

Overview of Laws Regulating Antibiotics in Livestock & Policy

Positions of Stakeholder Groups

Prepared for: Association for the Bar for the City of New York's Committee on
Animal Law and Health Law Committee

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I. BACKGROUND

A. What are Antibiotics?

1. **Definition** – Antibiotics belong to a class of drugs called “antimicrobials”. Although bacteria live everywhere and play an important function in the human body, some bacteria are harmful and lead to sickness. Among these illnesses are food borne illnesses, commonly called food poisoning. Antibiotics can inhibit the growth of this negative bacteria that causes infections and illness.

2. **Classes of Antibiotics** –

- i) Aminoglycosides (e.g., gentamycin, neomycin, spectinomycin, and streptomycin)
- ii) Bambermycins (e.g., bambermycin, flavophospholipol)
- iii) Beta-Lactams
- iv) Penicillins (e.g., penicillin and amoxycillin)
- v) Cephalosporins (e.g., cefotaxime)
- vi) Glycopeptides (e.g., vancomycin—not approved for animal use)
- vii) Ionophores (e.g., monensin)
- viii) Lincosamides (e.g., lincomycin)
- ix) Macrolides (e.g., erythromycin, tylosin)
- x) Polypeptides (e.g., bacitracin)
- xi) Quinolones (e.g., fluoroquinolones)
- xii) Streptogramins (e.g., virginiamycin)
- xiii) Sulfonamides (e.g., sulfa drugs)
- xiv) Tetracyclines (e.g., chlortetracycline and oxytetracycline)

See Jacquie Jacob, “Antibiotics Approved for Use in Conventional Poultry Production,”
Extension, May 5, 2015, available at <http://www.extension.org/pages/66981/antibiotics->

[approved-for-use-in-conventional-poultry-production#.VYQonPIVhBc](#) (last visited June 19, 2015).

B. Comparison to Antimicrobials, Vaccines, Hormones & Feed Additives

	<u>Definition</u>	<u>Purpose</u>	<u>Regulatory Agencies</u>
Antibiotics	<p>Antibiotics belong to a class of drugs called “antimicrobials”. Antibiotics can inhibit the growth of this bad bacteria that causes infections and illness.</p> <p>An ANTIBIOTIC is a low molecular substance produced by a microorganism that at a low concentration inhibits or kills other microorganisms.¹</p>	<p>1) to treat sick animals, 2) to control and prevent the spread of infection, and 3) to promote growth and increase food consumption</p>	USDA & FDA
Antimicrobials	<p>“An ANTIMICROBIAL is any substance of natural, semisynthetic or synthetic origin that kills or inhibits the growth of microorganisms but causes little or no damage to the host.</p> <p>All antibiotics are antimicrobials, but not all antimicrobials are antibiotics.”²</p>		
Vaccines	<p>“A vaccine is a product that produces immunity from a disease and can be administered through needle injections, by mouth, or by aerosol.</p> <p>A vaccination is the injection of a killed or weakened organism that produces immunity in the body against that organism.</p> <p>An immunization is the process by which a person or animal becomes protected from a</p>	Preventing disease	USDA-APHIS

¹ See Antimicrobial Resistance Learning Site, available at <http://amrls.cvm.msu.edu/pharmacology/antimicrobials/antimicrobials-an-introduction> (last visited June 12, 2015)

² See Antimicrobial Resistance Learning Site, available at <http://amrls.cvm.msu.edu/pharmacology/antimicrobials/antimicrobials-an-introduction> (last visited June 12, 2015)

	disease. Vaccines cause immunization, and there are also some diseases that cause immunization after an individual recovers from the disease.” ³		
Hormones	Hormones are chemicals naturally produced in the body. However, in terms of livestock, these include natural estrogen, progesterone, testosterone, and their synthetic versions	Increases growth rate ⁴	FDA
Feed Additives	Food supplements given to farm animals that may include, <i>inter alia</i> , vitamins, amino acids, fatty acids and minerals. Antibiotics used in feed are a type of feed additive.	Supplement nutrition	

C. Legal Definitions

1. Feed Additive

- i) A **substance added to feed in micro quantities to fulfill a specific nutritional need**; i.e., essential nutrients in the form of amino acids, vitamins, and minerals. See, 7 CFR § 205.2 (emphasis added).
- ii) “The term ‘food additive’ means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in

³ See vaccines.gov available at <http://www.vaccines.gov/basics> (last visited June 12, 2015).

⁴ See FDA’s “Steroid Hormone Implants Used for Growth in Food-Producing Animals” available at <http://www.fda.gov/AnimalVeterinary/SafetyHealth/ProductSafetyInformation/ucm055436.htm> (last visited June 12, 2015).

food) to be safe under the conditions of its intended use; except that such term does not include

- (1) a pesticide chemical residue in or on a raw agricultural commodity or processed food; or
- (2) a pesticide chemical; or
- (3) a color additive; or
- (4) any substance used in accordance with a sanction or approval granted prior to September 6, 1958, pursuant to this chapter, the Poultry Products Inspection Act [21 U.S.C. 451 et seq.] or the Meat Inspection Act of March 4, 1907, as amended and extended [21 U.S.C. 601 et seq.];
- (5) a new animal drug; or
- (6) an ingredient described in paragraph (ff) in, or intended for use in, a dietary supplement.”

See 21 U.S.C. § 321 (s).

2. Antibiotic

- i) Any drug (except drugs for use in animals other than humans) composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other drug intended for human use containing any quantity of any chemical substance which is produced by a micro-organism and **which has the capacity to inhibit or destroy micro-organisms in dilute solution** (including a chemically synthesized equivalent of any such substance) or any derivative thereof. See 21 U.S.C. § 321 (jj). It is also used in livestock raised for meat, milk and eggs.
- ii) According to the AVMA: Antibiotics are substances that are actually produced by one microorganism and have the ability to kill or inhibit the growth or multiplication (reproduction) of other microorganisms.

3. Vaccine

- i) The term “vaccine” means any substance designed to be administered to a human being for the prevention of 1 or more diseases. See 26 U.S.C. § 4132 (a)(2). Also used in livestock raised for meat, milk and eggs.

4. Hormone

- i) The term "hormone" is used broadly to describe a **chemical substance formed in some organ of the body**, such as the adrenal

glands or the pituitary, and carried to another organ or tissue, where it has a specific effect. Hormones include, for example, estrogens, progestins, androgens, anabolic steroids, and adrenal corticosteroids, and synthetic analogs... See 21 CFR § 310.530 (emphasis added)

5. **Biologics**

- i) All viruses, serums, toxins, and analogous products of natural or synthetic origin, such as diagnostics, antitoxins, vaccines, live microorganisms, killed microorganisms, and the antigenic or immunizing components of microorganisms intended for use in the diagnosis, treatment, or **prevention of diseases of animals**. See 7 CFR § 205.2(3).

6. **Biological products.**

- i) The term *biological products*, also referred to in this subchapter as biologics, biologicals, or products, shall **mean all viruses, serums, toxins (excluding substances that are selectively toxic to microorganisms, e.g., antibiotics)**, or analogous products at any stage of production, shipment, distribution, or sale, which are intended for use in the treatment of animals and which act primarily through the direct stimulation, supplementation, enhancement, or modulation of the immune system or immune response. The term 'biological products' includes but is not limited to vaccines, bacterins, allergens, anti- bodies, antitoxins, toxoids, immunostimulants, certain cytokines, antigenic or immunizing components of live organisms, and diagnostic components, that are of natural or synthetic origin, or that are derived from synthesizing or altering various sub- stances or components of substances such as microorganisms, genes or genetic sequences, carbohydrates, proteins, antigens, allergens, or anti- bodies. See, 9 CFR 101.2 (emphasis added).

D. **Purposes of Antibiotics**

1. **FDA Approved Uses.** The Food and Drug Administration (“FDA”) has currently approved antibiotics use in livestock for three reasons:
 - i) to treat sick animals,
 - ii) control and prevent the spread of infection, and
 - iii) to promote growth and increase food consumption which in turn increases meat, eggs, and/or dairy from animals.

See National Agricultural Law Center’s “Congressional Research Service- Antibiotic Use in Food Animals: FDA’s Current Activities” available at <http://nationalaglawcenter.org/wp-content/uploads/assets/In%20Focus/IF00017.pdf> (last visited May 13, 2015); see also FDA’s “From an Idea to the Marketplace: The Journey of an Animal Drug through the Approval Process available at <http://www.fda.gov/AnimalVeterinary/ResourcesforYou/AnimalHealthLiteracy/ucm219207.htm> (last visited May 31, 2015).

2. Description of Uses

i) *Therapeutic*

- a) Treating Sickness. The most common reason for treating livestock with antibiotics is to fight off infection of a sick animal and prevent others from getting sick. If livestock producers did not treat sick animals, many would suffer and die, which would be inhumane.
- b) Preventing Infection. Human and animal health treatment differs. In humans, doctors tend to treat the individual. In farm animals, veterinarians tend to treat the herd.
- c) Controlling Infection. Sometimes symptoms do not appear for days so if one animal is sick, it makes sense to treat the entire herd. Sickness among a large herd can affect food supply and drive up the price of meat as well.

- ii) *Growth Promotant*. Antibiotics kill the naturally occurring gut flora in livestock, which allows the farm animals’ bodies to use the food they consume more effectively. See Antimicrobial Resistance Learning Site’s “Growth Promotion” available at <http://amrls.cvm.msu.edu/pharmacology/antimicrobial-usage-in-animals/non-therapeutic-use-of-antimicrobials-in-animals/use-of-antibiotics-in-animals-for-growth-promotion> (last visited May 23, 2015) (for a list of ways that sub-therapeutic levels of antibiotics promote growth). Use of antibiotics increases feed efficiency (and input costs) when looking at the animals’ intake over the output (e.g., meat or milk).

E. Resistance v. Residues

Resistance	Residues
“Antibiotic resistance occurs when an antibiotic has lost its ability to effectively	Traces of antibiotics in feed, in some cases, as a result of administering antibiotics to

<p>control or kill bacterial growth; in other words, the bacteria are "resistant" and continue to multiply in the presence of therapeutic levels of an antibiotic.”⁵</p>	<p>livestock used for meat and dairy. There are maximum antibiotic limits allowed in food products (i.e., Maximum Residue Limits or “MRLs”).</p> <p>Techniques used for detection and analysis of drug residues include: ELISA, HPLC, liquid chromatography, gas chromatography, and paper chromatography. See Nisha, A.R., “Antibiotic Residues - A Global Health Hazard” Veterinary World, Vol. 1(12):375-377 at 376 available at http://www.veterinaryworld.org/2008/December/Antibiotic%20Residues%20-%20A%20Global%20Health%20Hazard.pdf (last visited June 19, 2015).</p>
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F. Current Use of Antibiotics Among Species

1. **Beef Cattle** – Primarily used to treat sickness. Also used as a growth promotant during times of stress. Some feedyards use antibiotics. Popular antibiotics in the beef cattle industry include:

Product	Company	Active Ingredient	Use	How it is administered	Prescription or OTC
Aureomycin®		chlortetracycline (a/k/a “CTC”) ⁶	Used during the growing phase (not the finishing stage) including pre-weaning and weaning	Feed	OTC

⁵ Alliance for the Prudent Use of Antibiotics (“APUA”) available at http://www.tufts.edu/med/apua/about_issue/about_antibioticres.shtml (last visited June 19, 2015).

⁶ Aureomycin and “CTC” are used interchangeably in the livestock industry.

2. **Dairy Cattle** – Primarily used to treat sickness. Also used as a growth promotant during times of stress. Popular antibiotics in the dairy industry include:

Product	Company	Active Ingredient	Use	How it is administered	Prescription or OTC
Aureomycin®		chlortetracycline (a/k/a “CTC”)	Used during the growing phase (not the finishing stage) including pre-weaning and weaning	Feed	OTC

3. **Sheep & Goats** – Primarily used to treat sickness. The frequency of use among the sheep and goat industry is lower than compared to bovine animals. Popular antibiotics in the sheep and goat industry include:

Product	Company	Active Ingredient	Use	How it is administered	Prescription or OTC
Aureomycin®		chlortetracycline (a/k/a “CTC”)	Used during the growing phase (not the finishing stage) including pre-weaning and weaning	Feed	OTC

4. **Pigs** – In comparison to ruminant animals, the swine industry uses antibiotics as a growth promotant more frequently. Also used to treat sick hogs. Popular antibiotics in the pig industry include:

Product	Company	Active Ingredient	Use	How it is administered	Prescription or OTC
Tylan [®] Premix	Elanco Animal Health	tylosin	Improve weight gain, feed efficiency and carcass yield; used more in the finishing phase	Feed	OTC
Aureomycin [®]		Chlortetracycline (a/ka/ "CTC")	Used in the early growing phase	Feed	OTC

5. **Poultry** – In comparison to ruminant animals, the poultry industry uses antibiotics as a growth promotant more frequently. Example antibiotics in the poultry industry include:

Product	Company	Active Ingredient	Use	How it is administered	Prescription or OTC
Terracylin [®]	Philbro Animal Health	Oxytetracycline	Treat infectious disease	Feed	OTC

G. **Costs of Using Antibiotics**

1. ***Cost of Antibiotics with Beef Cattle.***

- i) Livestock producers must constantly weight the cost – benefit analysis when choosing to use antibiotics.
- ii) The best illustration of the costs be found at the Virginia Cooperative Extension of Virginia Tech-Virginia State University available at https://pubs.ext.vt.edu/400/400-008/Table_1.html (last visited June 13, 2015) (example of injectable antibiotics for beef cattle with price point). It has been recreated below:

Antibiotic	Tradename	OTC or Rx	Dosage	Indications	Approximate Cost for 500 lbs for 3 days
Penicillin	Pfi-Pen G, Agricillin, Procaine Pen G	OTC	1ml/100 lbs. Once a day	Bacterial pneumonia, Organisms susceptible	\$ 0.90
Penicillin	Durpen, Benzape, Pen BP-48	OTC	2ml/150 lbs.	Bacterial pneumonia, Upper respiratory disease, Blackleg	\$ 0.90
Oxytetracycline	Terramycin, Agrimycin-100, Oxy-Tet 100	OTC	5ml/100 lbs. Sub Q ⁷ (Status SQ)	Organisms susceptible to oxytetracycline	\$1.50
Oxytetracycline	Liquamycin LA-200, Procure 200, Biocor 200	OTC	5ml/100 lbs. Every other day	Bacterial pneumonia, foot rot, Pinkeye	\$2.10-2.50
Erythromycin	Erythro-200, Erythromycin-200, Gallimycin-200	OTC	.5 - 1 ml/100 lbs. Once a day	Pneumonia, mastitis, metritis, foot rot, wt. loss prevention	\$.75-\$1.50
Tylosin	Tylan 200, Tylosin Injection	OTC	4 ml/100 lbs. Once a day	Respiratory disease, foot rot, calf diphtheria	\$1.40
Sulfadimethoxine	Albon Inj. 40%, Sulfadadinj	OTC	31.2 ml/500 lbs., 15.6 ml/500 lbs. Intravenous ⁸	Respiratory disease, foot rot, calf diphtheria	\$5.25
Amoxicillin	Amoxi-Inject	Rx	1.5 -2 ml/100 lbs. IM or Sub Q	Respiratory disease, foot rot	\$7.50-\$10.00
Ampicillin	Polyflex	Rx	75 -1.25 ml /100 lbs.	Respiratory disease	\$8.10 - \$13.35

⁷ “Sub-Q” refers to subcutaneous, or under the skin.

⁸ This is referred to as an “intravenous” (i.e., into the vein) injection.

Ceftiofur Sodium	Naxcel	Rx	1-2 ml/100 lbs.	Respiratory disease, foot rot	\$7.50-\$15.00
Tilmicosin	Micotil 300 Injection	Rx	1.5 ml / 100 lbs. once SQ	Respiratory disease Metaphaylaxis	\$11.25
Florfenicol	Nuflor Injectable Solution	Rx	3.0ml/ 100 lbs. repeat in 48 hr; 6 ml/ 100 lbs. SQ once	Respiratory disease, High Risk cattle	\$ 14.00
Ceftiofur Hydrochloride	Excenel	Rx	1-2 ml daily to every other day	Respiratory disease	\$8 -\$11.25
Sulfamethazine Cow	Sustain III Sulfamax	OTC	1 Bolus per 200lbs	Susceptible bacterial infection	\$7.50
Sulfamethazine Calf	Sustain III Sulfamax	OTC	1 Bolus/50 lbs.	Susceptible bacterial infection	\$2.50
Enrofloxacin	Baytril	Rx	3.5 — 5.5 ml / 100 lbs. once; 1.1-2.3 ml/ 100 lbs. Daily for 3 days SQ	Respiratory disease	\$12- \$23

2. *Cost of Antibiotic Use with Other Species*

H. Positions on Antibiotic Use

1. *Livestock Commodity Groups & Agriculture Organizations*

i) National Cattlemen’s Beef Association (“NCBA”) – www.beef.org

a) *CH 3.4 2011/Renewed Floroquinolone Use*

“THEREFORE BE IT RESOLVED, NCBA recognizes and **endorses the FDA regulations for floroquinolone** use which clearly **prohibit the extra label use** of this class of antibiotics.”

See NCBA’s “National Cattleman’s Beef Association 2015 Policy Book” available at

<http://cqrcengage.com/beefusa/file/I7xRZnVNCDC/2015%20>

[NCBA%20Policy%20Book.pdf](#) (last visited June 11, 2015)
(emphasis added).

b) *CH 3.10 2013/Amended Judicious Use of Antibiotics and Drugs*

WHEREAS, the use of **antimicrobial agents** and other modern compounds is **necessary at times** to preserve life and prevent suffering in the face of disease in cattle, and

WHEREAS, **indiscriminant use** of antimicrobials may lead to the development of bacterial resistance, possibly impacting both animal and human health, and

WHEREAS, it is recognized that cattle producers have an obligation to **protect animal health**, and

WHEREAS, it is further recognized that there is an obligation to protect human health by **promoting food safety**,

THEREFORE BE IT RESOLVED, NCBA advocates the **judicious use of antimicrobials**, other compounds, and drugs. Issues involving the use of such products in animals and humans must be resolved using **sound, peer-reviewed science** without influence of emotion or political agendas, and

BE IT FURTHER RESOLVED, NCBA advocates the use of antimicrobials, other compounds, and drugs as outlined in the **Quality Assurance Guidelines**⁹ for both beef and dairy cattle, as appropriate.

Id. (emphasis added)

c) *CH 3.12 2013/Renewed Reclassification of Polyether Ionophores*

WHEREAS, the **feeding of polyether ionophores** (monensin, lasalocid, laidlomycin, etc) to cattle decreases the feed needed for growth, and increases feed efficiency, and

⁹ More information on NCBA's Beef Quality Assurance ("BQA") Program and recommended guidelines can be found at <http://www.bqa.org/> (last visited June 16, 2015). See, e.g., "Cattle Care & Handling Guidelines," available at http://www.bqa.org/CMDocs/bqa/CCHG2015_Final.pdf (last visited June 16, 2015) (Page 8 memorializes "A Producer's Guide for Judicious Use of Antimicrobials in Cattle").

WHEREAS, polyether ionophores **do not function as therapeutic or sub-therapeutic antibiotics** when fed to cattle, are not used as therapeutic agents in human medicine, and are not a concern for antibiotic resistance in cattle or humans, and

WHEREAS, polyether ionophores are categorized as coccidiostats when fed to poultry, and function to reduce methane production in cattle,

THEREFORE BE IT RESOLVED, NCBA strongly urges the Food and Drug Administration (FDA) and other appropriate agencies to re-classify polyether ionophores to reflect their true function as modifiers of rumen fermentation and coccidian prevention compound.

BE IT FURTHER RESOLVED, NCBA strongly urges FDA and other appropriate agencies to discontinue classification of polyether ionophores as antibiotics.

Id. (Emphasis added).

ii) American Dairy Association and Dairy Council Inc. (“ADADC”)
– www.adadc.com

iii) National Pork Producers Council – www.nppc.org

- a) “The health and welfare of animals is a key concern of pork producers. NPPC advocates **science-based approaches** to swine health and production. **Healthy animals make safe food**, and animal agriculture must continue to develop new methods to provide a safe, nutritious, food supply. **NPPC opposes legislation that would dictate on-farm production practices**, including outlawing individual housing for sows and **banning products such as antibiotics** that help producers care for their pigs.”

See NPPC’s “Animal Health & Food Safety” available at <http://www.nppc.org/issues/animal-health-safety/> (last visited June 11, 2015) (emphasis added); see also NPPC’s “Antimicrobials/Antibiotics” available at <http://www.nppc.org/issues/animal-health-safety/antimicrobials-antibiotics/> (last visited June 11, 2015).

- b) “**Antibiotics are one of the tools used by veterinarians and producers to quickly address clinical and subclinical disease**

and keep animals healthy and productive. Through pork farmers rely on antibiotics to keep their herds healthy, **they also use a variety of tools to keep their pigs happy and healthy**, including veterinarian care, good nutrition, proper and humane housing, and personal care.”

See NPPC’s “Animal Health & Food Safety” available at <http://www.nppc.org/issues/animal-health-safety/> (last visited June 11, 2015) (emphasis added); see also NPPC’s “Statement From NPPC President Howard Hill On White House Executive Order on Antibiotic Resistance” available at <http://www.nppc.org/2014/09/statement-from-nppc-president-howard-hill-on-white-house-executive-order-on-antibiotic-resistance/> (last visited June 11, 2015).

- c) “In its executive order on combating antibiotic resistant bacteria, the White House acknowledged something that the National Pork Producers Council has been saying for years: **More epidemiological research is needed to understand the key drivers of increased antibiotic resistance.** America’s pork producers, who abide by a strict antimicrobial stewardship program outlined in the industry’s **Pork Quality Assurance Plus (PQA Plus®)**¹⁰ certification program, are committed to protecting public health and producing safe food. They work **hand-in-hand with veterinarians to minimize the need for and use of antibiotics**, particularly antibiotics important in human medicine. And all antibiotics used in pork production are approved by FDA. NPPC is pleased that the administration agrees that more research is needed and looks forward to working further with FDA and USDA on determining the most informed and appropriate solutions for combating antibiotic resistant bacteria.”

See NPPC’s “Animal Health & Food Safety” available at <http://www.nppc.org/issues/animal-health-safety/> (last visited June 11, 2015) (emphasis added).

- iv) American Sheep Industry Association – www.sheepusa.org

- a) *1-08:95:R15 Over-the-Counter Drugs*

WHEREAS there are relatively few medications labeled to treat sheep diseases, and

¹⁰ More information on the Pork Quality Assurance Plus program can be found at <https://www.pork.org/pqa-plus-certification/> (last visited June 16, 2015).

WHEREAS **judicious use of antibiotics** and anthelmintics is necessary to alleviate animal pain and suffering and ensure animal health and welfare, and

WHEREAS the shortage of food-animal veterinarians is a significant issue to the sheep industry, and

WHEREAS the **availability of FDA-approved, over-the-counter (OTC) antibiotics** and anthelmintics is necessary in order for producers to have access to these essential medications when needed.

See ASI's "2015 American Sheep Industry Association (ASI) Policy" available at http://amhealthmaster.http.internapcdn.net/AMHealthMaster/DOCUMENT/SheepUSA/ASI_PolicyBook2015_assembled.pdf (last visited June 11, 2015).

- v) American Goat Federation – [www.americangoatfederation](http://www.americangoatfederation.com)
- vi) American Poultry Association – www.amerpoultryassn.com
- vii) National Turkey Federation – www.eatturkey.com
 - a) "The National Turkey Federation believes the FDA guidance document on antibiotic use creates a **science-based framework to preserve the therapeutic benefits of antibiotics that farmers and their veterinarians currently rely on for disease treatment**, control and prevention. Turkey producers and processors are committed to the wellbeing of farm animals and the safety of the food supply. Medications are an important part of that process. Because antibiotic resistance is a public health concern, **several layers of protection have been put in place to ensure that animal antibiotics do not affect public health.**"

See NTF's "Antibiotics" available at <http://www.eatturkey.com/content/antibiotics> (last visited June 11, 2015) (emphasis added); see also National Turkey Federation's "Standards of Conduct" available at <http://www.eatturkey.com/standards> (last visited June 11, 2015).

- b) “To ensure proper animal and public health, any medications will be administered in a judicious fashion in accordance with the NTF’s Comprehensive Residue Avoidance Program and the American Association of Avian Pathologist’s Judicious Use Guidelines. The turkey industry adopts Standards of Conduct to ensure the industry’s practices align with its Code of Ethics.”

Id. (emphasis added).

viii) American Farm Bureau – www.fb.org

- a) “AFBF Policy: Given current data on the risk assessment of livestock antibiotics, Farm Bureau opposes restricting the use of antibiotics. It is important that decision-makers review demonstrated scientific evidence of the risks and benefits of potential future actions. Farm Bureau has serious concerns about the effects of removing important antibiotics and classes of antibiotics from the market, which would handicap veterinarians and livestock and poultry producers in their efforts to maintain animal health and protect our nation’s food supply. Further limiting or eliminating animal antibiotic use for livestock will have negative economic and animal health consequences. Farm Bureau supports:

- (1) Sound science as the basis for decision-making and policy development regarding antibiotics/antimicrobials used in food animal production;

- (2) Use of the National Antimicrobial Resistance Monitoring System, the National Animal Health Monitoring System and the Department of Agriculture’s food safety monitoring system to address issues of antimicrobial resistance trends in food-borne bacteria and animal health;

- (3) Regulation of antibiotics/antimicrobials at the national level to avoid a state-by-state patchwork of regulation;

- (4) A multi-agency approach to on-farm antimicrobial-resistant bacteria trend research and surveillance between the Animal and Plant Health Inspection Service, Agricultural Research Service, Food Safety and Inspection Service, and livestock producers; and

(5) Rather than limitations or elimination of animal health and food safety protection tools, Farm Bureau would accept veterinarian oversight of antibiotic use, where veterinarian oversight is defined as a working relationship with a licensed veterinarian and allow for the purchasing of animal pharmaceuticals using a prescription without the requirement of purchasing directly from a veterinarian.

See American Farm Bureau Federation’s “Preserving Antibiotics Access” available at <http://www.fb.org/issues/docs/antibiotics15.pdf> (last visited June 11, 2015).

ix) American Agri-Women – www.americanagriwomen.org

a) “AAW supports the responsible use of antibiotics and other industry approved treatments to safeguard animal health.”

See American Agriwomen’s “2015 AAW Position Statements” available at <http://www.americanagriwomen.org/files/AAW%20PositionStatements%20Spring15.pdf> (last visited June 11, 2015).

x) National Sustainable Agriculture Organization – www.sustainableagriculture.net

a) “The National Sustainable Agriculture Coalition works closely with the Union of Concerned Scientists and Keep Antibiotics Working who are leading a grassroots campaign to win legislation that will phase out the nontherapeutic use of antibiotics as feed additives for animals.” See NSC’s “Antibiotic Resistance” available at <http://sustainableagriculture.net/our-work/issues/research-and-extension/antibiotic-resistance/> (last visited June 11, 2015)

xi) Animal Agriculture Alliance – www.animalagalliance.org

a) “Fact: Banning or severely restricting the use of antimicrobials in animals may negatively impact a veterinarian's ability to protect animal health and prevent suffering from disease, which can lead to poor animal welfare.”

See Animal Agricultural Alliance’s “Quick Facts About Antibiotics” available at <http://www.animalagalliance.org/educate/#antibiotics> (last

visited June 11, 2015); See also Animal Agricultural Alliance’s letter to Panera Bread, re: “antibiotic free” advertisements, dated August 6, 2013 available at <http://animalagalliance.org/images/upload/FINAL%20Letter%20to%20Panera%20Draft.pdf>) last visited June 11, 2015);

2. *Veterinarians*

i) American Veterinary Medical Association – www.avma.org

a) *Judicious Use Principles*

Disease prevention strategies, such as appropriate husbandry and hygiene, routine health monitoring, and vaccination, **should be included as part of a comprehensive animal/herd health plan.** Once disease has occurred, other management and intervention strategies may be considered prior to antimicrobial treatment.

Judicious use of all antimicrobials should include appropriate veterinary oversight. Extra label use of antimicrobials must meet all the requirements of the veterinarian-client-patient relationship as defined in the AMDUCA amendments to the Federal Food, Drug, and Cosmetic Act and its regulations.

Extralabel use in food animals necessitates an extralabel withdrawal interval to be assigned by the attending veterinarian, on the basis of information on the species, dose, route, and frequency of treatment, in conjunction with available scientific pharmacokinetic data.

Antimicrobials requiring a prescription must be used only by, or under the order of, a licensed veterinarian. This should include a veterinarian-client-patient relationship.

A Veterinary Feed Directive must be issued only by a licensed veterinarian in the course of the veterinarian’s professional practice. This should include a veterinarian-client-patient relationship.

Accurate records of treatment and outcome should be maintained. Antimicrobials should be used in animals only after careful review. Use narrow-spectrum antimicrobials whenever appropriate. Use microbial culture and antimicrobial

susceptibility results to aid in the selection of antimicrobials when clinically relevant. Regimens for antimicrobial treatment, control, or prevention of disease should be based upon current scientific and clinical principles, such as microbiological and pharmacological tenets. Antimicrobial use should be confined to appropriate clinical indications. Inappropriate uses such as for uncomplicated viral infections should be avoided. To minimize selective pressure, therapeutic exposure to antimicrobials should be minimized by treating only for as long as needed for the desired clinical response. Limit therapeutic antimicrobial treatment to ill or at-risk animals, treating the fewest animals indicated. Minimize environmental contamination with antimicrobials whenever possible.”

See American Veterinary Medical Association’s “Judicious Therapeutic Use of Antimicrobials-Position Statement” available at <https://www.avma.org/KB/Policies/Pages/Judicious-Therapeutic-Use-of-Antimicrobials.aspx> (last visited June 11, 2015)

3. *Meat*

i) American Meat Institute (“AMI”)

- a) “The use of antibiotics is a conventional production practice. Animals raised without antibiotics do not produce a safer or higher quality product than those raised in a conventional manner.” See AMI’s “FactSheet-Antibiotic Use in Livestock Production: Ensuring Meat Safety” available at <https://www.meat institute.org/index.php?ht=a/GetDocumentAction/i/56994> (last visited June 13, 2015).

4. *Consumer Groups & Environmental Organizations*

i) Natural Resources Defense Council (“NRDC”)

- a) NRDC sued the FDA to compel the agency to issue mandatory rules that put an end to the routine use of antibiotics on animals that are not sick and don't need them.

See Natural Resources Defense Council’s “Food, Farm Animals, and Drugs” available at <http://www.nrdc.org/food/saving-antibiotics.asp> (last visited June 11, 2015).

ii) Center for Science in the Public Interest

- a) “This voluntary approach is flawed in light of FDA’s public health mission. Legislation such as ‘The Preservation of Antibiotics for the Medical Treatment Act’ would provide clearer standards to limit the use of eight classes of antibiotics, deemed critically important for use in human medicine, that are also used in animal agriculture. This Act provides a more rigorous measure to address the problem of antibiotic resistance by specifically addressing uses of antibiotics in animal agriculture that are critical to treatment of human disease.”

See CSPI’s “Antibiotic Resistance in Foodborne Pathogens, May 2013” available at http://cspinet.org/new/pdf/outbreaks_antibiotic_resistance_in_foodborne_pathogens_2013.pdf (last visited June 11, 2015).

iii) Food Animal Concerns Trust (“FACT”)

- a) “FACT’s long standing work on eliminating the routine use of antibiotics in food animals is starting to pay off with big changes in the way chickens are raised. Now we need to start putting more effort into turkeys, pigs, and cattle.” See FACT’s homepage available at <http://foodanimalconcerns.org/> (last visited June 11, 2015).

5. Food Suppliers

i) Walmart

- a) “Walmart believes that antibiotics should be used "responsibly" in farm animals, and the company is asking suppliers to:
- (1) Adopt and implement the Judicious Use Principles of Antimicrobial Use from the American Veterinary Medical Association (AVMA) including accurate record keeping, veterinary oversight and limiting antimicrobial treatment to animals that are ill or at risk.
 - (2) Adopt and implement Voluntary Guidance for Industry #209 from the Food and Drug Administration in their own

operations and their industry producer programs, including eliminating growth promotion uses of medically important antibiotics

(3) Promote transparency by providing a report on antibiotics management to Walmart and publicly report antibiotic use on an annual basis.”

See Meatingplace’s “Walmart weighs in on antibiotic use in food animals” available at <http://www.meatingplace.com/Industry/News/Details/58530?allowguest=true> (last visited June 13, 2015).

6. *International Organizations*

i) Food and Agriculture Organization of the United Nations

a) The prudent use of antimicrobials in livestock and aquaculture sector is essential in light of the increased demand for animal proteins by a rapidly growing world population expected to exceed 9.6 billion by 2050. Intensifying production means additional challenges in disease management and even higher potential for increased antimicrobial resistance.” See Food and Agriculture Organization of the United Nation’s “Antimicrobial Resistance” available at <http://www.fao.org/antimicrobial-resistance/en/> (last visited June 14, 2015).

ii) World Health Organization

a) “Antibacterial drugs are sometimes used in animal husbandry for disease prevention and (in half of the countries in the world) as growth promoters, involving mass administration,” the WHO report said. “...Urgent action is needed to avoid inappropriate use, and to reduce antibiotic usage in animal husbandry and aquaculture, as well as in humans.”

See Environmental Working Group’s Article “World Health Organization Says Antibiotic Resistance Sweeping Globe” available at <http://www.ewg.org/release/world-health-organization-says-antibiotic-resistance-sweeping-globe> (last visited June 14, 2015).

II. FEDERAL LAWS REGULATING ANTIBIOTICS

A. Role of Regulatory Agencies

1. *U.S. Department of Agriculture (“USDA”)*

- i) Overview of USDA Regulation: USDA is the cabinet-level agency that regulates antibiotics in meat, poultry, and eggs.
- ii) Food Safety Inspection Service (“FSIS”): Pursuant to the Federal Meat Inspection Act (“FMIA”), the Poultry Productions Inspection Act (“PPIA”) and the Egg Products Inspection Act (“EPIA”), FSIS is the USDA sub-agency that oversees food labeling and whether meat or poultry is misbranded.
 - a) *Random Tests at USDA-Inspected Slaughter Facilities*
 - (1) FSIS randomly tests carcasses or animal used for meat for the presence of antibiotics. See 9 CFR § 310.21.
 - (2) FSIS also samples carcasses from any farms that have been cited for violations in the past.
 - b) *Violators are Published with FSIS*
 - (1) Violations are published on the FSIS website and penalties include jail time and fines. See FSIS Residue Violation Information System available at http://www.fsis.usda.gov/wps/wcm/connect/f69f356d-0ae7-4007-b334-bca63c6703a0/Residue_IPP.pdf?MOD=AJPERES (last visited June 11, 2015).
- iii) Agriculture Marketing Service (“AMS”): This sub-agency of the USDA certifies foods as “organic” via the National Organic Program (“NOP”) that prohibits antibiotics.

2. *Food and Drug Administration (“FDA”)*

- i) Overview of FDA Regulation:
 - a) FDA an agency of the Department of Health and Human Services (“HHS”).
 - b) In terms of food and antibiotic use in livestock, it regulates food and drugs in livestock animals excluding meat, poultry,

and eggs (regulated by USDA). FDA regulates labels on drug (such as species, usage, dosage, and withdrawal period).

ii) Center for Veterinary Medicine (“CVM”):

- a) CVM is a sub-agency of the FDA which oversees the safety and effectiveness of animal drugs and the approval process for same.
- b) Approves antibiotic use in livestock for disease treatment, disease control, disease prevention, and nutritional efficiency.

iii) Positions by FDA on Antibiotic Use

- a) *Encouraging Healthy Living Environments* - The FDA encourages judicious use of antibiotics and veterinarians recommend taking great care to prevent sickness and infection in the first place by keeping animals’ living quarters hygienic. See National Agricultural Law Center’s “Congressional Research Service-Antibiotic Use in Food Animals: FDA’s Current Activities” available at <http://nationalaglawcenter.org/wp-content/uploads/assets/In%20Focus/IF00017.pdf> (last visited May 13, 2015).
- b) *Mitigate use of Antibiotics as a Growth Promotant & Encouraging more Veterinary Guidance* - Currently, the FDA has a voluntary program in place to encourage judicious use of antibiotics in livestock. The program is designed to limit and eventually vitiate antibiotic treatment for growth purposes and to bring the use of antibiotic treatment under the control of veterinarians. See FDA’s “Guidance for Industry #213” available at <http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM299624.pdf> (last visited May 14, 2015); see also American Veterinary Medical Association’s “Antimicrobial Fact Sheet for Veterinarians” available at https://www.avma.org/KB/Resources/Reference/Documents/antimicrobial_fact_sheet_veterinarians.pdf (last visited May 31, 2015).
- c) *Veterinary Feed Directive* - The FDA is working towards all antibiotics for livestock needing a Veterinary Feed Directive (“VFD”). Currently, livestock producers do not need a VFD

for certain over-the-counter antibiotics. “When adequate directions cannot be written in a manner that enables a layperson to use a drug safely and for the purposes for which it is intended, the drug is restricted to use under veterinary oversight as an Rx or VFD product.” See FDA’s “Guidance for Industry #213” available at <http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM299624.pdf> (last visited May 14, 2015). The FDA hopes to achieve its goals by 2016. See, 21 CFR 558.6 (discussing the oversight and procedures regulating VFD’s).

3. *Centers for Disease Control and Prevention (“CDC”)*

- i) Overview: The CDC is part of the Department of Health and Human Services and safeguards the health of our country. One way it does this is by monitoring antibiotic resistance.
- ii) NARMS: National Antimicrobial Resistance Monitoring System (“NARMS”) is a sub-agency of the CDC.
 - a) *Players*: Composed of the FDA, CDC, USDA’s FSIS
 - b) *Purposes*: Its primary purpose is to track antibiotic resistance in the United States. The primary objectives of the NARMS program are to:
 - (1) Monitor trends in antimicrobial resistance among foodborne bacteria from humans, retail meats, and animals;
 - (2) Disseminate timely information on antimicrobial resistance to promote interventions that reduce resistance among foodborne bacteria;
 - (3) Conduct research to better understand the emergence, persistence, and spread of antimicrobial resistance; and
 - (4) Assist the FDA in making decisions related to the approval of safe and effective antimicrobial drugs for animals.

See FDA’s “NARMS 2010 Executive Report” available at <http://www.fda.gov/downloads/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/NationalAntimicrobialResistanceMonitoringSystem/UCM312360.pdf> (last visited May 13, 2015).

B. **Food Safety**

1. The Code of Federal Regulations also provides guidance for making food safe even if the animal were treated with antibiotics during its lifetime. See, e.g., 21 CFR § 510.110, and part(c), specifically, which states that “unauthorized and unsafe residues of antibiotics cannot be permitted in food obtained from treated animals.” See also 21 CFR § 510.112. This is regulated by FDA.

C. **FDA Approval Process**

1. *FDA Must Approve Antibiotics*

- i) Federal Food, Drug, and Cosmetic Act (“**FFDCA**” or “**FDCA**”) prohibits an animal drug to be sold into interstate commerce unless it has been approved by an Approved New Animal Drug Application (“**NADA**”).
- ii) FDA does approve the use of antibiotics in livestock and must approve all antibiotics (for humans, animals, and livestock). See 21 CFR § 530 and see Animal Health Institute’s “FDA Approval”, available at <http://www.ahi.org/issues-advocacy/animal-antibiotics/fda-approval>, last visited May 23, 2015.

2. *FDA Can Prohibit Entire Class of Antibiotics*

- i) FDA can prohibit use of an entire class of drugs in selected animal species if FDA determines that:
 - a) an acceptable analytical method needs to be established and such a method has not or cannot be established; or
 - b) the “extra-label use” (See II.D.2.ii.b) of the drug or drug class presents a public health risk. FDA can also limit the prohibition on extra-label use to specific species, indications, dosage forms, routes of administration, or a combination of these. See 21 CFR § 530.41.

D. **Regulation of the Administration of Antibiotics**

1. *Approved Methods*

- i) Injection

- a) *Preferred for Sick Animals.* Very sick animals are almost always given antibiotics via injection (either under the skin or in the muscle depending on the drug being used. (Other methods include oral consumption and mixing the medication with the animals' feed.) This is because sick animals may be unable to take oral medication or medication mixed in the feed if they are not eating well. Young animals that catch a highly contagious and dangerous bacterial infection, such as pneumonia, might also be given injectable antibiotics.
- b) *Prescription is Usually Required.* Most antibiotics administered via injection require a prescription.

ii) Ingestion

a) *Feed*

(1) This is the typical method for growth promotants

(2) Many antibiotics that are administered via feed are OTC and do not require a prescription; however, FDA would like for there to be more movement on antibiotics being administered via feed to require a prescription

(3) See 21 CFR 558.15-Antibiotic, nitrofurans, and sulfonamide drugs in the feed of animals

b) *Water*

2. *Over-the-Counter v. Prescription*

i) Over the Counter (“OTC”)

a) *Generally* – There are some antibiotics that do not require a prescription

b) *Usage*

ii) By Veterinarian

a) *Generally* – Prescriptions are required for many antibiotics. Veterinarians can prescribe and livestock producers can administer antibiotics in a way that will optimize therapeutic efficacy, minimize resistance to antibiotic drugs, and protect

animal and human health. Antibiotics are given under the direction of a veterinarian and include dosage and usage instructions.

b) “*Extra-Labeling*”

(1) Extra-label drug use (“**ELDU**”) occurs when a drug in an animal is used in a manner that is not in accordance with the approved labeling. This can mean using a drug in a species for which it is not labeled, at a different dosage rate, frequency or route of administration, for diseases other than those on the label, or with a different withdrawal time than that listed.

(2) Only a veterinarian can make the necessary determination to use a drug in an extra-label manner. See American Veterinary Medical Association, “Animal Medicinal Drug Use Clarification Act (AMDUCA)” available at <https://www.avma.org/KB/Resources/Reference/Pages/AMDUCA.aspx> (last visited May 31, 2015). See also 21 CFR § 530 and 21 CFR § 530.41 (list of drugs that are prohibited for extra-label use in animals).

(3) For example, if a livestock animal is really sick, a veterinarian might allow for an antibiotic to be administered at a level that exceeds the dosage allowed on the label.

(4) This is done only in rare instances. Veterinarians are reluctant to ever treat an animal extra-label.

(5) If a livestock producer exceeds the dosage of the antibiotic without an extra-label prescription then he/she is in “violation” – if caught then this producer will be added to violators list. See American Veterinary Medical Association’s “Extralabeling Drug Use and AMDUCA: FAQ” available at <https://www.avma.org/KB/Resources/FAQs/Pages/ELDU-and-AMDUCA-FAQs.aspx> (last visited June 11, 2015).

E. **Regulation of Withdrawal Periods**

1. **Overview.** The animal’s body will eventually metabolize the antibiotic and eliminate it from its system. However, there are withdrawal periods for the time in between when the livestock was treated with antibiotics and the time of slaughter. This reduces any concentration of the antibiotic that

might still be present in the animal’s body (and thus in the milk, meat, or eggs). See, e.g., American Meat Institute, “The Facts About Antibiotics in Livestock & Poultry Production” available at <https://www.meatinstitute.org/index.php?ht=a/GetDocumentAction/i/99943> (last visited June 19, 2015).

2. **Withdrawal Period.** Time withdrawal period is set by the FDA and is different for each drug and species. See, e.g., FDA’s “FDA Approved Animal Drug Products for NADA Number: 113-232” available at <http://www.accessdata.fda.gov/scripts/AnimalDrugsAtFDA/details.cfm?dn=113-232> (last visited May 13, 2015). See, e.g., American Veterinary Medical Association’s Compendium of Veterinary Products database data for beef cattle available at http://www.sdbqa.com/test/WithdrawalTimeChart/usa_wt_1510.pdf (last visited June 11, 2011).

3. **Example Withdrawal Periods Per Drug Used in Beef Cattle.**

i) The best illustration of this can be found at the Virginia Cooperative Extension of Virginia Tech-Virginia State University available at https://pubs.ext.vt.edu/400/400-008/Table_1.html (last visited June 13, 2015) (example of injectable antibiotics for beef cattle with price point). It has been recreated (in relevant part) below:

Antibiotic	Trade name	OTC or Rx	Dosage	Indications	Slaughter Withdrawals
Penicillin	Pfi-Pen G, Agricillin, Procaine Pen G	OTC	1ml/100 lbs. * Once a day	Bacterial pneumonia, Organisms susceptible	10 days
Penicillin	Durpen, Benzapen, Pen BP-48	OTC	2ml/150 lbs.*	Bacterial pneumonia, Upper respiratory disease, Blackleg	30 days
Oxytetracycline	Terramycin, Agrimycin-100, Oxy-Tet 100	OTC	5ml/100 lbs. Sub Q ¹¹ (Status SQ)	Organisms susceptible to oxytetracycline	18 days (Status SQ)

¹¹ “Sub-Q” refers to subcutaneous, or under the skin.

Oxytetracycline	Liquamycin LA-200, Procure 200, Biocor 200	OTC	5ml/100 lbs. Every other day	Bacterial pneumonia, foot rot, Pinkeye	28 days
Erythromycin	Erythro-200, Erythromycin-200, Gallimycin-200	OTC	.5 - 1 ml/100 lbs.* Once a day	Pneumonia, mastitis, metritis, foot rot, wt. loss prevention	14 days
Tylosin	Tylan 200, Tylosin Injection	OTC	4 ml/100 lbs.* Once a day	Respiratory disease, foot rot, calf diphtheria	21 days
Sulfadimethoxine	Albon Inj. 40%, Sulfadiazine	OTC	31.2 ml/500 lbs., 15.6 ml/500 lbs. Intravenous	Respiratory disease, foot rot, calf diphtheria	5 days
Amoxicillin	Amoxi-Inject	Rx	1.5 -2 ml/100 lbs. IM or Sub Q	Respiratory disease, foot rot	25 days
Ampicillin	Polyflex	Rx	75 -1.25 ml /100 lbs.	Respiratory disease	6 days
Ceftiofur Sodium	Naxcel	Rx	1-2 ml/100 lbs.	Respiratory disease, foot rot	None
Tilmicosin	Micotil 300 Injection	Rx	1.5 ml / 100 lbs. once SQ	Respiratory disease Metaphaylaxis	28 days
Florfenicol	Nuflor Injectable Solution	Rx	3.0ml/ 100 lbs. repeat in 48 hr; 6 ml/ 100 lbs. SQ once	Respiratory disease, High Risk cattle	28 days; 38 days
Ceftiofur Hydrochloride	Excenel	Rx	1-2 ml daily to	Respiratory disease	2 days

			every other day		
Sulfamethazine Cow	Sustain III Sulfamax	OTC	1 Bolus per 200lbs	Susceptible bacterial infection	12 days
Sulfamethazine Calf	Sustain III Sulfamax	OTC	1 Bolus/50 lbs.	Susceptible bacterial infection	12 days
Enrofloxacin	Baytril	Rx	3.5 — 5.5 ml / 100 lbs. once; 1.1-2.3 ml/ 100 lbs. Daily for 3 days SQ	Respiratory disease	28 days

F. **Food Labeling**

1. **Regulatory Authorities**

i) ***U.S. Department of Agriculture (“USDA”)***

- a) FSIS requires approval of food labeling of meat, poultry, liquid eggs and cooked eggs before it enters commerce. See 21 U.S.C. 607(d) and U.S.C. 457(c).
- b) USDA’s FSIS also regulates some “marketing claims” including “no antibiotics used”. FSIS approves these marketing claims based on information provided by the producer. More info on USDA “marketing claims” discussed below.
- c) USDA’s Agriculture Marketing Service (“AMS”) regulates the National Organic Program (and the labeling of the word “organic”) which prohibits antibiotic use.

ii) ***Food & Drug Administration (“FDA”)***

- a) FDA regulates the labeling of shelled eggs and milk.
- b) Along with AMS, FDA regulates shelled raw eggs.¹²

¹² Shelled eggs are the eggs you buy in the 12 pack from the store regulated by FDA. On the other hand, the USDA regulates egg products, including liquid, frozen and dehydrated eggs.

c) Regulates the marketing claim of “no antibiotics used”

iii) ***Federal Trade Commission (“FTC”)***

a) The Federal Trade Commission (“FTC”) Act of 1914 prohibits deceptive marketing claims from entering commerce. The FTC investigates complaints of unfair or deceptive claims.

2. National Organic Program

i) For food to be labeled as “organic” under the National Organic Program (“NOP”), there must not be any administration of antibiotics under any circumstances; therefore, this could be viewed “antibiotic free” label regulation.

a) If the animal gets sick in an “organic” livestock operation and organic approved methods fail, the animal may receive antibiotics, but then cannot be labeled as “organic” anymore under the NOP. See 7 CFR § 205.238(c)(7).

b) 7 CFR § 205.238(c)(2) states that “[t]he producer of an organic livestock operation must not administer any animal drug, other than vaccinations, preventives, and pain relief medications, in the absence of illness.”

c) Even a list of allowed and prohibits synthetic substances under 7 CFR § 205.603(a)(8), referenced in 7 CFR § 205.105 excludes substances that have antibiotics. See also U.S. Government Publishing Office, “The National List of Approved and Prohibited Substances” available at <http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=9874504b6f1025eb0e6b67cadf9d3b40&rgn=div6&view=text&node=7:3.1.1.9.32.7&idno=7#sg7.3.205.g.sg0> (last visited May 31, 2015). Only a few drugs, such as vaccines, are approved for animals to be sold as “organic”.

ii) Under 7 CFR 205.2 “organic production” is defined as: “A production system that is managed in accordance with the Act and regulations in this part to respond to site-specific conditions by integrating cultural, biological, and mechanical practices that foster

cycling of resources, promote ecological balance, and conserve biodiversity.”

3. Milk

- i) 21 CFR 510.106 provides for labeling of antibiotics and antibiotic-containing drugs intended for use in milk-producing animals. This regulation says that:

Whenever the labeling of an antibiotic drug included in the regulations in this chapter suggests or recommends its use in milk-producing animals, the label of such drugs shall bear either the statement "**Warning: Not for use in animals producing milk, since this use will result in contamination of the milk**" or the statement "**Warning: Milk that has been taken from animals during treatment and for ___ hours after the latest treatment must not be used for food**", the blank being filled in with the figure that the Commissioner has authorized the manufacturer of the drug to use. The Commissioner shall determine what such figures shall be from information submitted by the manufacturer and which the Commissioner considers is adequate to prove that period of time after the latest treatment that the milk from treated animals will contain no violative residues from use of the preparation. If the Commissioner determines from the information submitted that the use of the antibiotic drug as recommended does not result in its appearance in the milk, the Commissioner may exempt the drug from bearing either of the above warning statements.

(Emphasis Added).

4. Marketing Claims

- i) *USDA Regulated Marketing Claims*







- a) All USDA label marketing claims must be approved by FSIS to determine if they are truthful and not misleading. See USDA Agricultural Marketing Service’s “Grading, Certification, and Verification”, available at: <http://www.ams.usda.gov/AMSV1.0/processverified> (last visited May 23, 2015).
- b) As mentioned above, the USDA’s FSIS is responsible for labeling meat and poultry, liquid eggs and cooked egg.
- c) Look for the “USDA Process Verified” for this claim because the shield means that this was verified.
- d) “No Antibiotics Used” The label “no antibiotics used” requires the producer to submit food formulations, pharmaceutical invoices, or other appropriate documentation verifying that animals have received antibiotics by any means. They also must provide how they care for and treat sick animals.
- (1) Variations of this Marketing Claim include:
- i. No Added Antibiotics
 - ii. No Antibiotics Added
 - iii. No Antibiotics Administered
 - iv. Raised without antibiotics-for meat and poultry only
- (2) In order to use this marketing claim, the animals must have never been treated with antibiotics. See “United States Standards for Livestock and Meat Marketing Claims” available at <https://www.csuchico.edu/grassfedbeef/documents/Product%20Claims.pdf> (last visited June 12, 2015). The farm must prove to the USDA that there were no antibiotics given.
- e) “Antibiotic Free” and “No Antibiotic Residue” are not USDA Process Verified Marketing Claims – These terms can mean anything, as it is not a phrase regulated by the USDA. It is merely a marketing tool since any meat packaged to sell cannot have antibiotics (i.e. withdrawal period). See USDA-FSIS- <http://www.fsis.usda.gov/OPPDE/larc/Claims/RaisingClaims.pdf> (page 3).

ii) **FDA Regulated Marketing Claims**

- a) According to the FDA, there are no specific requirements regarding antibiotic-free labeling on milk, so this label falls under their general ‘truthful and not misleading’ requirements.

iii) **Third Party Marketing Claims Regarding Antibiotics**

MARKETING CLAIM	DESCRIPTION	CITATION	LABEL
Food Alliance (FA) Certified (third party verification)	Never given sub-therapeutic doses of antibiotics. Animals could have been treated with antibiotics if they were sick, but if they were sick and receiving antibiotics at the time of slaughter (or time of milking), they <u>cannot</u> be labeled as Food Alliance Certified.	Food Alliance- http://foodalliance.org/about/principles-explained/no-hormones-or-nontherapeutic-antibiotics (last visited June 11, 2015)	
Animal Welfare Approved (third party verification)	Never given sub-therapeutic doses of antibiotics. Animals could have been treated with antibiotics if they were sick, but if they were sick and received antibiotics, the time of slaughter (or time of milking), must be delayed until after 2X the length of the regulated withdrawal period set by the FDA	Animal Welfare Approved- http://animalwelfareapproved.org/about/ (last visited June 11, 2015)	

<p>American Grassfed Certified - for dairy, beef, and lamb only (no poultry or eggs)</p> <p>Grass-fed (generally)</p>	<p>Never given antibiotics. This is not to be confused with the label “100% Grassfed” which does not mean that the animals was never given antibiotics; it only means that the animals were exclusively fed 100% grass and forage.</p> <p>This is not required to be verified or follow specific standards</p>	<p>American Grassfed- http://www.americangrassfed.org/about-us/our-standards/</p> <p>(last visited June 11, 2015)</p>	
<p>Certified Humane Raised and Handled (third party verification)</p>	<p>Not treated with antibiotics, <u>unless</u> they are sick, in which case they are treated only under veterinarian supervision.</p>	<p>Certified Humane- http://certifiedhumane.org/how-we-work/overview/</p> <p>(last visited June 11, 2015)</p>	

iv) *Unregulated Claims*

- a) Natural. The term “natural” is not regulated. It only means nothing, like color, has been added to the meat, it has no artificial ingredients, or it is minimally processed. These animal could have been treated with antibiotics. There is no third party verification for this phrase.
- b) Others. There are a plethora of other claims that are unregulated that agriculture producers may use on their label, including but not limited to, “local” and “humane”.

III. POLICY

A. **Pending Legislation in U.S. Congress**

- 1. H.R. 1552: Preservation of Antibiotics for Medical Treatment Act of 2015 – To amend the Federal Food, Drug, and Cosmetic Act to preserve the effectiveness of medically important antimicrobials used in the treatment of human and animal diseases.

2. S. 621: Preventing Antibiotic Resistance Act of 2015 – To amend the Federal Food, Drug, and Cosmetic Act to ensure the safety and effectiveness of medically important antimicrobials approved for use in the prevention and control of animal diseases, in order to minimize the development of antibiotic-resistant bacteria.
3. S. 287: Safe Food Act of 2015 – To establish the Food Safety Administration to protect the public health by preventing foodborne illness, ensuring the safety of food, improving research on contaminants leading to foodborne illness, and improving security of food from intentional contamination, and for other purposes.
4. S. 609: Safe Food Act of 2015 – To establish the Food Safety Administration to protect the public health by preventing foodborne illness, ensuring the safety of food, improving research on contaminants leading to foodborne illness, and improving security of food from intentional contamination, and for other purposes.

B. Pending Legislation in New York State

1. NY A01486: Requires poultry products treated with antibiotics containing arsenic to bear a label so indicating.
2. NY A01843: Requires poultry products treated with antibiotics containing arsenic to bear a label so indicating.

C. FDA Proposed Rules and Regulations

1. May 19, 2015: FDA proposes rule to collect antimicrobial sales and distribution data by animal species.

“The additional data would improve understanding of how antimicrobials are sold or distributed for use in major food-producing animals and help the FDA further target its efforts to ensure judicious use of medically important antimicrobials.”
2. June 2, 2015: FDA Regulation to Help Ensure Judicious Use of Antibiotics in Food-Producing Animals

“The U.S. Food and Drug Administration announced today the Veterinary Feed Directive (VFD) final rule, an important piece of the agency’s overall strategy to promote the judicious use of antimicrobials in food-producing animals...The VFD final rule outlines the process for authorizing use of VFD

drugs (animal drugs intended for use in or on animal feed that require the supervision of a licensed veterinarian) and provides veterinarians in all states with a framework for authorizing the use of medically important antimicrobials in feed when needed for specific animal health purposes. The VFD final rule continues to require veterinarians to issue all VFDs within the context of a veterinarian-client-patient relationship (VCPR) and specifies the key elements that define a VCPR.”

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