This 2010 Summary Report is final as of 10/31/11. An earlier draft of the summary report was posted erroneously on 10/28/11. It did not contain the final results. We were still adjusting classifications and numbers including a late submission from a drug sponsor. The mistake was realized and we issued the final summary report which reflected the correct numbers on 10/31/11. We apologize for any confusion this may have caused.

2010

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 User Fee Amendments of 2008 (ADUFA) (110 P.L. 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 applications for new animal drugs containing an antimicrobial active ingredient submit an 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 interactions (including drug resistance), efficacy, and safety of antibiotics approved for use in both humans and food-producing animals (H. Rpt. 110-804).

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 monthly sales and distribution data for the preceding calendar year. These reports are separate from periodic drug experience reports that are required under 21 CFR 514.80(b)(4).

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 510.600 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 2010 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 reference, this table also lists the specific drugs in each class for which there were actively marketed animal drug products. This summary report includes antimicrobial drugs that are specifically approved for antibacterial uses or are known to have antibacterial properties. Some antimicrobial drug products are approved and labeled for use in multiple species, including both food- and nonfood-producing animals, such as dogs and horses. For these products, sales and distribution data was not required to be reported to FDA by species.

.

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: 2010 Sales and Distribution Data Reported by Drug Class

	Antimicrobial Class	Annual Totals (kg[1])
Domestic	*Aminoglycosides*	200,794
	Cephalosporins[2]	24,588
	Ionophores	3,821,138
	Lincosamides[2]	154,653
	Macrolides[2]	553,229
	Penicillins[2]	870,948
	Sulfas[2]	506,218
	Tetracyclines[2]	5,592,123
	NIR[2,3]	1,517,447
Export[4]	*Tetracyclines*[2]	9,968
	NIRE[2,5]	206,566

[1] 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.

[2] Includes antimicrobial drug products which are approved and labeled for use in multiple species, including both food- and nonfood-producing animals, such as dogs and horses.

[3] 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: Aminocoumarins, Amphenicols, Diaminopyrimidines, Fluoroquinolones, Glycolipids, Pleuromutilins, Polypeptides, Quinoxalines, Streptogramins

[4] Only includes exports of FDA-approved, US-labeled antimicrobial drugs approved for use in food-producing animals. Export totals from 2009 summary report inadvertently included some non-FDA-approved antimicrobial drug products, which resulted in an incorrect, larger number.

[5] 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: Aminocoumarins, Aminoglycosides, Amphenicols, Cephalosporins, Diaminopyrimidines, Fluoroquinolones, Glycolipids, Ionophores, Lincosamides, Macrolides, Penicillins, Pleuromutilins, Polypeptides, Sulfas, Quinoxalines, Streptogramins.

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

Aminocoumarins
Novobiocin

Aminoglycosides
Apramycin
Gentamicin
Neomycin
Spectinomycin

Amphenicols
Florfenicol

Cephalosporins
Ceftiofur
Cephapirin

Diaminopyrimidines
Ormetoprim

Fluoroquinolones
Danofloxacin
Enrofloxacin

Glycolipids
Bambermycins

Ionophores
Laidlomycin
Lasalocid
Monensin
Narasin
Salinomycin
Semduramicin

Lincosamides
Lincomycin
Pirlimycin

Macrolides
Carbomycin
Erythromycin
Oleandomycin
Tilmicosin
Tulathromycin
Tylosin

Penicillins
Amoxicillin
Ampicillin
Cloxacillin
Penicillin

Pleuromutilins
Tiamulin

Polypeptides
Bacitracin
Polymixin B

Quinoxalines
Carbadox

Streptogramins
Virginiamycin

Sulfas
Sulfachlorpyridazine
Sulfadiazine
Sulfadimethoxine
Sulfamerazine
Sulfamethazine
Sulfaquinoxaline

Tetracyclines
Chlortetracycline
Oxytetracycline
Tetracycline