Veterinary Products and Novel Food Label Statements

Jesse J. Sevcik Elanco Animal Health jsevcik@elanco.com May 4, 2017



Antibiotic Statements in Food Labeling





Source: Accessed 25 April 2017 <u>https://www.washingtonpost.com/news/speaking-of-science/wp/2015/10/28/what-does-raised-without-antibiotics-mean-and-why-is-it-important/?utm_term=.98f6ff9e4ed7</u>

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.



Source: http://www.fda.gov , http://fsis.usda.gov, accessed on 26 April 2017.

Responsible Use of Antibiotics

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

Contains Nonbinding Recom Contains Nonbinding Recommendation. #209 #120 #213 **Guidance for Industry** Guidance for Industry **Guidance for Industry** Small Entity Compliance Guide New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Veterinary Feed Directive Regulation The Judicious Use of Medically Important Producing Animals: Recommendations for Drug Sponsors for **Questions and Answers Antimicrobial Drugs in Food-Producing Animals** Voluntarily Aligning Product Use Conditions with GFI #209 This version of the guidance corrects a typographical error in Q&A II.C.6. Submit comments on this guidance at any time. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20282, Submit electronic commensus on the guidance at <u>http://www.regulations.gov</u>. All written comments should be identified with the Docket No. FDA-2010-D-0994. This guidance document makes revisions to the final guidance that was made available in March 2009 to reflect the VFD final rule published in June 2015. Submit comments on this guidance at any time. Submit written comments to the Division of Dockets Management (HF-Ar505), Food and Drug Administration, 500 Fibres Lane, Rm, 1061, Rockville, MD 20852, Submit electronic comments to <u>http://www.resulations.gov</u>. All written comments should be identified with the Docket No. FDA-2011-D-0889. Submit comments on this guidance at any time. Submit electronic comments to http://www.coulations.com/. Submit written comments to the Division of Deckett Manager (1974-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20832. All written comments should be distrified with the Docket New TDA-2010-N-0155. For further information regarding this document, contact William T. Flynn, Center for Veterinary Medicine (HFV-1), Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, 240-276-0804. E-mail: william.ft/mnifida.hstr.gov. For further information regarding this document, contact William T. Flynn, Center for Veterinary Medicine (HFV-1), Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, 240-276-9084. E-mail: <u>william (Byurgi Rh Ihs gov</u>. Inther information regarding this document, contact <u>Dragon Monicilovic</u>, Center for rinary Medicine (HFV-226), Food and Drug Administration, 7529 Standish Place, volls MD 70845 340-402-35944, e-mail: dragam monicilovic@fla.hbs.avv. copies of this guidance document may be requested from the Com Additional expises of this guidance document may be requested from the Policy and Regulation Staff (IFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, and may be viewed on the Internet at either http://www.fika.gov/AnimaVeterinaryAfeletink.htm of http://www.fikalation.azv, Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, and may be viewed on the Internet at either http://www.Rla.gov/AnimalVeterinary/GuidanceComplianceEnforcem stry/default.htm or http://www.regulations.gov. U.S. Department of Health and Human Services U.S. Department of Health and Human Services Food and Drug Administration Center for Veterinary Medicine Food and Drug Administration Center for Veterinary Medicine U.S. Department of Health and Human Services Food and Drug Administration Center for Veterinary Medicine April 13, 2012 December 2013 Guidance for Industry (GFI) #209 - The Guidance for Industry (GFI) #120 - The Guidance for Industry (GFI) #213 - The "What" "VFD" "How"



Source: http://www.fda.gov, accessed on 26 April 2017.

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...



Ionophore Risk

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 antibioticresistance...
- 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 coselection."

– 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: <u>http://fsis.usda.gov</u>, 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?

Raised Without Antibiotics

Raised Without Antibiotics Important to Human Medicine

These farms never use antibiotics.

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



Source: <u>http://fsis.usda.gov</u>, 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

Drug-free

IMMUNOLOGY, HEALTH, AND DISEASE

Impact of a drug-free program on broller chicken growth performances, gut health, Clostridium pertringens and Campylobacter jejuni occurrences at the farm level

M-L. Gaucher, *11 S. Quesey,* A. Letellier,* J. Arsenault, and M. Bouliname^{1,1}

"Rounds Oute in Main Solos, Pachalogi and Mandalogi Department, Vicencery Faculty, Converse of Mannets, CP 2000, Schgweitz, Queller, Canade JS SC, 'Oane in Andre Round, Faculty Canada (2017), and Senter and Pacific Rounds, Mannets, CP 2000, Schweitz, CM Mandalogi Department, Senter and Pacific Rounds (2017), Neurosci Pacific Rounds, 2017), and Senter and Pacific Rounds (2017), Pacific Pacific Rounds, Pacific Rounds, Pacific Rounds, 2017), and Senter and Pacific Rounds (2017), Pacific Pacific Rounds, Pa Visterinory Faculty, University of Montreal, CP 5000, St-Hyacostle, Queller, Canada JSS 7C6

ABSTRACT The use of antimicrobial agents us feed additions in positry production is a public health con-cern due to the control increase in antimicrobial resis-Although some alternative products are commerable, little is known on their potential imon fock health and productivity. A properties i modeling 1.55 million birds was conducted on mercial broker farms in Quiber, Canada, to without on the second s and anticoccidal drugs by a drug-free program ing improved broading conditions, anticoccidal scient, essential of-based feed addrives, and waedification. Various productivity and health pawere compared between barrs allocated to extend and the drug-free program. Zootschtern write munitured as productivity eried, and microscopic gut health was evaluorfringens and Campplobactor opp. perforagens carriage lessis.

INTRODUCTION

CDs are record

I antibiation used as growth pr were discovered during the 1940's and have

d to the rapid expansion of the peri-

riduide (Dibner and Richards, 2007;

strains were recovered from feeal samples col ing farm visits. (Instridiant perfetagence counts were used as positry health indicators and Compylobacter pressince was noted as well. The drupfree ; prevagence was poster as were, and unique program within ratio and a decrease in mean live weight at shoughter and in daily weight gain. An increased ineilence of merroric enteritis ornhrodo and subclinical enterits cases, as well as an increase in little mointure content at the end of the reading period were also ob served for this program. Mean microscopic intestinal losion sentes and prevalence of Campylobacter exloring terically different between the two tion were not stall groups but the drug free program was associated with groups not use using tool program and another with ing to the current study design, the results suggest that substitution of antihiotic growth promoters and anticonstructions, limit and least noticenter content. confided drugs by a drug five program impacts waters

Key words: bruke chicken, drup-from, growth performance, got health, Classradown performance 2015 Poultry Science 94:1791-1801

> the possible development of resistant bacteria (Dibner and Richards, 2005). In the last two decades, many superts of antimicrobial use, incheling keng-term sub-therapeutic mage in intensiv to contribute to the development and spread of resistant barteria (Aarestrup et al., 2000; Aarestrup et al. 2001; Anno et al., 2007; MCARTINES et al., party cold 2004). Evidence from many studies suggest that bar uris carrying antibiotic resistance genes that can be transmitted from animals to homans (Folster et al. 112 Longinghen et al., 200; Salin et al., 2012, 2011; White et al., 2002). Based on

http://dx.doi.org/10.3382/ps/per142 2007; McDermott et al., 2002; Shen,

ut of a healthy and functional inmet, allowing, in part, poultry producers to benefits of the high-yield bruilers'

Clinical necrotic enteritis outbreaks (% flocks)

Subclinical enteritis cases (% flocks)

27.45

49.02

Source: Gaucher M-I, et al. "Impact of a drug-free program on broiler chicken growth performances, gut health, Clostridium perfringens and Campylobacter jejuni occurrences at the farm level." Poult Sci. 2015 August:94(8):1791-1801.

GCAAFFNON00206

RWA Exceeding Demand, Increased Mortality



GCAAFFNON00206

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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Source: <u>http://www.pewtrusts.org/en/research-and-analysis/issue-</u> briefs/2017/03/trends-in-us-antibiotic-use , accessed on 25 April 2017.

Case 1:08-md-01982-RDB Document 121 Filed 05/11/10

THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MARYLAND

IN RE: TYSON FOODS INC., CHICKEN Civil Action No .: RAISED WITHOUT ANTIBIOTICS CONSUMER LITIGATION

MEMORANDUM OPINION

A class of Consumer Plaintiffs sued Defendant Tyson Foods, Inc. ("T Tyson's "Raised Without Antibiotics" ("RWA") promotional claims about it were misleading, and asserting claims under state consumer protection statute The Parties have reached a settlement agreement. Now pending is Plaintiffs Approval of Settlement (Paper No. 99), Class Counsel's Motion for Award of and Expenses (Paper No. 101), and Friends for Neighborhood Progress, Inc. Included as a Cy Pres Recipient (Paper No. 118). A Fairness Hearing was he at the conclusion of which this Court approved the settlement. Accordingly, reasons, the above motions are GRANTED.

BACKGROUND

On January 25, 2008, Sanderson Farms, Inc. and Perdue Farms, Inc. Inc. for violations of the Lanham Act in a case before this Court entitled San and Perdue Farms, Inc. v. Tyson Foods, Inc., Civil No. RDB-08-210. The St plaintiffs alleged that Tyson's RWA promotional claims about its chicken pre and misleading. On April 22, 2008, this Court granted the plaintiffs' motion injunction, holding that certain RWA claims were literally false and that othe

PETITION BEFORE THE UNITED STAT FOOD SAFETY AND I

ANIMAL LEGAL DEFENSE FUND 170 E. Cotati Ave. Cotati, CA 94931 707-779-2055

Filed with

Petitioner.

TOM VILSACK in his official capacity as Secretary. United States Department of Agriculture 1400 Independence Avenue SW

Washington, DC 20250

and

ALFRED ALMANZA in his official capacity as Administrator Food Safety and Inspection Service United States Department of Agriculture 1400 Independence Avenue SW Washington, DC 20250

CITIZEN'S PETITION SEEKING MANDA TO PREVENT THE SALE OF

L INTRODUCTION

Pursuant to applicable Food Safety and I § 392, and the Administrative Procedure Act, 9 Defense Fund ("ALDF") submits this petition for Department of Agriculture's ("USDA") FSIS tal

Food Labeling: Is Mandatory Antibiotic Claim Labeling Needed?

By Brian Sylvester

mid increasing consumer concerns of developing bacterial resistance to antibiotics, meat and poultry producers are racing to market chicken, beef, and pork raised without antibiotics. The hot-button issue of superbug antibiotic resistance in humans has fomented an upswing 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 nonuse of antibiotics.1

As it stands, the key federal agency regulating antibiotic marketing claims, the U.S. Department of Agriculture (USDA),



Brian P. Sylvester is an Associate at Keller and Heckman LLP in Washington, DC. Prior to entering private practice, he served as a regulatory lawyer at USDA from 2009 does not mandate that labeling state the use or nonuse 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 nonuse of antibiotics in food production.2 As of this writing, ALDF's petition remains under review by USDA as a rulemaking petition. This article contends that mandatory antibiotic labeling is not needed because existing federal law and policy serve to adequately inform consumers of the nonuse 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

March/April 2015 UPDATE

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Source: US District Courts, Eastern District of Maryland, http://www.mdd.uscourts.gov/, USDA Food Safety Inspection Service petition page, http://fsis.usda.gov Food and Drug Law Institute, members section http://www.fdli.org, accessed on 25 April 2017.

FDU

Consumers Want Meaningful Information



72%

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



67%

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



Source: Why Consumers Purchase Meats and Poultry Raised Without Antibiotics, ORC International, January 2017. Consumer Reports, "Meat on Drugs," Available at <u>http://www.meatwithoutdrugs.org</u> GCAAFENON00206

A closer look at why consumers purchase RWA



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



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



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



67% do so because they "don't want to contribute to human antibiotic resistance."

Source: Why Consumers Purchase Meats and Poultry Raised Without Antibiotics, ORC International, January 2017.

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.



Source: 1 Why Consumers Purchase Meats and Poultry Raised Without Antibiotics, ORC International, January 2017., Consumers Union Report *ibid.*

Thank you!







Source: Data from Rennier Associates, Inc. Published 7 April 2017 at http://www.thepoultrysite.com/poultrynews/38439/while-new-data-show-growth-for-nae-production-responsible-antibiotic-usage-still-holding-its-own/



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

May 4, 2017 2017 FDLI Annual Conference

> Richard Cleland* Assistant Director Division of Advertising Practices Federal Trade Commission

* 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.

FDLI

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?





Contact Information

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