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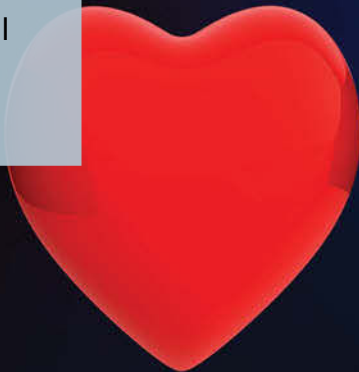
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Food Labeling: Is Mandatory Antibiotic Claim Labeling Needed?

By Brian Sylvester

Amid 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),

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.



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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). FSIS administers the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA).³ The FMIA and the PPIA authorize FSIS to approve labels for meat and poultry products before they are marketed in interstate commerce.⁴ Under FSIS regulation, there is no requirement to disclose antibiotic use or nonuse claims on labeling.⁵ However, if such claims are made, FSIS requires them to be truthful, accurate, and not misleading.⁶ To facilitate compliance with this requirement, FSIS administers guidance applicable to antibiotic nonuse claims discussed more fully below.⁷ The Federal Trade Commission Act (FTCA) complements the FSIS regulatory scheme by requiring all food claims, including antibiotic nonuse claims, to be truthful, accurate, and not misleading, with an emphasis on advertising.⁸

FTC Regulation

In practice, the FTC takes primary responsibility for regulating food *advertising*, while FSIS exercises regulatory authority over meat and poultry *labeling*. Nevertheless, the FTC does retain the authority to regulate meat and poultry labeling under Sections 12 and 15 of the FTCA, which delegate to the FTC authority to regulate *any* advertisement that is “misleading in a material respect.”⁹ To date, no FTC enforcement actions have been brought in the antibiotic nonuse claims arena, however, retailers and restaurants interested in making such claims are not immune from potential FTC enforcement actions. In general, retailers and restaurants must comply with FTC’s requirement that all such claims (express and implied) have a reasonable basis that reasonable consumers can understand. That is, when making antibiotic nonuse claims, retailers and restaurants must ensure that such claims

are adequately substantiated, truthful, and not misleading. From a practical standpoint, the FTC will likely not initiate an enforcement action regarding antibiotic nonuse claims that comply with USDA regulations and policy.

USDA Regulation and Policy

To ensure that animal raising claims, such as antibiotic nonuse claims, are truthful, accurate, and not misleading, as required by USDA regulation, such claims must be submitted to USDA’s FSIS for approval prior to marketing in interstate commerce.¹⁰ Commonly approved claims regarding the nonuse of antibiotics in food production include: “no antibiotics,” “no antibiotics added,” “no antibiotics ever,” and “no antibiotics added ever.”¹¹ Under USDA policy, FSIS approves such claims if the producer provides the Agency with sufficient documentation demonstrating that the animals were raised without antibiotics.¹² Sufficient documentation may include: 1) a detailed written protocol explaining controls for assuring the production claim; 2) a signed affidavit declaring that the claims are not false or misleading; and 3) evidence demonstrating product tracing and segregation from time of slaughter and/or further processing through packaging and wholesale or retail distribution.¹³

Complementing FSIS’ label review for antibiotic claims, USDA’s Agricultural Marketing Service (AMS) administers a voluntary USDA Process Verified Program called Never Ever 3 (NE3).¹⁴ NE3 serves as a tool for meat and poultry producers to market their products with the claim “No Antibiotics Ever” with a supporting USDA Process Verified seal to assure consumers of the products’ antibiotic-free status.¹⁵ AMS verifies compliance with the NE3 requirements by having meat

and poultry program participants submit their marketing programs to AMS for verification and monitoring under an approved USDA Process Verified Program.¹⁶ The USDA Process Verified Program ensures that the NE3 requirements are supported by a documented quality management system.

A number of food manufacturers and restaurant establishments are working within the USDA regulatory framework described above to market antibiotic-free products in response to increasing consumer demand. As antibiotic nonuse claims proliferate in the coming years, so too will challenges to the integrity of these claims. In 2008, one such challenge took the form of Lanham Act litigation and demonstrates that in cases where an oversight in USDA label review may result in the marketing of products with false and misleading antibiotic nonuse claims, the Lanham Act sweeps in to remove such claims from the marketplace.

Lanham Act Litigation Involving Antibiotic Marketing Claims

The Lanham Act protects businesses against the unfair competition of misleading advertising or labeling.¹⁷ A plaintiff that prevails on a Lanham Act claim can obtain an injunction against the false or misleading advertising, as well as damages and, in certain cases, attorneys’ fees.¹⁸

In 2008, Sanderson Farms (Sanderson) and Perdue Farms (Perdue) filed a Lanham Act lawsuit against Tyson Farms (Tyson).¹⁹ The subject of the lawsuit was an advertising campaign that featured the claims “Raised Without Antibiotics” and “Raised Without Antibiotics That Impact Antibiotic Resistance in Humans.”

By way of background, in the summer of 2007, Tyson obtained approval from FSIS to label its chicken products

as “Raised Without Antibiotics” even though Tyson continued to treat its chicken with ionophores, a class of antibiotics used exclusively in animal medicine. Later that year, FSIS advised Tyson that the Agency had erred in its approval, explaining that the use of ionophores constituted antibiotic use and so the “Raised Without Antibiotics” claim was not an approvable claim. Tyson and FSIS agreed to reword Tyson’s claim to read, “Raised Without Antibiotics That Impact Antibiotic Resistance in Humans” and FSIS approved this reworked claim on December 19, 2008.²⁰ Nevertheless, Tyson’s competitors sued Tyson under the Lanham Act, alleging that Tyson did not halt the use of the “Raised Without Antibiotics” claim, and that even the reworked “Raised Without Antibiotics That Impact Antibiotic Resistance in Humans” claim was confusing and misleading.²¹

During trial, Tyson officials also acknowledged that they injected eggs several days before they hatched with antibiotics (gentamicin) that are approved for use in humans. Tyson defended this practice, explaining that injecting eggs with antibiotics did not undermine the “Raised Without Antibiotics” label because the term “raised” is understood to cover the period that begins with hatching.²² The court rejected this argument, finding that consumers did not generally understand the term “raised” as defined by Tyson and thus the claim “Raised Without Antibiotics” for birds that were treated with antibiotics pre-hatch was “literally false.”²³ Ultimately, the court issued an injunction ordering Tyson to pull both claims²⁴ and Tyson settled the lawsuit with Sanderson and Perdue shortly thereafter.²⁵

In this case, although only competitors

had standing to bring the Lanham Act lawsuit, some might argue that consumers emerged winners because: (1) Tyson removed the allegedly false and misleading antibiotic nonuse claims from the marketplace, and (2) FSIS formally rescinded its approval of Tyson’s claims.²⁶ On the latter point, FSIS has since issued draft guidance requiring more rigorous documentation to substantiate antibiotic nonuse claims for label submissions.²⁷ Coupled with the fact that no other Lanham Act lawsuit has since been lodged against meat and poultry industry players for false and misleading antibiotic nonuse claims, it appears clear that FSIS’ label review, as it stands, serves to adequately inform consumers of the nonuse of antibiotics in food-producing animals, effectively providing consumers with antibiotic-free options.

Notwithstanding the demonstrated effectiveness of the present regulatory framework to ensure the integrity of antibiotic nonuse claims, the ALDF feels that more stringent regulation of antibiotic claims is needed and has filed a rulemaking petition to this effect.

The ALDF Petition

On May 16, 2013, ALDF filed a citizen’s petition with FSIS requesting that the Agency initiate rulemaking to mandate antibiotic use and nonuse claims on meat and poultry product labels.²⁸ ALDF’s petition argues that mandating such labeling would allow consumers concerned about the potential human health risks posed by sub-therapeutic antibiotic use in food-producing animals to make informed decisions when purchasing these products. Citing to studies indicating that consumers are concerned about the potential health risks posed by antibiotics in meat and poultry,²⁹ the petition contends that the present labeling system fails to provide

consumers with a “consistent, accurate way of differentiating between meat that comes from animals raised with antibiotics from that which does not”³⁰ and, therefore, is inherently misleading.³¹

Consumer Confusion?

ALDF may be imagining consumer confusion where none exists. In reality, consumers are distinguishing between antibiotic-free foods versus antibiotic-treated foods, and are increasingly demanding antibiotic-free meat and poultry products that are so labeled. A 2012 Consumer Reports survey indicated that 61% of respondents would pay more for antibiotic-free meat or poultry.³² Presumably, consumers concerned about the potential health risks associated with antibiotic-treated foods recognize that meat and poultry products that are not labeled or advertised as antibiotic-free have or could have been sourced from animals treated with antibiotics, and it is for this reason that such consumers are increasingly demanding and willing to pay more for antibiotic-free foods.

At the behest of increasing consumer pressure, more and more leading food companies are offering antibiotic-free meat and poultry options. For example, in October 2014, Perdue Farms unveiled a new product line – Simply Smart breaded chicken – a USDA Process Verified product sourced from chickens that have never been fed antibiotics.³³ The USDA process verified seal reads: “No Antibiotics Ever.” Purdue’s new antibiotic-free product line comes on the heels of the nation’s largest chicken chain in annual sales – Chick-fil-A – announcing earlier in 2014, that it would stop sourcing chickens treated with antibiotics within five years.³⁴

ALDF Misunderstands USDA Law

In general, ALDF's attack on USDA's voluntary labeling scheme for antibiotic claims misunderstands USDA's statutory mandate to ensure that labeling is truthful and not misleading. From a food safety standpoint, USDA's obligation to ensure that labeling is truthful and not misleading means that the Agency must require labeling that fully discloses material facts with respect to human health risks that may flow from the consumption of a particular meat or poultry product.

For example, under current USDA law, the failure to indicate the presence of a known allergen on a meat or poultry product label would render the product misbranded and necessitate the removal of the product from commerce, because the product is unsafe for certain consumers.³⁵ In contrast, the failure to indicate antibiotic use on a meat or poultry product label would not render the product misbranded or necessitate the removal of the product from commerce, because the use of antibiotics in food-producing animals, within FDA-prescribed parameters, is considered safe. Of course, FDA recognizes the potential human health risks posed by the *abuse* of sub-therapeutic antibiotics in food-producing animals and, to that end, has been working with industry to promote the judicious use of antibiotics in food-producing animals.³⁶ In addition, consumers can rest assured that USDA's National Residue Testing Program serves to prevent the distribution in commerce of any meat or poultry products possessing antibiotic residue levels considered to be unsafe by FDA standards.³⁷ Based on the foregoing, antibiotic-treated meat and poultry products that end up in the marketplace are considered safe, and so the appropriate use

of antibiotics in food-producing animals does not trigger a statutory requirement that USDA mandate labeling affirmatively disclosing antibiotic use.

Conclusion

Mandatory antibiotic claim labeling is not needed. Existing federal law and policy provide a sound regulatory framework that facilitates the marketing of antibiotic-free foods and validates the accompanying antibiotic nonuse claims as truthful and not misleading. Accordingly, because existing federal law and policy provides concerned consumers with antibiotic-free options, no antibiotic claim-specific labeling requirements are warranted. To be sure, heightened consumer fears of superbug *antibiotic* resistance combined with consumers trending towards "healthier" foods will result in the increased production and marketing of antibiotic-free foods and sets the stage for additional challenges to the current regulatory scheme. ▲

1. See e.g., *Rep. Louise Slaughter, Animal Legal Defense Fund, and Public Interest Coalition Call for Labeling of Meat from Antibiotic-Dosed Animals*, Animal Legal Defense Fund Press Release (August 6, 2013), available at <http://aldf.org/press-room/press-releases/rep-louise-slaughter-animal-legal-defense-fund-and-public-interest-coalition-call-for-labeling-of-meat-from-antibiotic-dosed-animals/> and Consumer Union letter to FSIS (June 18, 2012), http://notinmyfood.org/press_release/cu-letter-to-usda-expresses-concern-about-confusing-claims-about-antibiotics-on-meat.
2. See Animal Legal Defense Fund Petition Before the United States Department of Agriculture, Food Safety and Inspection Service (May 16, 2013) (ALDF Petition), available at http://www.fsis.usda.gov/wps/wcm/connect/12aeca93-4d3e-4ac7-b624-d5fc0b0dbae0/Petition_Animal_Legal_Defense_Fund_060313.pdf?MOD=AJPERES.
3. Federal Meat Inspection Act (FMIA), 21 U.S.C. § 621 *et seq.* and the Poultry Products Inspection Act (PPIA), 21 U.S.C. § 451, *et seq.*
4. 21 U.S.C. § 607(d) (meat); 21 U.S.C. § 457(c) (poultry).
5. The implementing regulations of the FMIA and the PPIA are set forth at 9 C.F.R. Parts 300 – 500.
6. 9 C.F.R. § 317.8 (2014).
7. See *Unpublished Draft FSIS Statement of Labeling Guidance Documentation Needed to Substantiate Animal Production Claims for Label Submissions*, provided to Brian P. Sylvester of Keller and Heckman LLP by FSIS on November 20, 2014.
8. See Federal Trade Commission Act (FTCA), 15 U.S.C. §§ 45, 52, 55 (2014).
9. *Id.* at §§ 52, 55.
10. See *Unpublished Draft FSIS Statement of Labeling Guidance Documentation Needed to Substantiate Animal Production Claims for Label Submissions*.
11. See *FSIS Outline of Animal Production Claims*, available at <http://www.fsis.usda.gov/OPPDE/larc/Claims/RaisingClaims.pdf> and *Meat and Poultry Labeling Terms Guidance*, USDA-FSIS (October 24, 2014), available at <http://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/food-labeling/meat-and-poultry-labeling-terms/meat-and-poultry-labeling-terms>.
12. See *id.*
13. See *Unpublished Draft FSIS Statement of Labeling Guidance Documentation Needed to Substantiate Animal Production Claims for Label Submissions*.
14. NE3 prohibits producers from administering antibiotics to livestock "whether through feed, water, or by injection, from birth to slaughter," including *in ovo*. See *Never Ever 3 (NE3)*, USDA Agricultural Marketing Service (April 6, 2009), available at <http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5066028>.
15. The current NE3 program guidance does not specifically address poultry, but a revised guidance document addressing poultry is in the pipeline. At present, parties interested in marketing poultry under the NE3 program must contact the Agency for poultry-specific guidance. As of October 31, 2014, nine broiler complexes were listed under this program. See Dr. Craig A. Morris, Deputy Director Administrator of USDA, *Presentation at National Chicken*

- Council 60th Annual Meeting*, AMS (October 30, 2014), available at <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5109596>.
16. The requirements for the USDA Process Verified Program are defined in *GVD 1001 Procedure* (April 16, 2009), available at <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STEL-DEV3103489>.
 17. Lanham Act, 15 U.S.C. § 1125 (2014).
 18. *See id.*
 19. *Sanderson Farms, Inc. v. Tyson Foods*, 547 F. Supp. 2d 491 (D.Md. 2008).
 20. *Id.* at 497.
 21. Plaintiffs cited a consumer survey showing that 63.4% of consumers thought that the reworked claim meant that Tyson did not use any antibiotics in its chicken when, in fact, Tyson used ionophores in the feed for the life of its chicken. *Sanderson Farms, Inc. v. Tyson Foods*, 547 F. Supp. 2d 491, 504 (D.Md. 2008).
 22. *Id.* at 494.
 23. *Id.* at 505, 508.
 24. *Id.* at 509.
 25. The lawsuit inspired the filing of eight (8) state consumer fraud lawsuits by twenty-two (22) plaintiffs challenging Tyson's nonuse of antibiotics claims. These actions were consolidated into multidistrict litigation, and Tyson ultimately paid consumers upwards of \$5 million, with each class member eligible to receive up to \$50 in a January 2010 settlement. *See Plaintiffs' Memorandum of Points and Authorities in Support of Motion for Preliminary Approval of Settlement and Judge's Preliminary Approval Order*, Tyson Foods, Inc. Chicken Raised Without Antibiotics Consumer Litigation (D.Md. 2008) (No. 1:08-md-01982-RDB). *See also, Tyson Foods Settles Suit Challenging 'No Antibiotics' Claim*, Consumer Affairs, January 17, 2010, available at http://www.consumeraffairs.com/news04/2010/01/tyson_suit.html.
 26. *See FSIS News Release* (June 3, 2008), available at http://www.fsis.usda.gov/wps/portal/fsis/newsroom/news-releases-statements-and-transcripts/news-release-archives-by-year/news-release-archives-by-year-2008!/ut/p/a0/04_Sj9CPykyssy0xPLMnMz0vMAf-GjzOINAg3MDC2dDbwMDIH-Q08842MTDy8_YwNtMvyDbUREAz-bjixQ!!/?1dmy¤t=true&urile=wcm%3Apath%3A/fsis-archives-content/internet/main/newsroom/news-releases-statements-and-transcripts/news-release-archives-by-year/archives/ct_index203.
 27. *See Unpublished Draft FSIS Statement of Labeling Guidance Documentation Needed to Substantiate Animal Production Claims for Label Submissions*.
 28. *See* ALDF Petition, available at: http://www.fsis.usda.gov/wps/wcm/connect/12aeca93-4d3e-4ac7-b624-d5fc0b0dbae0/Petition_Animal_Legal_Defense_Fund_060313.pdf?MOD=AJPERES.
 29. *Meat on Drugs*, Consumer Reports, June 2012, note 48 at 8, available at https://www.consumerreports.org/content/dam/cro/news_articles/health/CR%20Meat%20on%20Drugs%20Report%2006-12.pdf.
 30. *See* ALDF Petition, *supra* note 27, at 27.
 31. *See id.* at 25.
 32. *Meat on Drugs*, *supra* note 28, at 3.
 33. *See* Perdue Farms Press Release (October 15, 2014), available at: http://www.perdufarm.com/News_Room/Press_Releases/details.asp?id=1125&title=PERDUE%20SIMPLY%20SMART%20breaded%20products%20now%20USDA%20Process%20Verified%20for%20no%20antibiotics%20ever.
 34. *See Our Journey: Antibiotic-Free Chicken*, Chick-fil-A Press Release, <http://www.chick-fil-a.com/antibiotic-free>.
 35. The FMIA and PPIA require all ingredients used to formulate meat and poultry products to be declared in the ingredients statement on product labeling. A product is misbranded under the FMIA or PPIA when it contains ingredients, including known allergens, that are permitted but are not declared on product labeling. 21 U.S.C. §§ 601(n) and 610(d) (meat); 21 U.S.C. 453(h) and 458(2)-(3) (poultry); 9 C.F.R. § 317.2 (meat); 9 C.F.R. § 381.118 (poultry). When FSIS becomes aware of a misbranded product, the Agency requests a Class I or II product recall on the basis that the product poses a risk to human health. If the company refuses to recall the misbranded product, FSIS retains the authority to detain and seize the product. 21 U.S.C. § 672 (meat); 21 U.S.C. § 467a (poultry).
 36. Several months after the filing of the ALDF petition, FDA issued Final Industry Guidance on December 11, 2013, setting forth a plan to help phase out the use of medically important antimicrobials in food animals for food production purposes. *See* Guidance For Industry (GFI) 213, *Guidance for Industry on New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI 209; Guidance 213* (December 2013), available at <http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM299624.pdf>. Although the Guidance is voluntary, all twenty-six animal drug manufacturers affected by GFI 213 have agreed to fully adopt the strategy set forth therein. *See FDA Secures Full Industry Engagement on Antimicrobial Resistance Strategy*, FDA News Release (June 30, 2014), available at <http://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm403285.htm>.
 37. *See U.S. National Residue Program for Meat, Poultry, and Egg Products, 2014 Residue Sampling Plans*, United States Department of Agriculture, Food Safety and Inspection Service, Office of Public Health Science (June 2014), available at <http://www.fsis.usda.gov/wps/wcm/connect/533beea8-1bcf-468e-a13b-531232b2af2f/2014-Blue-Book.pdf?MOD=AJPERES>.