Overview of FDA Historical and Current Antimicrobial Sales and Distribution Data Collection and Analysis

CDC/USDA/FDA Data Collection Public Meeting
Washington, DC
September 30, 2015

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Center for Veterinary Medicine
U.S. Food and Drug Administration

Section 105 of the Animal Drug User Fee Amendments of 2008

- Requires animal drug companies to annually report to FDA the amount of antimicrobial drugs they sell or distribute for use in food-producing animals.
- Requires FDA to issue annual summary reports of the sales and distribution data.

Animal Drugs Containing Antimicrobial Active Ingredients

- Sponsor of the drug shall submit amount of each antimicrobial active ingredient in the drug that is sold or distributed for use in food-producing animals, including information on any distributor-labeled product.

- Specify the amount of each antimicrobial active ingredient —
  - by container size, strength, and dosage form;
  - by quantities distributed domestically and quantities exported; and
  - 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.

Animal Drugs Containing Antimicrobial Active Ingredients

Each report under this paragraph shall—

- Submitted not later than March 31 each year;
- Cover the period of the preceding calendar year; and
- Include separate information for each month of such calendar year.

Form FDA 3744 – Antimicrobial Animal Drug Distribution Report (page 1)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Center for Veterinary Medicine

ANTIMICROBIAL ANIMAL DRUG DISTRIBUTION REPORT

Form Approved: OMB No. 0910-0659
Expiration Date: 11/30/2016
(See Burden Statement below)

Firm and Application Information

Application Type	Application Number

Firm Name	Date Submitted

Food Animal Dosage Form Information

Dosage Form(s)	Production Class(es)

Animal Species Category

☐ Food Animal ☐ Food and Non-Food Animal

Target Food Animal(s)

Indication(s)

Please complete the form and submit it to the address below.

Food and Drug Administration
Center for Veterinary Medicine
7500 Standish Place, HFV-199
Rockville, MD 20855

The burden time for this collection of information is estimated to average 3.0 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to the address to the right.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

Please do NOT send this form to the above PRA Staff email address.

FORM FDA 3744 (4/14) PSC Publishing Services (301) 443-6740 EF Page ____

Form FDA 3744 – Antimicrobial Animal Drug Distribution Report (page 2)

Total of All Quantities Sold or Distributed *(Domestic and Export)*

1st Active Ingredient

2nd Active Ingredient

3rd Active Ingredient

Domestic Quantities

Domestic Quantities Sold/Distributed by Month – **Unit of Measure for 1st Active Ingredient**	Domestic Quantities Sold/Distributed by Month – **Unit of Measure for 2nd Active Ingredient**	Domestic Quantities Sold/Distributed by Month – **Unit of Measure for 3rd Active Ingredient**

YEAR:	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Annual Total
1st Active Ingredient													
2nd Active Ingredient													
3rd Active Ingredient													

Export Quantities

Export Quantities Sold/Distributed by Month – **Unit of Measure for 1st Active Ingredient**	Export Quantities Sold/Distributed by Month – **Unit of Measure for 2nd Active Ingredient**	Export Quantities Sold/Distributed by Month – **Unit of Measure for 3rd Active Ingredient**

YEAR:	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Annual Total
1st Active Ingredient													
2nd Active Ingredient													
3rd Active Ingredient													

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Form FDA 3744 – Antimicrobial Animal Drug Distribution Report (page 3)

Individual Product Information		
Dosage Form	Container Size	Container Size Units
1st Active Ingredient	2nd Active Ingredient	3rd Active Ingredient
1st Active Ingredient Strength – Numerator Number	*2nd Active Ingredient Strength – Numerator Number*	*3rd Active Ingredient Strength – Numerator Number*
1st Active Ingredient Strength – Numerator Unit	*2nd Active Ingredient Strength – Numerator Unit*	*3rd Active Ingredient Strength – Numerator Unit*
1st Active Ingredient Strength – Denominator Number	*2nd Active Ingredient Strength – Denominator Number*	*3rd Active Ingredient Strength – Denominator Number*
1st Active Ingredient Strength – Denominator Unit	*2nd Active Ingredient Strength – Denominator Unit*	*3rd Active Ingredient Strength – Denominator Unit*

Quantities of Individual Product Sold or Distributed *(Domestic and Export)*		
Domestic and Export Quantities Sold/Distributed by Month – **Unit of Measure for 1st Active Ingredient**	Domestic and Export Quantities Sold/Distributed by Month – **Unit of Measure for 2nd Active Ingredient**	Domestic and Export Quantities Sold/Distributed by Month – **Unit of Measure for 3rd Active Ingredient**

YEAR:	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Annual Total
1st Active Ingredient													
2nd Active Ingredient													
3rd Active Ingredient													

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Section 105 of the Animal Drug User Fee Amendments of 2008 (cont. 2)

- FDA may share information reported under this paragraph with the Antimicrobial Resistance Task Force established under section 247d–5 of title 42.

Section 105 of the Animal Drug User Fee Amendments of 2008 (cont. 3)

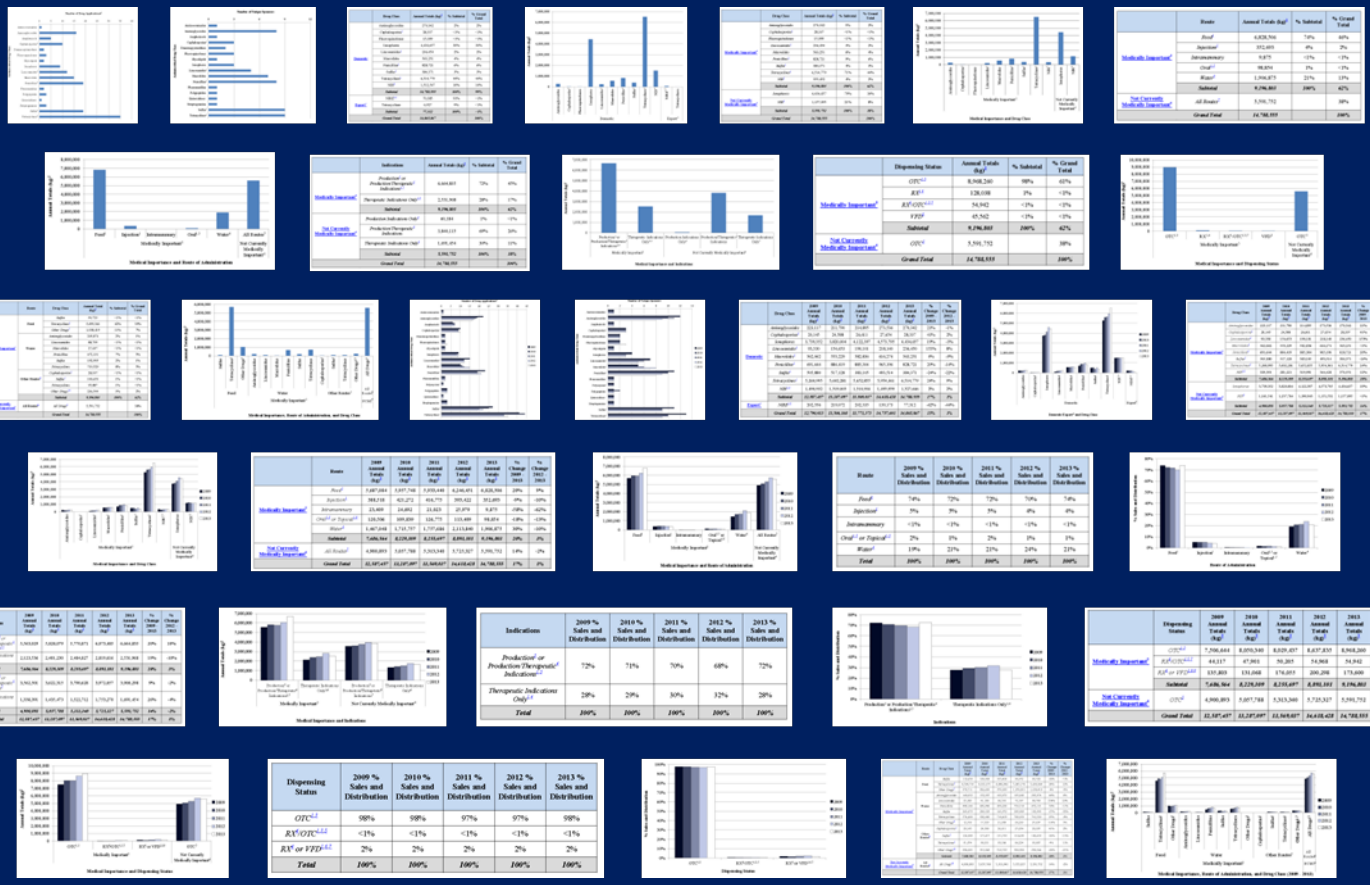
- FDA shall make summaries of the information reported under this paragraph publicly available, except that—
  - Summary data shall be reported by antimicrobial class, and no class with fewer than 3 distinct sponsors of approved applications shall be independently reported; and
  - Data shall be reported in a manner consistent with protecting both national security and confidential business information.

Processing and Analysis of Data

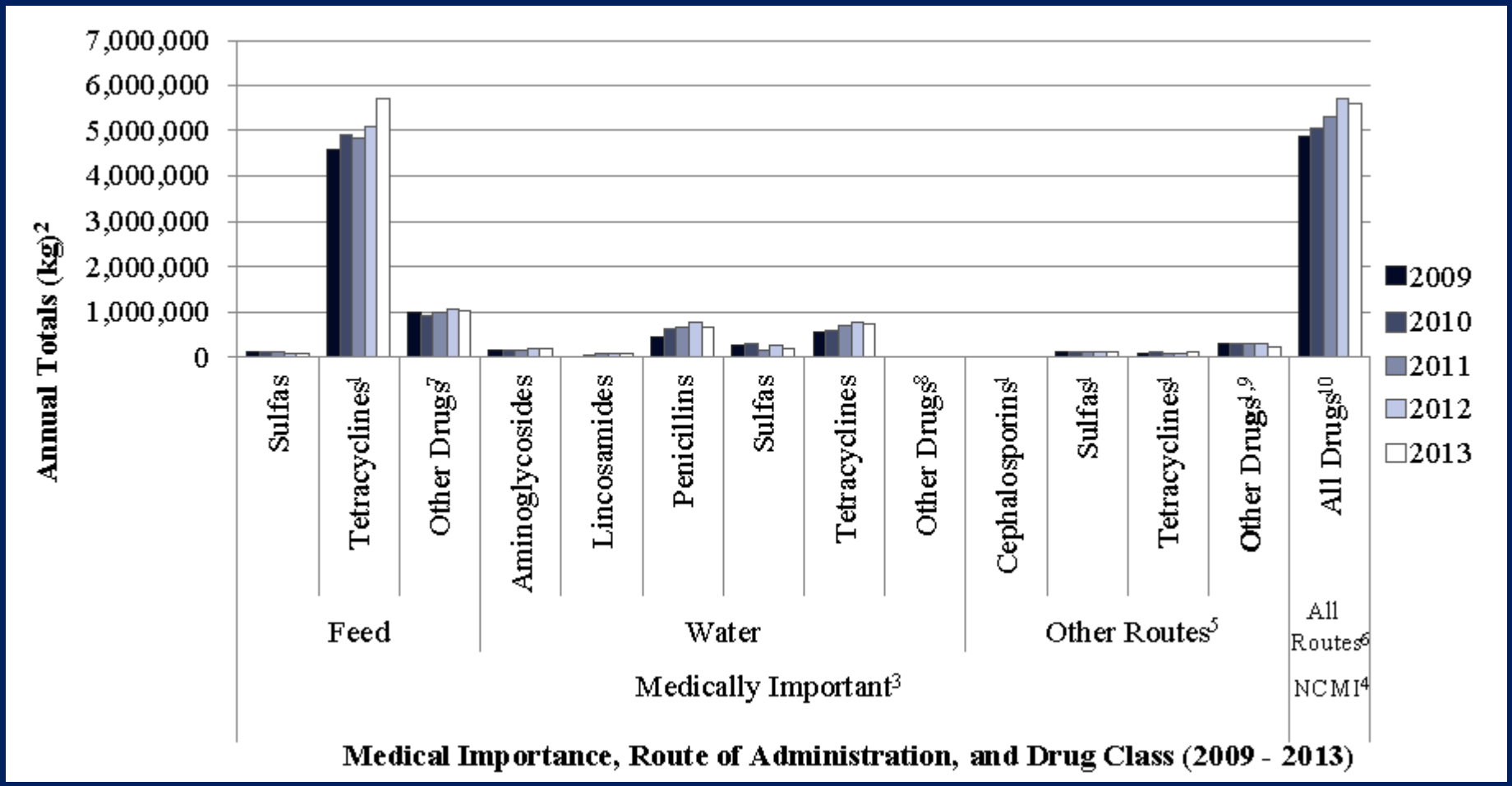
2009 Sales Summary Report (published December, 2010 – 3 pages)

	Antimicrobial Class	Annual Totals (kg[1])
Domestic	*Aminoglycosides*	339,678
	Cephalosporins	41,328
	Ionophores	3,740,627
	Lincosamides	115,837
	Macrolides	861,985
	Penicillins	610,514
	Sulfas	517,873
	Tetracyclines	4,611,892
	NIR[2]	2,227,366
Export	*Tetracyclines*	515,819
	NIRE[3]	1,115,728

2013 Sales Summary Report (published April, 2010 – 56 pages)



2013 Sales Summary Report



Protecting both national security
and confidential business information

Limitations

- Veterinarians (with certain exceptions) can legally use drugs in an extralabel manner
- Majority of animal feed drugs are approved for multiple indications
- Approved for use in both food- and nonfood-producing animals
- Approved for multiple routes of administration, and as OTC and prescription drugs
- Approved and labeled for use in:
  - multiple species
  - for multiple indications
  - with multiple dosage regimens

Limitations (cont.)

- Because of all these variations - assumptions cannot be made about actual product use

- Sales data represent summary of volume of product sold or distributed through various outlets by the manufacturer intended for sale to the end user
- And not the volume of product ultimately purchased by the end user for administration to animals

Proposed Rulemaking
Federal Register - May 20, 2015

- Requires sponsors to submit species-specific estimates of antimicrobial sales for cattle, swine, chickens, and turkeys.
- Includes provision to improve the timeliness of annual summary report of sales data by requiring the FDA to publish its annual summary report by December 31 of the following year.
- Written comments on the proposed rule by August 18, 2015