Veterinary Products and Novel Food Label Statements

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Antibiotic Statements in Food Labeling

Important to know about antibiotics

- USDA prohibits illegal residues of antibiotics in food.
- FDA evaluates food safety prior to approval of food animal medicines.
- USDA regulates the meat and poultry labels under the meat acts. Labels must be approved prior to interstate commerce.

Responsible Use of Antibiotics

FDA issued guidance(s) to modify the use of medically important antibiotics in food-producing animals

Guidance for Industry (GFI) #209 – The “What”

Guidance for Industry (GFI) #213 – The “How”

Guidance for Industry (GFI) #120 – The “VFD”

The 3-Step Risk Assessment Process

✓ An antibiotic must select for foodborne bacteria that acquire antibiotic-resistance in food animals during treatment

✓ Release

✓ A person must ingest meat from a treated animal that is contaminated with those same antibiotic-resistant foodborne bacteria

✓ Exposure

✓ The person that ingests these bacteria must become sick with a bacterial infection that cannot be appropriately treated with antibiotics as a result of those animal-derived antibiotic-resistant bacteria

✓ Consequence
No Risk vs. Low Risk: Macrolides

The use of macrolides in food animals could potentially compromise human health risk; all of the risk criteria are met.

- An antibiotic must select for foodborne bacteria that acquire antibiotic-resistance…
- A person must ingest meat from a treated animal that is contaminated…
- The person that ingests these bacteria must become sick with a bacterial infection…
The use of ionophores in food animals does not create a risk to human health because none of the risk criteria are met.

- An antibiotic must select for foodborne bacteria that acquire antibiotic-resistance…
- A person must ingest meat from a treated animal that is contaminated…
- The person that ingests these bacteria must become sick with a bacterial infection…
“One key exception is the ionophore group. Not only are they unrelated to anything used in human medicine, but they have a unique mechanism of action which has not been demonstrated to select for any type of human resistance, even through co-selection.”

– Dr. Mike Apley, Kansas State University

Source: http://www.beefmagazine.com/antibiotics/6-antibiotic-myths-explained
Raised Without Antibiotics

What does this mean?

Raised Without Antibiotics
Prohibits all antibiotics.

Raised Without Antibiotics
Important to Human Medicine
Prohibits all antibiotics important to human medicine. This allows products such as ionophores to be used.

Source: http://fsis.usda.gov, accessed on 26 April 2017. USDA allows similar terms to raised without antibiotics. These are the larger categories of the label.
Raised Without Antibiotics

*What it does not mean?*

These farms never use antibiotics.

Generally, these farms will treat the animals that experience illness with medically important antibiotics.

Source: [http://fsis.usda.gov](http://fsis.usda.gov), accessed on 26 April 2017. USDA allows similar terms to raised without antibiotics. These are the larger categories of the label.
Removing Medicine Doesn’t Eliminate Disease

Clinical necrotic enteritis outbreaks (% flocks) Subclinical enteritis cases (% flocks)

Drug-free 27.45 49.02

RWA Exceeding Demand, Increased Mortality

Sales of Medically Important Antibiotics is Trending Up

Drivers behind 26% increase from 2009 to 2015 unclear due to data limitations

Source: U.S. Food and Drug Administration
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Food Labeling: Is Mandatory Antibiotic Claim Labeling Needed?

By Brian Sylvestre

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mid increasing consumer concerns of developing bacterial resistance to antibiotics, meat and poultry products are rife in market. Chicken, beef, and pork raised without antibiotics. The hot button issue of superbug antibiotic resistance in humans has fomented an uproar in consumer advocacy groups questioning the adequacy of the regulatory framework governing the use of antibiotics in food-producing animals and, in particular, the marketing claims applied to meat and poultry products indicating the use or non-use of antibiotics.

As it stands, the key federal agency regulating antibiotic marketing claims, the U.S. Department of Agriculture (USDA), does not mandate that labeling state the use or non-use of antibiotics in meat or poultry products. However, the Animal Legal Defense Fund (ALDF) has petitioned the USDA, calling for mandatory antibiotic claim labeling. ALDF argues that the use of antibiotics in food-producing animals poses a risk to human health and, as such, consumers expect meat and poultry product labels to indicate the use or non-use of antibiotics in food production. As of this writing, ALDF’s petition remains under review by USDA as a rulemaking proceeding. This article contends that mandatory antibiotic labeling is not needed because existing federal law and policy already inform consumers of the nature of antibiotics in food-producing animals, effectively providing antibiotic-free options to consumers concerned about the potential adverse health effects of consuming antibiotic-treated meat and poultry.

The Regulatory Framework

Overview

The labeling of meat and poultry products primarily falls under the jurisdiction of USDA’s Food Safety and Inspection Service (FSIS).
Consumers Want Meaningful Information

Widespread antibiotic use in food animals...creating new superbugs that cause illnesses that antibiotics cannot cure.

72%

Of the U.S. consumer who purchase RWA 67% do so because they don’t want to contribute to antibiotic resistance in people.

Consumers who purchase RWA do so because they are concerned about resistant infections and antibiotic effectiveness in people.

A closer look at why consumers purchase RWA

Responses from the 29% who say they regularly purchase RWA.

86%  Nearly all (86%) purchase beef, pork or poultry labeled as “produced without antibiotics” because it is “healthier for their family and them.”

54%  54% do so because they believe purchasing products labeled “produced without antibiotics” reduces the use of medically important antibiotics in animal production.

67%  67% do so because they “don’t want to contribute to human antibiotic resistance.”

Conclusion

Labeling and advertising statutes require statements to be truthful and not misleading. Both conditions are important.

7 of 10 Consumers who purchase RWA do so because they are concerned about resistant infections and antibiotic effectiveness in people.¹

We need a refined approach that builds on acceptance of label and desired public health outcomes for responsible use of medically important antibiotics.

Thank you!
Impact of current “Raised Without Antibiotics” Labeling Policy

1. Does not allow producers to use ionophores

2. No ionophores = no prevention for necrotic enteritis → more sick animals

3. More sick animals treatable only with medically important antibiotics

4. More medically important on-farm increases resistance risk for people.

5. Antibiotics needed by people become less effective.
RWA Label Driving Increased Use of Medically Important Antibiotics

Source: Salois, M., and Heskett, E. *Raised without antibiotics can lead to more use of medically important antibiotics.* December 2016.
Pet Products and FTC Enforcement

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2017 FDLI Annual Conference

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* Mr. Cleland’s statements reflect his own views, and do not necessarily reflect the views of the Commission or any individual Commissioner.
Mars Petcare US, Inc. (Dec. 13, 2016)

• The FTC’s complaint alleged that Mars’ representations that
  – With Eukanuba brand dog food, dogs live 30 percent or more longer than their typical lifespan; and
  – Eukanuba brand dog foods enable dogs to live exceptionally long lives,

Were false, misleading, or unsubstantiated.
Mars Petcare US, Inc.

• The FTC’s complaint also alleged that Mars falsely represented that:
  – Scientific tests prove that, with Eukanuba, dogs live 30 percent or more longer than their typical lifespan; and
  – Scientific tests prove that Eukanuba brand dog foods enable dogs to live exceptionally long lives.
Mars Petcare US, Inc.

• According to the complaint:
  – “Among other things, the evidence relied on by [Mars] for its representations concerning the Eukanuba brand dog food consisted primarily of results from a single study, the results of which showed no significant difference in the median age at death of the dogs in the study relative to the typical age at death of the dogs of the same breed.”
Mars Petcare US, Inc.

• The order requires Mars to possess competent and reliable scientific evidence to substantiate claims about the health benefits of its pet foods.
Supporting Advertising Claims

- Establishment claims
- Reasonable basis claims
Establishment Claims

Where an advertisement represents, either expressly or by implication, that the claim is supported by a certain amount or level of substantiation, the advertiser must possess, prior to dissemination of the advertisement, at least that level of support for the claim.
Establishment Claims

– “Tests Prove . . .”
– “Doctors Recommend . . .”
– “Studies Show . . .”
– “Clinically Proven to . . .”

Evidence acceptable to the relevant scientific community to demonstrate that claims are true.
Determining the Reasonable Basis

• Relevant factors include:
  – the type of claim (health or safety claim?)
  – the product (experience or credence claim?)
  – the consequences of a false claim
  – the benefits of a truthful claim
  – the cost of developing substantiation for the claim
  – the amount of substantiation experts in the field believe is reasonable
Competent & Reliable

• Competent means that the evidence is relevant to the claim. It doesn’t matter how good the evidence is if it doesn’t match the claim.

• Reliable goes to the design and methodology of the study and asks can the results of the research be reasonably extrapolated to support the advertised claim?
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