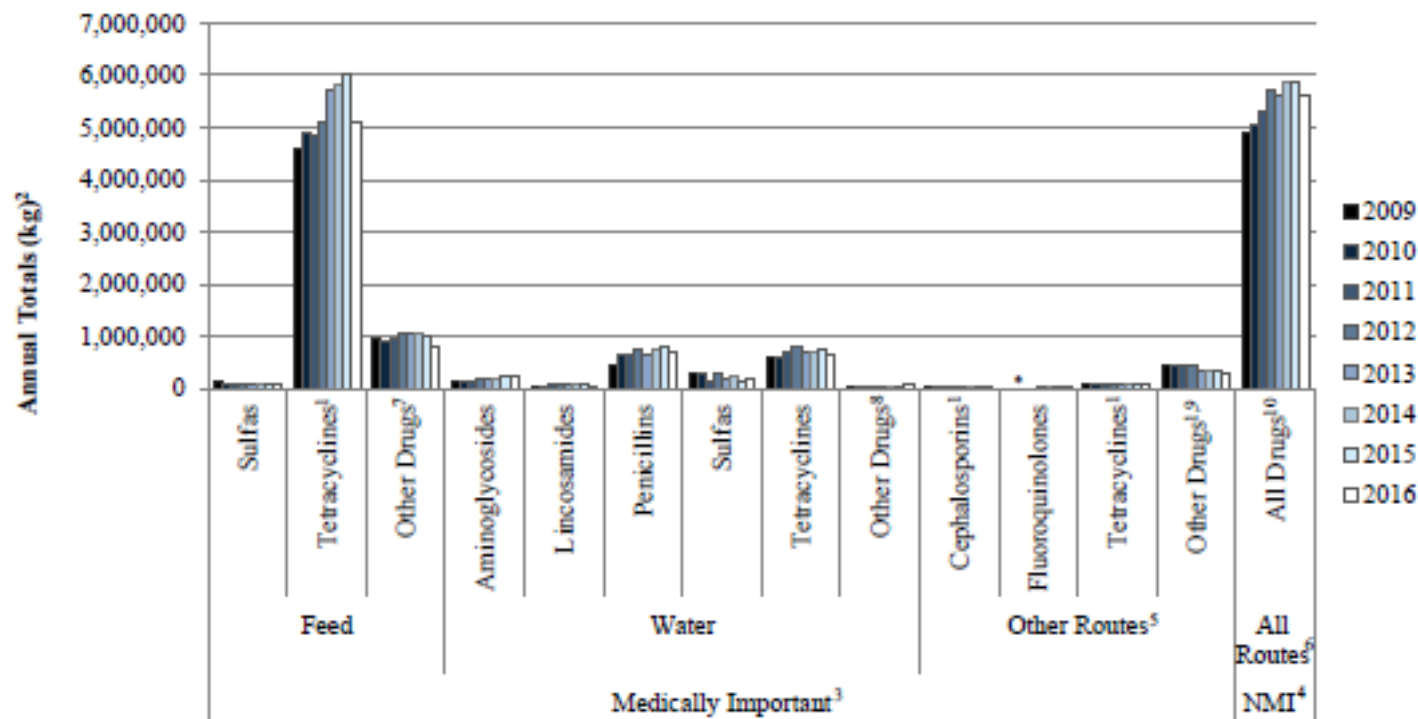
# 2016 Sales Report



- 67 pages
- 18 tables
- 23 figures



ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS<sup>1</sup>  
ACTIVELY MARKETED 2009-2016  
DOMESTIC SALES AND DISTRIBUTION DATA  
REPORTED BY MEDICAL IMPORTANCE, ROUTE OF ADMINISTRATION, AND DRUG CLASS



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



# Considerations

- Sales not indicative of how actually used in animals
- Sales in one year may result in use in another year
- Some sales may never result in use
- For non-feed drugs, vets might use in extralabel manner
- Some drug products approved:
  - for multiple species
  - for multiple indications
  - at multiple dosing regimens

# NADA 046-699 (tetracycline in feed)

## **CATTLE (Beef cattle)**

For the control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp susceptible to chlortetracycline

## **CATTLE (Beef cattle, over 700 pounds)**

For the control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline

## **CATTLE (Beef cattle, under 600 pounds)**

For the control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline

## **CATTLE (calves, beef, and non-lactating dairy)**

For the treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline

## **CATTLE (growing cattle over 400 pounds)**

Reduction of liver condemnation due to liver abscesses

# NADA 046-699 (tetracycline in feed)

## **CHICKENS (not laying eggs for human consumption)**

For the control of chronic respiratory disease and air sac infection caused by *Mycoplasma gallisepticum* and *Escherichia coli* susceptible to chlortetracycline

For the control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to chlortetracycline

For the reduction of mortality due to *Escherichia coli* infections susceptible to chlortetracycline

## **SHEEP (breeding)**

For reducing the incidence of (vibrionic) abortion caused by *Campylobacter fetus* infection susceptible to chlortetracycline.

# NADA 046-699 (tetracycline in feed)

## **SWINE**

For reducing the incidence of cervical lymphadenitis (jowl abscesses) caused by Group E *Streptococci* susceptible to chlortetracycline

For the control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis* susceptible to chlortetracycline

For the treatment of bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline

## **SWINE (breeding)**

For the control of leptospirosis (reducing the instances of abortion and shedding of leptospirae) caused by *Leptospira pomona* susceptible to chlortetracycline



# NADA 046-699 (tetracycline in feed)

## **TURKEYS (not laying eggs for human consumption)**

For the control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis) susceptible to chlortetracycline

For the control of hexamitiasis caused by *Hexamita meleagridis* susceptible to chlortetracycline

For the control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to chlortetracycline

## **TURKEYS (poults not over 4 weeks of age, not laying eggs for human consumption)**

For reduction of mortality due to paratyphoid caused by *Salmonella typhimurium* susceptible to chlortetracycline



# Inclusion of Estimated Species

- Proposed rule on **May, 2015**
- Public to provide comments by **August, 2015**
- Final rule published on **July, 2016**
- Revised summary first published on **December, 2017**



# Public Comments on Proposed Species Estimates

- Species-specific sales estimates are beneficial to understand:
  - How antimicrobials are used in food animals
  - The relationship between sales/use and antimicrobial resistance (i.e. with NARMS data)
  - The impact of policies and practices to mitigate antimicrobial resistance (e.g. GFI #213 and the VFD rule)

# Public Comments on Proposed Species Estimates

- Unclear how species-specific estimates will scientifically support USDA animal drug use surveys and NARMS resistance data
- Species-specific sales estimates are inappropriate to report because:
  - Can be inaccurate, especially due to the complications and inconsistencies of data collection
  - Do not constitute sound scientific data
  - Do not reflect actual usage
  - Are subject to misinterpretation due to lack of complete information
  - Do not constitute sufficient data to evaluate the impact of policies and trends in antimicrobial resistance

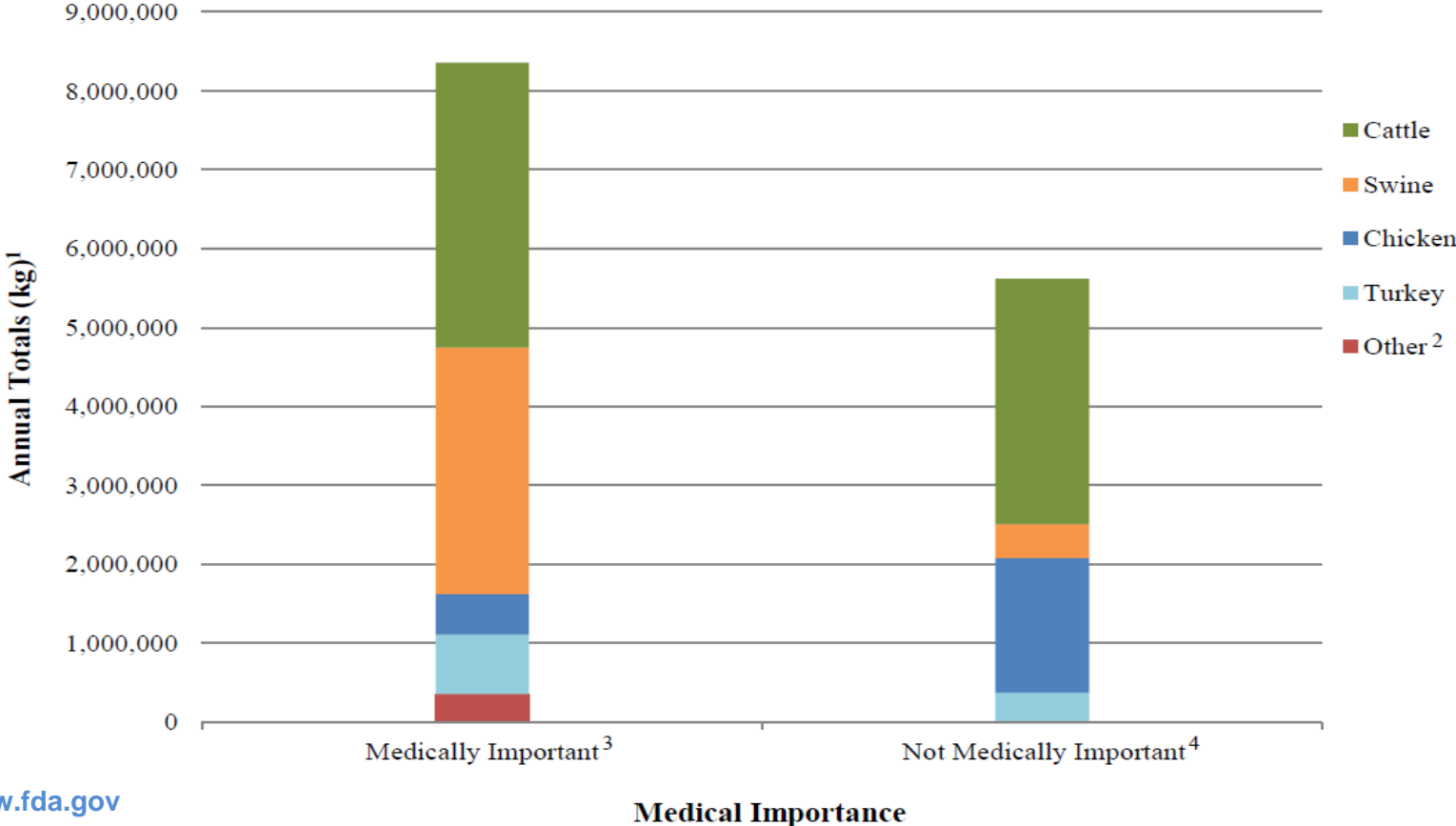




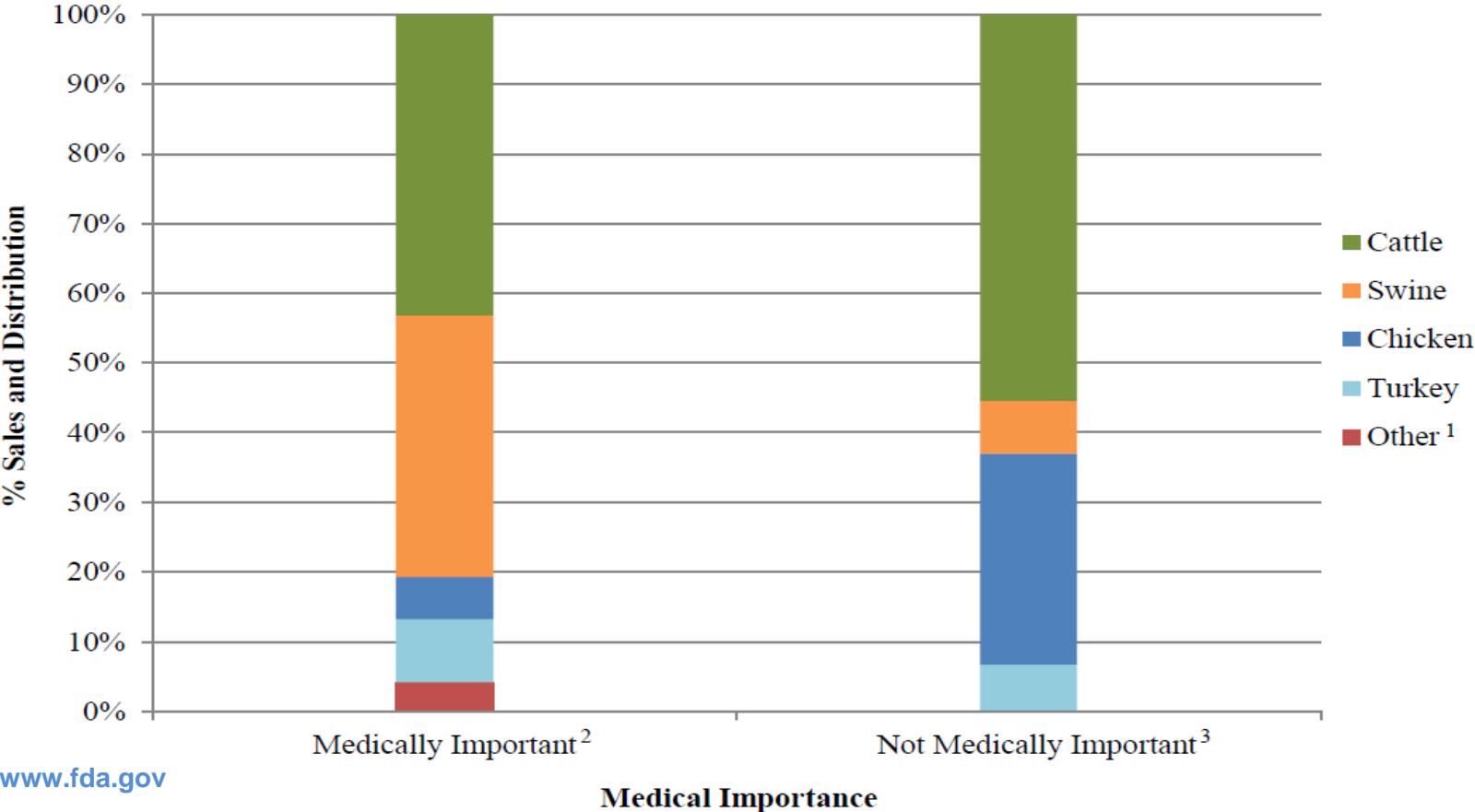
# Public Comments on Proposed Species Estimates

- Antimicrobial use should be monitored at the farm-level
- FDA should collaborate with USDA (ARS and especially APHIS) and CDC to enhance existing collection efforts of on-farm antimicrobial use data that is:
  - Accurate, detailed, and quantitative
  - Used to understand the relationship between usage and resistance trends
  - Used to evaluate the impact of policies
  - Used to construct targeted interventions

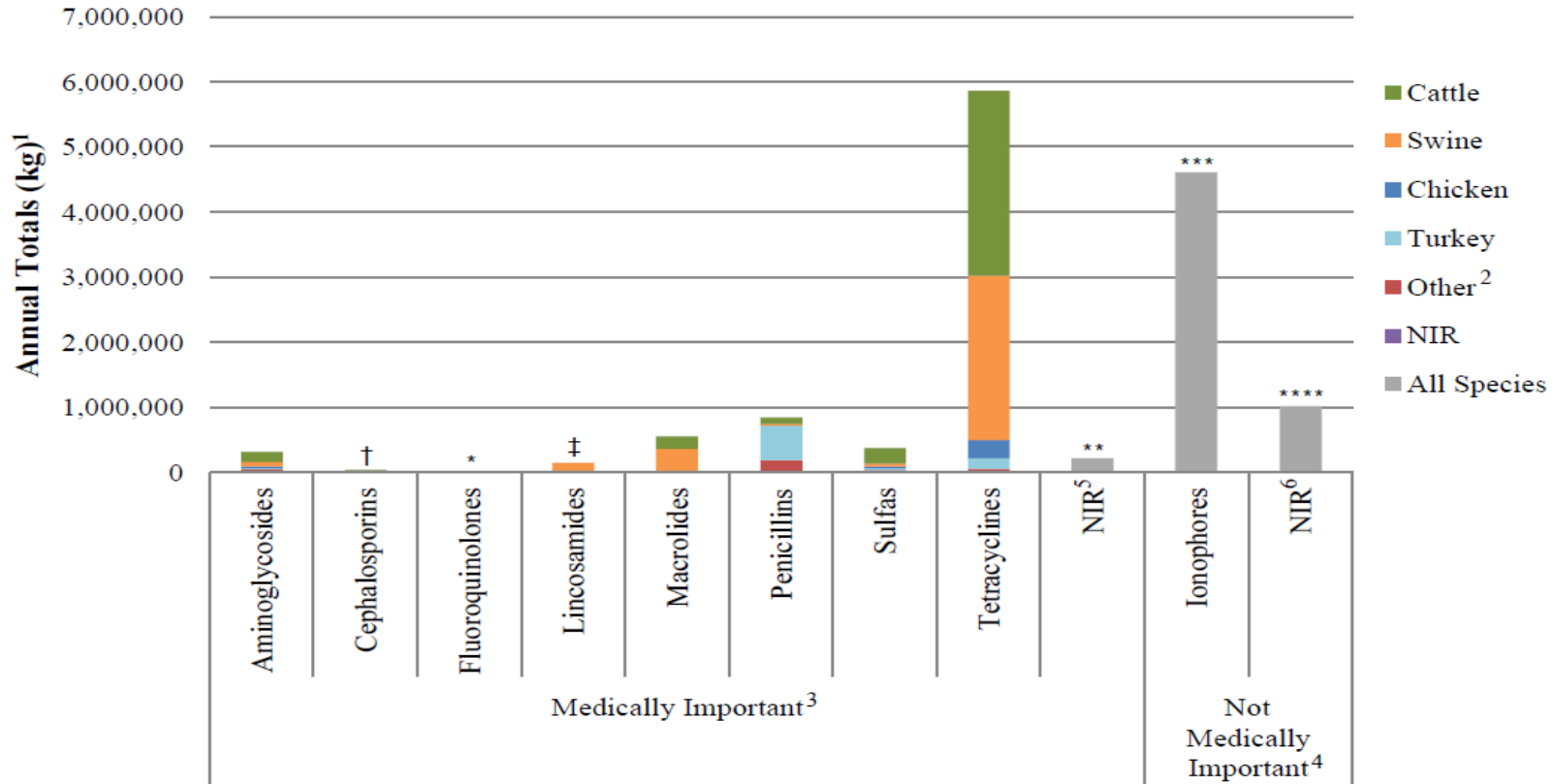
# 2016 US Domestic Sales and Distribution Medically Important Antimicrobials



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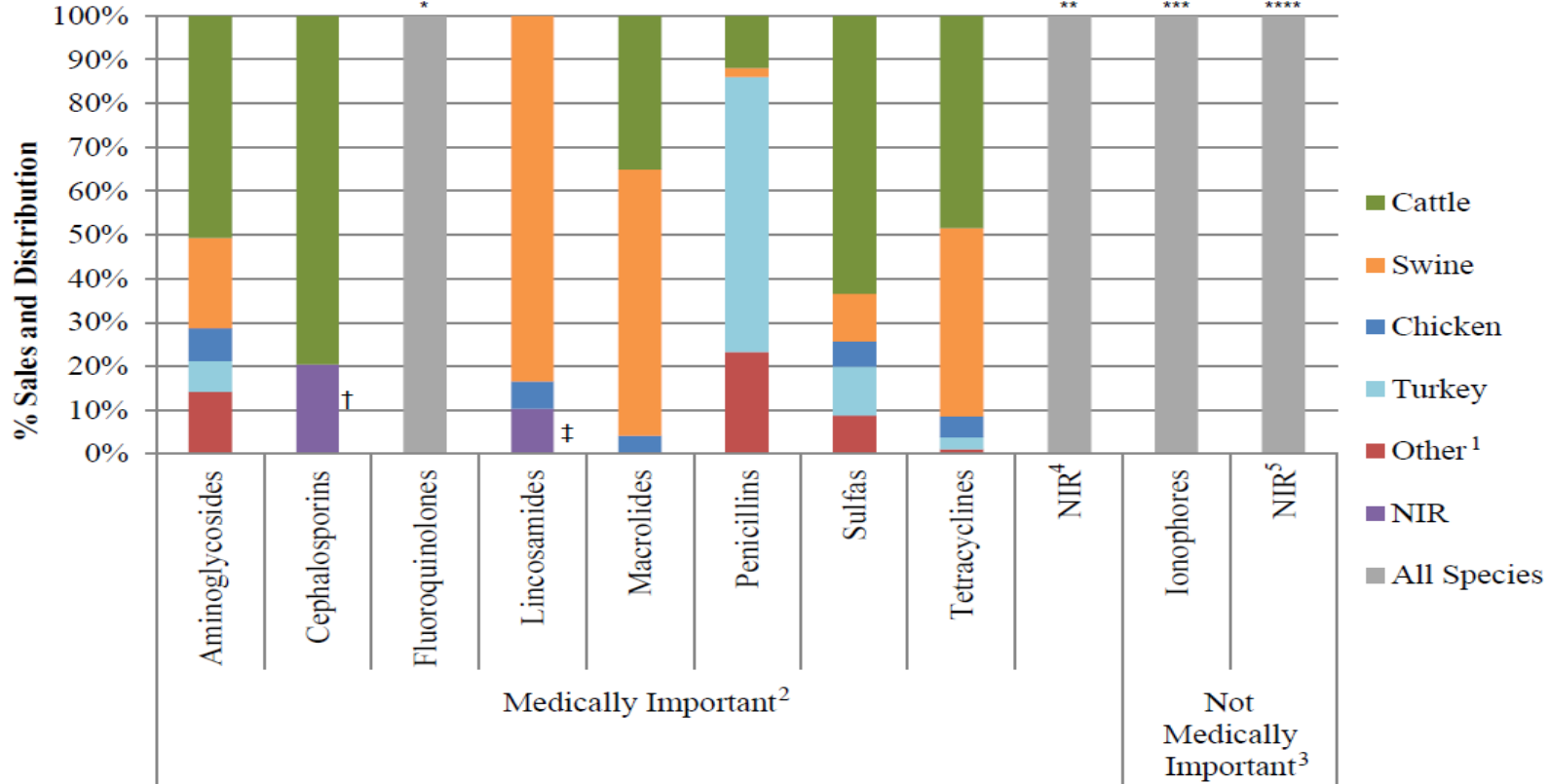


# 2016 US Domestic Sales and Distribution Medically Important Antimicrobials

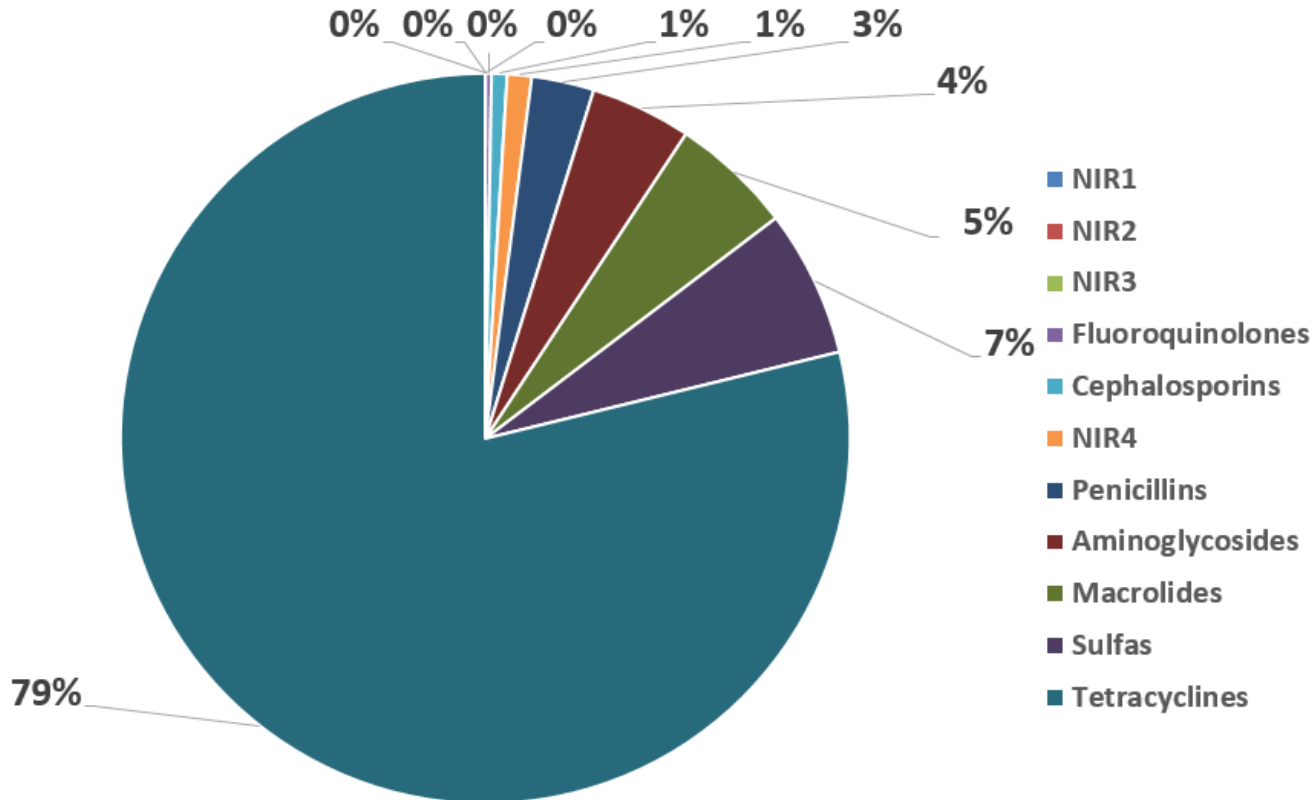


Medical Importance, Drug Class, and Estimated Species

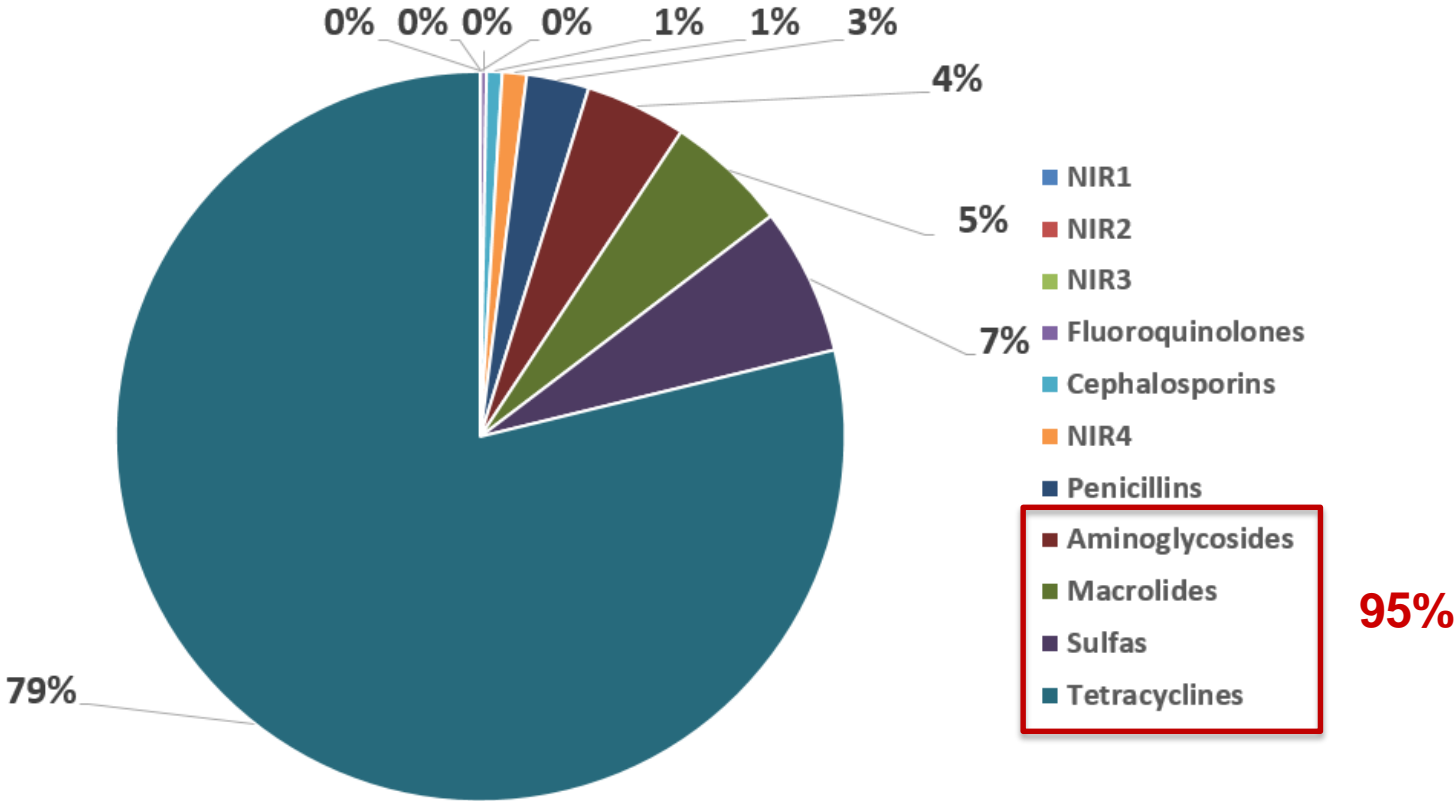
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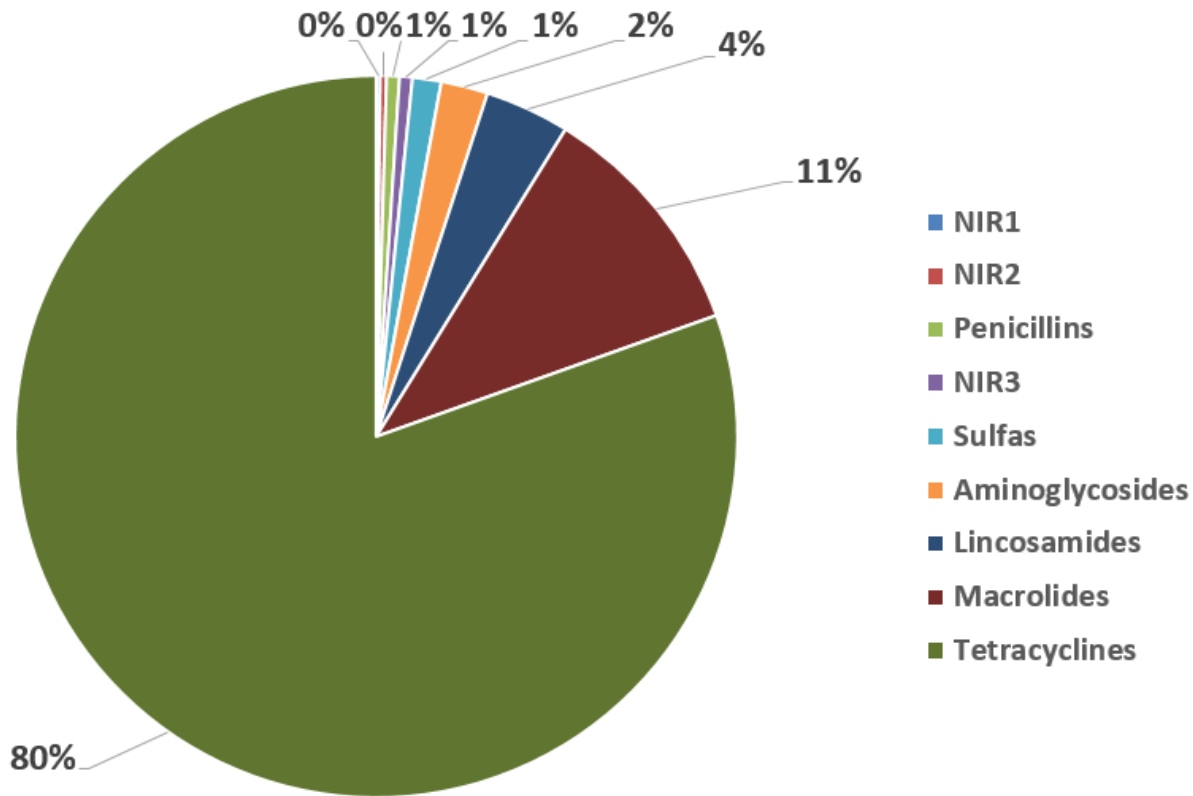
# 2016 US Domestic Sales and Distribution Medically Important Antimicrobials - Estimated Cattle



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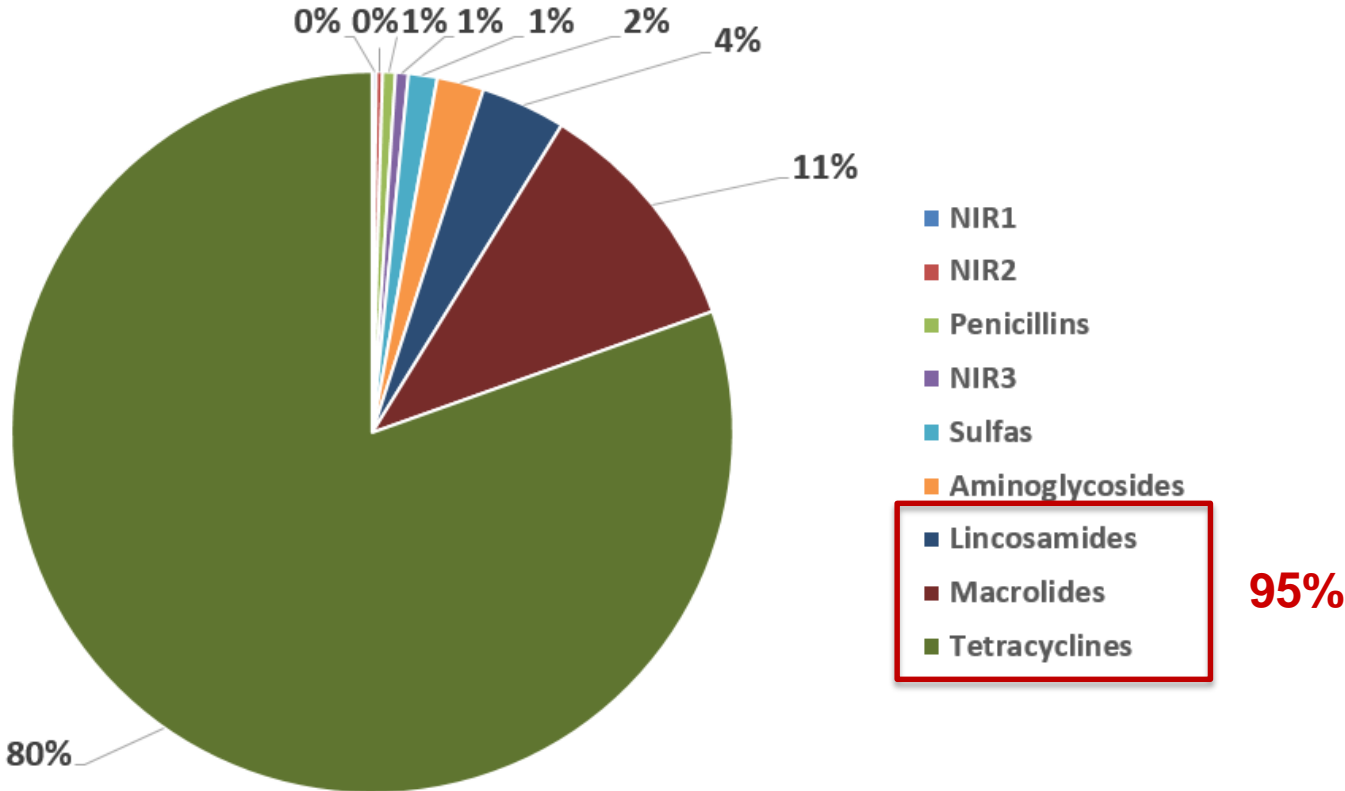


# 2016 US Domestic Sales and Distribution Medically Important Antimicrobials - Estimated Swine

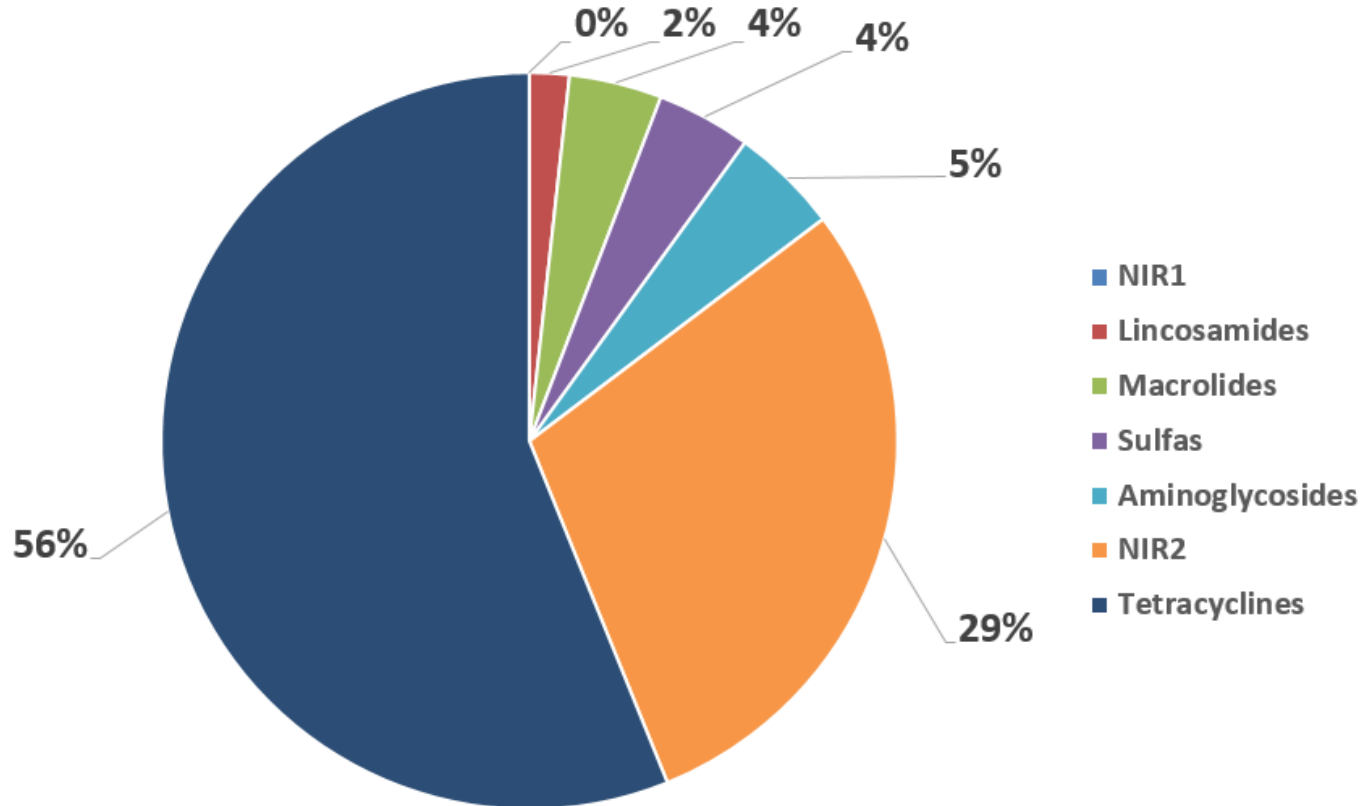




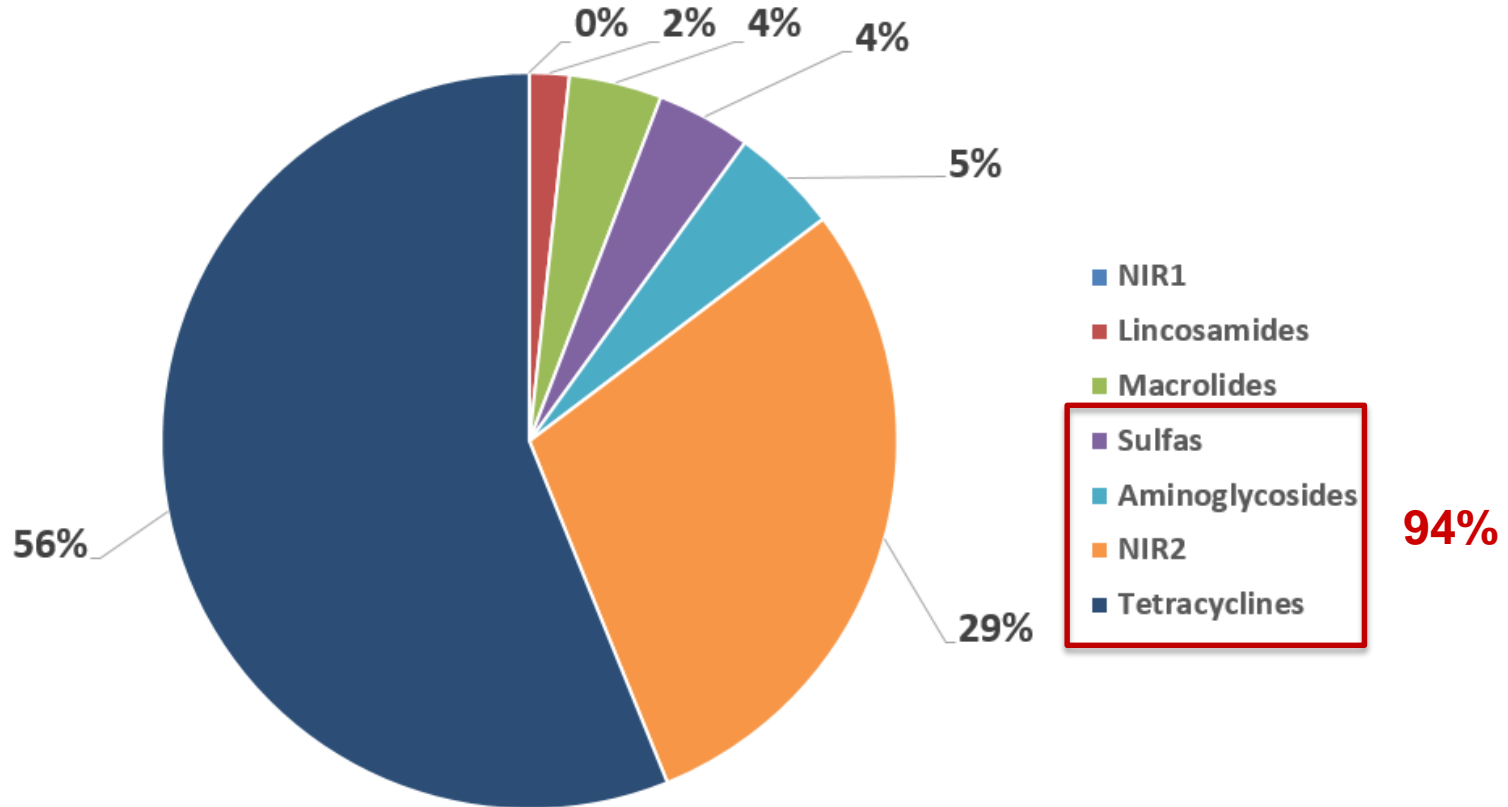
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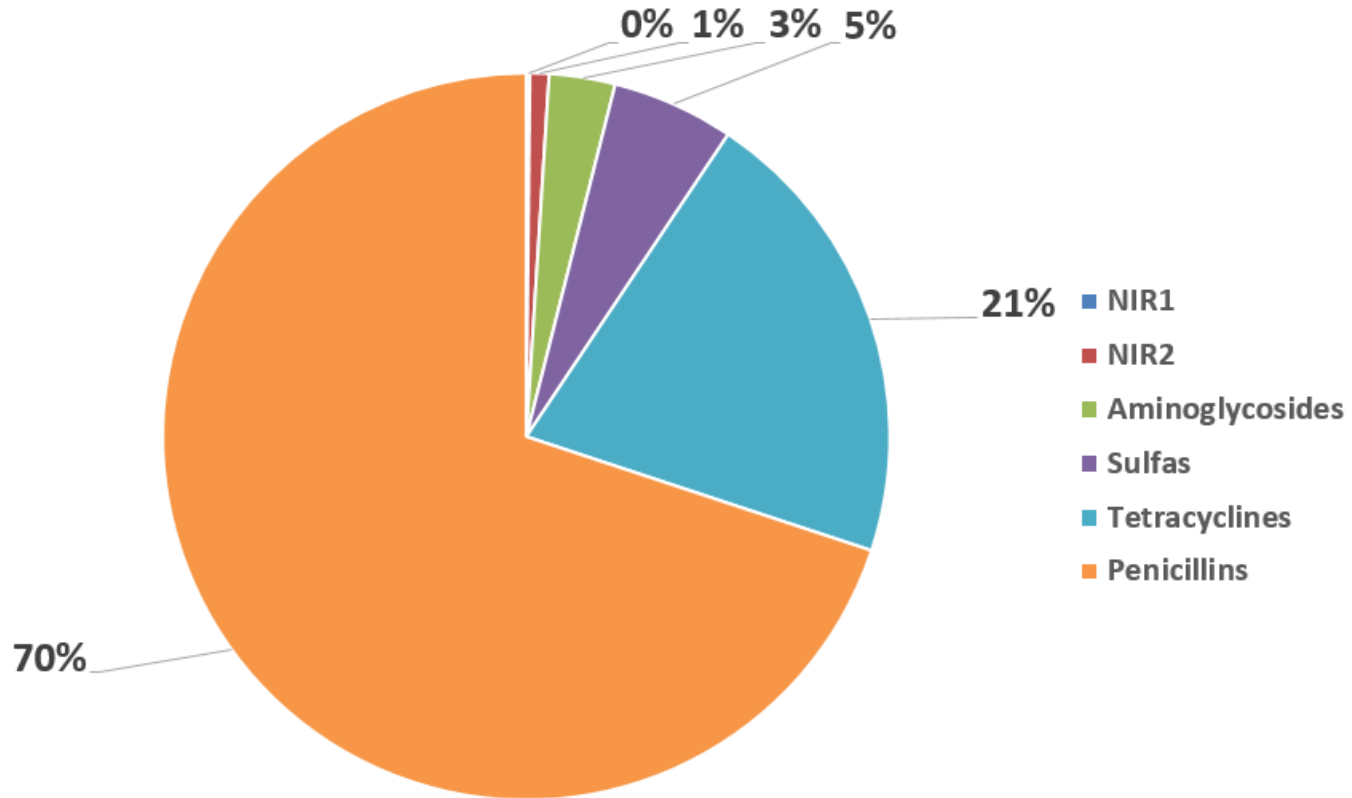
# 2016 US Domestic Sales and Distribution Medically Important Antimicrobials - Estimated Chickens



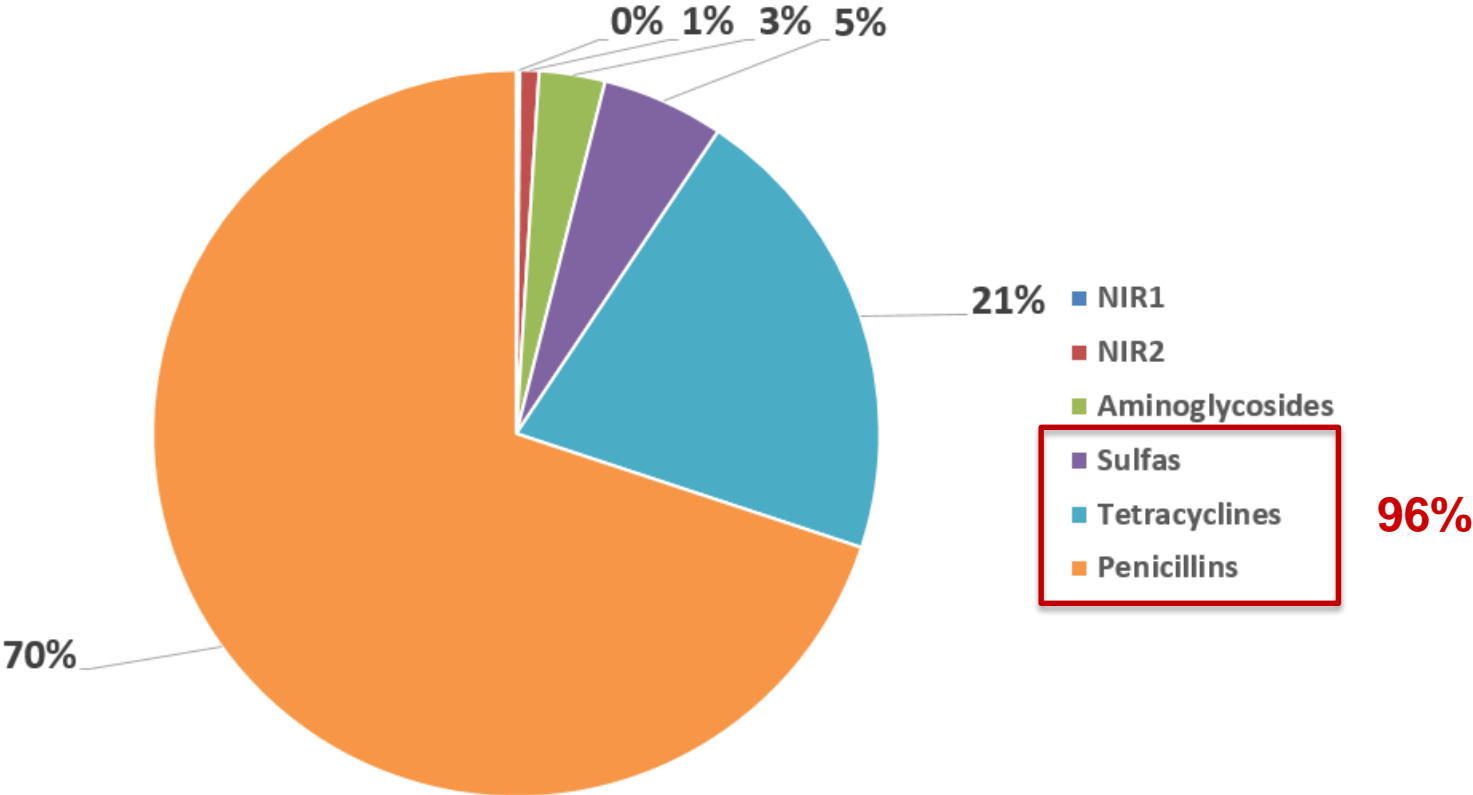
# 2016 US Domestic Sales and Distribution Medically Important Antimicrobials - Estimated Chickens



# 2016 US Domestic Sales and Distribution Medically Important Antimicrobials - Estimated Turkeys



# 2016 US Domestic Sales and Distribution Medically Important Antimicrobials - Estimated Turkeys





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