IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

SANDERSON FARMS, INC. and PERDUE FARMS, INC.,	*	
Plaintiffs,	*	
v.	*	Civil Case No. RDB-08-210
TYSON FOODS, INC.,	*	
Defendant.	*	

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MEMORANDUM OPINION

Plaintiffs Sanderson Farms, Inc. ("Sanderson") and Perdue Farms, Inc. ("Perdue") (collectively "Plaintiffs") bring this suit against Tyson Foods, Inc. ("Tyson" or "Defendant"), alleging violations of section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), which prohibits false or misleading advertising and unfair trade practices in interstate commerce. This action arises out of alleged advertisements disseminated by Tyson containing the claim that its chicken is "Raised Without Antibiotics" or "Raised Without Antibiotics that impact antibiotic resistance in humans." According to their Amended Complaint (Paper No. 45),[1] Plaintiffs seek preliminary and permanent injunctive relief, disgorgement of profits, attorney's fees, and other damages. This Court has jurisdiction pursuant to 28 U.S.C. § 1331.

Pending before this Court is Defendant's Motion to Dismiss (Paper No. 50) for failure to state a claim upon which relief can be granted. Plaintiffs' Supplemental Motion for a Preliminary Injunction (Paper No. 44) also remains pending, but will be addressed in a separate

[1] Plaintiffs' original Complaint also included Foster Farms, Inc. and the Truthful Labeling Coalition as named Plaintiffs, but these entities are no longer parties to the action.

Memorandum Opinion and Order. This Court held a lengthy hearing over four days on both motions, commencing on Monday, April 7, 2008, and concluding on Thursday, April 10, 2008. Oral argument was heard on Defendant's Motion to Dismiss primarily on April 7, 2008. At the conclusion of the hearing on April 10, 2008, this Court DENIED Defendant's Motion to Dismiss for reasons stated on the record. Specifically, this Court held that a label approved by the United States Department of Agriculture does not insulate a company from an allegation of non-label false advertising under the Lanham Act. This Memorandum Opinion and accompanying Order serve to supplement the reasons previously stated on the record.

BACKGROUND

Bound to accept all well-pleaded allegations as true, this Court has taken the following factual allegations largely from Plaintiffs' Amended Complaint. Plaintiffs allege that Tyson has been and continues to nationally advertise that its chicken is "Raised Without Antibiotics" by means of television commercials, radio spots, print ads, billboards, posters and other media. (Amend. Compl. ¶¶ 1, 2.) This language has been referred to by the parties in this litigation as Tyson's "unqualified RWA claim." Plaintiffs also allege that Tyson is advertising a similar claim, namely, that its chicken is "Raised Without Antibiotics that impact antibiotic resistance in humans." (*Id.* ¶ 17.) The latter qualified claim has been disseminated in several forms, including "Raised Without Antibiotics that Impact Human Antibiotic Resistance," "Raised Without Antibiotics ** No compounds used that create antibiotic resistance in humans," and "Chicken Raised Without Antibiotics that impact antibiotic resistance in humans." (*Id.* ¶ 18.) Combined, these latter claims have been referred to by the parties as Tyson's "qualified RWA claim."

The gravamen of the Amended Complaint is that the unqualified language "Raised Without Antibiotics" is literally false and that the qualifying language, "that impact antibiotic resistance in humans" and any of its variations, is ineffective at curing the literal falsity of the root language "Raised Without Antibiotics." (*Id*. ¶ 19.) Plaintiffs contend that both the unqualified and qualified RWA claims "deceive consumers and injure competitors and will continue to do so absent an injunction." (*Id*. ¶ 20.)

Plaintiffs allege that Tyson uses in its chicken feed hydrophobic molecules called ionophores, which are used to "disrupt transmembrane ion concentration gradients, required for the proper functioning and survival of microorganisms." (*Id*. ¶ 19.) Ionophores kill microorganisms in chicken, thereby yielding a larger, healthier, and more profitable production of chicken. (*Id*. ¶ 24.) Plaintiffs allege that ionophores are in fact antibiotics, despite Tyson's claim that its chicken is "Raised Without Antibiotics."

The Food Safety and Inspection Service ("FSIS") of the United States Department of Agriculture ("USDA") originally approved Tyson's use of a "Raised Without Antibiotics" label. FSIS subsequently revoked that approval and specifically stated that ionophores *are* antibiotics. Accordingly, FSIS informed Tyson that they could no longer use a product label claiming that the chicken contained therein was "Raised Without Antibiotics." (*Id.* ¶ 27.) Subsequently, the label was qualified to read "Raised Without Antibiotics that impact antibiotic resistance in humans." (*Id.*) On December 19, 2007, FSIS issued a document titled "USDA Labeling Guidance for Raised Without Antibiotic Claims and the Use of Ionophores," in which the agency stated as follows:

> It is longstanding FSIS policy that ionophores are antibiotics because they meet the [American Veterinary Medical Association

> ("AVMA")] definition.[2] The Food and Drug Administration [("FDA")] agrees that by strict definition, ionophores are antibiotics thus; poultry meat from birds to which ionophores have been administered is not eligible to bear a "RWA" claim.

(*Id.* ¶ 29.)

Because FSIS considers ionophores to be antibiotics, Plaintiffs allege in their Amended Complaint that Tyson's advertisements containing the claim "Raised Without Antibiotics" are false and misleading. (*Id.* ¶ 33.) They also allege that the advertisements are sufficiently distributed to constitute commercial advertising under the Lanham Act.[3] (*Id.*) Plaintiffs further contend that the advertisements constitute material misstatements likely to influence the decisions of consumers, (*id.* ¶¶ 34-36), and that the advertisements constitute an implied health and safety superiority claim over the chicken products of Sanderson and Perdue. (*Id.* ¶ 37.) These alleged Lanham Act violations are causing and will continue to cause irreparable injury to Plaintiffs for which there is no adequate remedy at law. (*Id.* ¶¶ 38-39.)

As part of their Amended Complaint, Plaintiffs have submitted a consumer survey conducted by Professor Michael B. Mazis. Plaintiffs describe the consumer survey in their Amended Complaint as follows*:*

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[2] The AVMA has defined an ionophore as "a chemical substance produced by a microorganism, which has the capacity, in dilute solutions, to inhibit the growth of or to kill other microorganisms." (Amend. Compl. ¶ 25.)

[3] Specifically, Plaintiffs allege, *inter alia*, that "Tyson continues to run various versions of its 'unqualified' raised without antibiotics television commercial, including on the following dates and channels: February 2, 2008 on channels WPLG, WFAA, KNXV, KTVT, WPLG, WFOR, KXAS, KPNX; February 3, 2008 on channel KPNX; February 4, 2008 on channel KPNX, February 9, 2008 on channel WPLG; February 10, 2008 on channels KPHO, KTVT, WFOR, KXAS, WTVJ, WFAA and KNXV; February 11, 2008 on channels KPHO, KTVT, WFOR, KXAS and WTVJ; February 12, 2008 on channels WFAA, KPIX, WPLG and KGO; and February 16, 2008 on channel KXAS." (*Id.* ¶ 32.)

> In February 2008, Professor Mazis conducted a survey of approximately 600 consumers in 28 shopping malls across the United States. There were four cells of approximately 150 respondents each shown different stimuli: two cells were shown an "unqualified" "Raised Without Antibiotics" Tyson claim; a third cell was shown a print stimulus with the "qualified" "Raised Without Antibiotics" claim; and a fourth cell was shown a "control" stimulus. Professor Mazis' survey demonstrates that approximately 59-63% of survey respondents perceived a false implied safety superiority message from these claims (regardless of whether the claim is "qualified" or "unqualified"). In addition, consumers appear deceived with regard to the "qualified" claim, and Professor Mazis concludes that many consumers appear to separate the "qualified" claim into two concepts: (1) Tyson's chicken has no antibiotics; and (2) because Tyson's chicken has no antibiotics, Tyson's chicken does not impact antibiotic resistance in humans.

Id. ¶ 40.) Because the Plaintiffs contend that the survey shows no demonstrable consumer impact by the qualified language, the claim "Raised Without Antibiotics that impact antibiotic resistance in humans" is also false and misleading to the consumer in violation of section 43(a) of the Lanham Act.

On March 14, 2008, Defendant filed the pending Motion to Dismiss. (Paper No. 50.) On March 18, 2008, Plaintiffs filed their Response (Paper No. 52) and, on March 27, 2008, Defendant filed its Reply (Paper No 58).[4]

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[4] Defendant's Motion to Dismiss was not filed until after the parties began discovery on Plaintiffs' pending Supplemental Motion for Preliminary Injunction. By the time this Court denied Defendant's Motion to Dismiss on the record at the April 10, 2008 hearing, this Court had already been privy to the extensive evidence and testimony offered by the parties on the Plaintiffs' Supplemental Motion for Preliminary Injunction.

By its very nature, however, Defendant's Motion to Dismiss relates only to the sufficiency of the Amended Complaint and whether it fails as a matter of law. Therefore, although this Court has become intimately familiar with the factual contentions of the parties and the underlying evidentiary support, this Motion to Dismiss will be dealt with the same as any other motion to dismiss—by testing the legal sufficiency of the Amended Complaint based on the allegations contained therein. A more extensive factual discussion of this case, including

STANDARD OF REVIEW

Defendant seeks to dismiss Plaintiffs' action pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure. In reviewing a complaint, this Court accepts all well-pleaded allegations of the complaint as true and construes the facts and reasonable inferences derived therefrom in the light most favorable to the plaintiff. *Venkatraman v. REI Sys., Inc.*, 417 F.3d 418, 420 (4th Cir. 2005); *Ibarra v. United States*, 120 F.3d 472, 473 (4th Cir. 1997); *Mylan Labs., Inc. v. Matkari*, 7 F.3d 1130, 1134 (4th Cir. 1993). Rule 8(a)(2) of the Federal Rules of Civil Procedure requires only a "short and plain statement of the claim showing that the pleader is entitled to relief." *Migdal v. Rowe Price-Fleming Int'l Inc.*, 248 F.3d 321, 325-26 (4th Cir. 2001); *see also Swierkiewicz v. Sorema N.A.*, 534 U.S. 506, 513 (2002) (stating that a complaint need only satisfy the "simplified pleading standard" of Rule 8(a)).

The Supreme Court of the United States recently explained that a "plaintiff's obligation to provide the 'grounds' of his 'entitlement to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atl. Corp. v. Twombly*, 127 S. Ct. 1955, 1964-65 (2007) (internal citations omitted). Nonetheless, detailed factual allegations are not needed to survive a motion to dismiss. *Id.* at 1964. Instead, a complaint must only contain "enough facts to state a claim to relief that is plausible on its face." *Id*. at 1974. Moreover, the Supreme Court determined that a properly plead complaint "may be supported by showing any set of facts consistent with the allegations." *Id*. at 1969.

DISCUSSION

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findings of fact, will be contained in the Memorandum Opinion addressing Plaintiffs' Supplemental Motion for Preliminary Injunction.

The Lanham Act prohibits the "false or misleading description of fact, or false or misleading representation of fact, which . . . in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities." 15 U.S.C. § 1125(a)(1)(B). The elements of a false advertising claim under the Lanham Act are as follows:

> (1) the defendant made a false or misleading description of fact or representation of fact in a commercial advertisement about his own or another's product;
>
> (2) the misrepresentation is material, in that it is likely to influence the purchasing decision;
>
> (3) the misrepresentation actually deceives or has the tendency to deceive a substantial segment of its audience;
>
> (4) the defendant placed the false or misleading statement in interstate commerce; and
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> (5) the plaintiff has been or is likely to be injured as a result of the misrepresentation, either by direct diversion of sales or by a lessening of goodwill associated with its products.

Scotts Co. v. United Indus. Corp., 315 F.3d 264, 272 (4th Cir. 2002) (citing *Cashmere & Camel Hair Mfrs. Inst. v. Saks Fifth Ave*., 284 F.3d 302, 310-11 (1st Cir.), *cert. denied,* 123 S. Ct. 485 (2002)). False advertising is actionable under the Lanham Act if the statement is false on its face or if, despite its truth, the statement is likely to mislead or confuse consumers because of the nature of the advertisement. *See C.B. Fleet Co. v. SmithKline Beecham Consumer Healthcare, L.P.*, 131 F.3d 430, 434 (4th Cir. 1997). This Court finds that Plaintiffs' Amended Complaint states sufficient factual allegations under section 43(a) of the Lanham Act to survive dismissal on a 12(b)(6) motion.

Nonetheless, Defendant argues that Plaintiffs' Amended Complaint fails as a matter of

law because the language that Plaintiffs allege to be false and misleading under section 43(a) of the Lanham Act—*i.e.*, the unqualified and qualified RWA claims—was approved for use on Defendant's chicken labels by FSIS, the USDA agency to which Congress has delegated the authority to regulate poultry labels. According to Defendant,

> courts uniformly have held that no Lanham Act cause of action lies regarding advertising claims that "comport substantively" with the label and labeling statements approved as accurate by the government agency vested with that approval authority. To hold otherwise would enable competitors like the plaintiffs here to use the Lanham Act to create a private cause of action, which the [Poultry Products Inspection Act, 21 U.S.C. § 451 *et seq.* ("PPIA")] expressly prohibits.

(Def.'s Mem. Supp. Mot. to Dismiss 2.) In support, Defendant relies on what has been termed the *Cytyc* line of cases, which includes *American Home Products Corp. v. Johnson & Johnson*, 672 F. Supp. 135 (S.D.N.Y. 1987), *Cytyc Corp. v. Neuromedical Systems, Inc.*, 12 F. Supp. 2d 296 (S.D.N.Y. 1998), and, most recently, *Prohias v. Pfizer, Inc*., 490 F. Supp. 2d 1228 (S.D. Fla. 2007).

In *Cytyc,* the defendant filed a counterclaim alleging that plaintiff promoted its product in a false and misleading manner in violation of the Lanham Act. 12 F. Supp. 2d at 301. Plaintiff moved to dismiss the case because many of the statements contained in the advertisements had been approved by the Food and Drug Administration ("FDA"). *Id.* Citing *American Home Products*, 672 F. Supp. at 145, the court determined that "representations by plaintiff that comport substantively with statements approved as accurate by the FDA cannot supply the basis for [defendant's] claims." *Cytyc Corp.*, 12 F. Supp. 2d at 301. The court continued: "Although [plaintiff's] statements do not correspond precisely to statements that the FDA has approved, the challenged statements discussed above are similar enough to the approved statements for the

Court to conclude, as a matter of law, that they are neither false nor misleading." *Id*.

In *Prohias,* a proposed nationwide class action alleged that the defendant pharmaceutical company, Pfizer, had engaged in false and misleading advertising under the consumer fraud acts of several states (not the federal Lanham Act) with respect to Pfizer's cholesterol-lowering drug Lipitor. Lipitor was originally approved by the FDA only to reduce cholesterol in certain patients, but in 2004 it was also approved to reduce the risk of heart attacks for women and the elderly with multiple risk factors for coronary heart disease. 490 F. Supp. 2d at 1230. The advertising in question in *Prohias* began running prior to and continued after the 2004 approval and depicted women and elderly people with their cholesterol numbers visible, accompanied by text warning that "high cholesterol is a risk factor for heart disease." *Id*. The plaintiffs alleged that these advertisements were false and misleading because there was no scientific support for the claim that Lipitor reduced the risk of heart disease in women or elderly people who did not already have heart disease or diabetes. *Id.* As to the post-2004 advertisements,[5] the court granted the defendant's motion to dismiss, finding that "even if the advertisements did not comport precisely with Lipitor's approved label . . ., the alleged advertisements generally comport with the approved label, and are therefore not misleading as a matter of law." *Id.* at 1235 (citing *Cytyc*, 12 F. Supp. 2d at 301).

Taken together, the *Cytyc* line of cases exemplify a broader proposition—namely, that federal courts should not unduly entangle themselves in regulatory agency decisions where the agency has special expertise in the subject matter and where, more importantly, doing so would

[5] The pre-2004 advertisements, which aired before the FDA approved *any* use of Lipitor for heart disease, survived Pfizer's motion to dismiss.

usurp the authority specifically delegated by Congress to that agency.

With Defendant's legal position in mind, this Court must address whether Defendant's unqualified claim, "Raised Without Antibiotics," and qualified claim, "Raised Without Antibiotics that impact antibiotic resistance in humans," are actionable under section 43(a) of the Lanham Act.

I. The Unqualified Claim — "Raised Without Antibiotics"

The *Cytyc* line of cases provide no defense to Plaintiffs' claim that advertisements containing the unqualified "Raised Without Antibiotic" claim are false and misleading. In fact, there is absolutely no tension between Plaintiffs' Lanham Act allegations and the USDA.

Defendant's reliance on the *Cytyc* line of cases is based exclusively on the position that "a Lanham Act claim cannot proceed against advertisements that simply repeat information that the government has approved to appear in labeling because the appropriate federal agency has determined that it is not false or misleading." (Def.'s Reply Mem. 1.) As alleged in Plaintiffs' Amended Complaint, FSIS has revoked Defendant's unqualified label, "Raised Without Antibiotics." (Amend. Compl. ¶27.) It is further alleged that FSIS issued a letter on December 19, 2007 that unambiguously stated that "[i]t is longstanding FSIS policy that ionophores are antibiotics" and that "poultry meat from birds to which ionophores have been administered is not eligible to bear a 'RWA' claim." (*Id.* ¶ 29.) Without current USDA approval for its label, Defendant cannot rely on the USDA's former (and briefly held) position to defend itself against allegations that it continues to run false and misleading advertisements carrying the "Raised Without Antibiotics" language.

Plaintiffs' Amended Complaint clearly states a claim upon which relief can be granted

with respect to the unqualified claim "Raised Without Antibiotics." Therefore, this portion of Plaintiffs' Amended Complaint survives Defendant's Motion to Dismiss.

II. The Qualified Claim — "Raised Without Antibiotics that impact antibiotic resistance in humans"

Defendant relies on the same cases to support its defense of Plaintiffs' claim that the use of "Raised Without Antibiotics that impact antibiotic resistance in humans" in advertisements is false and misleading to the consumer. As was previously discussed, Defendant has current approval from the United States Department of Agriculture to carry this language on its labels. Thus, this portion of Plaintiffs' Amended Complaint is distinguishable from the claim with respect to the "Raised Without Antibiotics" language.

Lanham Act claims often collide against the regulatory authority of the FDA. Extensive case law has developed on the issue, including the *Cytyc* line of cases. This case, however, involves the USDA and therefore the cases cited by Defendant are not directly on point. In fact, the parties have not submitted and this Court has been unable to locate a single federal case—published or unpublished—where a court has resolved the precise issue at bar, *i.e.*, whether a USDA-approved label insulates a company from allegedly false non-label advertising under the Lanham Act.[6] To a large extent, therefore, this case is one of first impression. For the reasons discussed in detail below, the *Cytyc* line of cases is distinguishable based on the limited

[6] One court highlighted this tension, but did not decide the issue. In *ConAgra, Inc. v. George A. Hormel & Co.*, 784 F. Supp. 700 (D. Neb. 1992), the court wrote that it "need not reach the question of whether or not the USDA guidelines are applicable in this case. Among other things, [plaintiff] argues that USDA guidelines cannot regulate advertising, as opposed to the regulation of labels, since the guidelines do not explicitly pertain to advertisements, as opposed to labels, and the authorizing statutes, 21 U.S.C. §§ 601(o) and 607, apply only to labels and not advertisements generally." *Id.* at 737 n.26. While this accurately reflects the issue presented in this case, the *ConAgra* decision does not work in favor of either party.

jurisdiction of the USDA. Moreover, to the extent that the *Cytyc* line of cases offer persuasive authority, this Court is not convinced that Plaintiffs' Amended Complaint must be dismissed as a matter of law. Plaintiffs' Lanham Act claim is therefore not barred simply because the USDA approved the Defendant's use of the qualified language "Raised Without Antibiotics that impact antibiotic resistance in humans" on labels.

A. The Limited Authority and Jurisdiction of the USDA under the Poultry Products Inspection Act

1. The USDA Does Not Have Jurisdiction over Advertising

Pursuant to the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, the FDA has significant authority and jurisdiction to regulate advertisements. FDA regulations plainly govern "prescription drug advertisements" and include the authority to regulate "[a]dvertisements broadcast through media such as radio, television, or telephone communications systems." 21 C.F.R. § 202.1. The Division of Drug Marketing, Advertising, and Communications ("DDMAC") within the FDA has "responsibility for reviewing prescription drug advertising and promotional labeling to ensure that the information contained in these promotional materials is not false or misleading." DDMAC Mission Statement, *available at* http://www.fda.gov/cder/ddmac/. FDA also prohibits restricted medical devices from "using false or misleading advertising." *See* 21 U.S.C. §§ 352(q)-(r). The FDA frequently brings enforcement actions against companies it believes are disseminating false and misleading advertisements.

Moreover, with respect to FDA's regulation of over-the-counter ("OTC") products, the FDA voluntarily abstains from exercising its jurisdiction over advertising in favor of the Federal Trade Commission ("FTC"). *See* Working Agreement Between FTC and FDA, 4 Trade Reg.

Rep. (CCH) ¶ 9,850.01 (1971). Nonetheless, the FDA reevaluates approvals under the FDCA through a monograph process involving an independent advisory review panel that submits recommendations to the FDA. *See, e.g., Kelso v. Bayer Corp.*, 398 F.3d 640, 643 (7th Cir. 2005) ("All OTC drug labeling required by a monograph or other regulation (*e.g.*, statement of identity, warnings, and directions) must appear in the specific wording established under the OTC drug monograph or other regulation." (internal citation omitted)); *Bristol-Myers Squibb Co. v. Teva Pharmaceuticals USA, Inc.*, 288 F. Supp. 2d 562, 574 (S.D.N.Y. 2003).

Pursuant to the Poultry Products Inspection Act ("PPIA"), 21 U.S.C. § 451 *et seq.*, the USDA has jurisdiction to approve all aspects of poultry product labels and labeling. In reviewing proposed labels and labeling for approval, FSIS seeks to ensure that they are not "false or misleading." *See* 21 U.S.C. § 457(b)-(c). FSIS does not, however, have any congressional authority to review advertisements. *See* Regulation of Advertising and Labeling, AH-715, Economic Research Service - U.S. Department of Agriculture, *available at* http://www.ers.usda.gov/publications/ah715/ah715c.pdf (stating that the FTC regulates advertising, while "FSIS regulates meat and poultry product labeling"). In fact, FSIS acknowledges that the FTC controls advertising issues in the poultry industry. *See* FSIS, A Guide to Federal Food Labeling Requirements for Meat and Poultry Products 18, *available at* http://www.fsis.usda.gov/PDF/ Labeling_Requirements_Guide.pdf ("An advertising claim may be deemed false or misleading if it is not adequately substantiated pursuant to FTC guidelines.").

In marked contrast to the FDA, the USDA does not have congressional authority to regulate advertising. While the "comport substantively" standard addressed in the *Cytyc* line of

cases may be appropriate in light of the expansive jurisdiction of the FDA, this Court finds the "comport substantively" standard inapplicable in this case based on the limited jurisdiction of the USDA.

2. Scope of Labeling Provisions

The scope of "labeling" is also at issue in this case and requires clarification. Label and labeling are defined in the PPIA as follows:

> The term "label" means a display of written, printed, or graphic matter upon any article or the immediate container (not including packaged liners) of any article; and the term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

21 U.S.C. § 453(s). Plaintiffs' Amended Complaint alleges that Defendant's "*non-label* advertising" is false and misleading under the Lanham Act. According to FSIS's definition, labeling should be interpreted broadly as all "product labels *and materials that accompany a product but are not attached to it, such as point-of-purchase (POP) materials*." *See* FSIS, Guide to Federal Food Labeling Requirements, at 5 (emphasis added).

Labeling may be prepared in such a manner that it is also effectively "commercial advertising and promotion" under the Lanham Act. *See Applied Med. Res. Corp. v. Steuer*, 527 F. Supp. 2d 489, 493 (E.D. Va. 2007) (stating that the four-part test used in *Fashion Boutique of Short Hills, Inc. v. Fendi USA, Inc.*, 314 F.3d 48 (2d Cir. 2002), has been "uniformly embraced by district courts in this Circuit"). As such, some labeling is actionable advertising. Point-of-purchase materials that merely restate the language approved for the label cannot fairly be characterized as advertising. As has become clear in this case, however, point-of-purchase materials that may well be considered labeling to FSIS often contain images and promotional

slogans in conjunction with the language approved for the label. This sort of labeling is merely advertising by another name. False and misleading images and slogans contained in a magazine advertisement are no less false and misleading, and consequently no less actionable under the Lanham Act, when they are transposed onto a piece of cardboard and placed in the poultry section of a grocery store. The fact that FSIS characterizes point-of-purchase materials as labeling will not insulate what is plainly an advertisement intended to induce consumers to purchase Defendant's product.

Therefore, Plaintiff's Amended Complaint fairly encompasses any labeling that, despite including language approved by the USDA, contains additional images and promotional slogans that effectively turn the labeling into an advertisement.

B. Distinction Between Labels and Advertising — *National Broiler Council v. Voss*

Despite not being directly on point, this Court finds *National Broiler Council v. Voss*, 44 F.3d 740 (9th Cir. 1994), persuasive. In *Voss*, the United States Court of Appeals for the Ninth Circuit addressed whether a state statute that made it illegal to "advertise, label, describe, otherwise hold out, or sell as 'fresh' poultry that is stored below 26 degrees" was preempted by the PPIA, which did not contain the same limitation. *Id*. at 743. The USDA had issued a regulation under the PPIA that permitted such chicken to be labeled "fresh." The plaintiffs, three poultry and meat trade associations, as well as the USDA, argued that the regulation made under the PPIA preempted the conflicting state statute. In his opinion specially concurring in the judgment, Judge O'Scannlain summarized the holding of the case, which he described as one involving "legal gymnastics": "[w]e . . . hold[], quite properly, that the California legislature is federally preempted from requiring that frozen chickens be *labeled* 'frozen.'" *Id.* at 749

(emphasis added).

The plaintiffs and the USDA also argued that the advertising portion of the state statute was preempted by the PPIA, but the court found that the advertising portion of the statute was functionally severable from the labeling portion and therefore was not preempted. The court wrote that the legislative purpose of the advertising portion of the state statute was to "protect consumers from misleading claims that previously frozen poultry is 'fresh'" and that the purpose of the statute would be enforced "even though the labeling restriction [could] no longer [be] enforced." *Id*. at 748. Judge O'Scannlain stated that

> the States are not without devices of their own to protect their citizens when Congress permits the federal bureaucracy to impose the absurd. California stores can still be required by state law to tell the truth in *advertising* and to *display* frozen chickens for what they are—"frozen"—even though the labels on the chickens themselves are required by federal law to say "fresh."

Id. at 749 (emphasis added).

Although the legal issues in the *Voss* case involve the severability and preemption of state statutory provisions, the case highlights the distinction between labels and advertising and constitutes judicial recognition that a label approved by the USDA may nonetheless be false or misleading in other contexts. Despite the fact that the specific language at issue was approved by the USDA for poultry labels, the Ninth Circuit determined that the language was nonetheless actionable as misleading under a state statutory analogue to the Lanham Act when used in advertising and in-store displays.[7]

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[7] Lending further support for Plaintiffs is the position taken by the National Advertising Division ("NAD") of the Better Business Bureau, an organization that adjudicates false advertising disputes, issues written decisions, and refers matters to the FTC when its decisions are not heeded. NAD's decisions are not binding on the parties before it, effectively making

C. Plaintiffs' Non-Label False Advertising Claim Does Not Infringe on the USDA's Jurisdiction to Regulate Labels Under the PPIA

It is well established that a party may not use the Lanham Act as a backdoor to private enforcement of the Food, Drug, and Cosmetic Act. *See, e.g., Mylan Labs., Inc. v. Matkari*, 7 F.3d 1130, 1139 (4th Cir. 1993) ("Mylan, in short, is not empowered to enforce independently the FDCA."), *cert. denied*, 510 U.S. 1197 (1994); *Sandoz Pharms. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 231 (3d Cir. 1990) (finding that the FDCA does not create private causes of action).

Federal courts have struggled to find a consistent line of demarcation between, on the one hand, cases that assert legitimate Lanham Act violations and, on the other, cases that assert Lanham Act violations as a means to achieve private enforcement of the FDCA.[8] The conflict between Lanham Act claims and the FDCA was addressed by this Court in *Pediamed Pharmaceuticals, Inc. v. Breckenridge Pharmaceutical, Inc.*, 419 F. Supp. 2d 715 (D. Md. 2006),

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them advisory. Despite this limited authority, however, voluntary compliance appears almost universal. *See, e.g., AMF, Inc. v. Brunswick Corp.*, 621 F. Supp. 456, 458 (E.D.N.Y. 1985).

In *Kraft Foods Global, Inc. v. Perdue Farms*, NAD Case No. 4576 (Oct. 20, 2006), *aff'd*, Report of Panel 141 (March 14, 2007), the NAD reviewed a label that had been approved by FSIS that said "no preservatives." The challenger, as the party bringing the action is called, argued that in fact the chicken product contained ingredients that qualified as preservatives. Although FSIS approved the label containing "no preservatives" as "accurate and not misleading," NAD independently determined that the words "no preservatives" were misleading to consumers when used in the advertising context.

[8] "The FDCA and the Lanham Act overlap to the extent that both regulate drug products in the marketplace. Courts have recognized the potential conflict between the two Acts and have struggled to define the proper scope of each law. Courts have come to the general conclusion that the FDA's enforcement of the FDCA is primarily concerned with the safety and efficacy of new drugs, while the Lanham Act is focused on the truth or falsity of advertising claims." *Axcan Scandipharm Inc. v. Ethex Corp.*, No. 07-2556, 2007 WL 3095367 (D. Minn. Oct. 19, 2007).

a case involving whether products manufactured by the parties were pharmaceutically equivalent. Notably, this Court explained that although a Lanham Act "claim cannot stand if it comes 'too close to the exclusive enforcement domain of the FDA,'" *id.* at 723 (citing *Summit Tech., Inc. v. High-Line Med. Instruments Co.*, 922 F. Supp. 299, 306 (C.D. Cal. 1996)), "[t]he FDA's administrative scheme should not be allowed to 'eviscerate a Lanham Act or related common law claim over which the agency has no jurisdiction.'" *Id.* (citing *Healthpoint Ltd. v. Stratus Pharms., Inc*., 273 F. Supp. 2d 769, 792-93 (W.D. Tex. 2001)). Surveying the applicable case law, this Court determined that courts "have drawn a line between claims that involve application and interpretation of the FDCA and its implementing regulations, and claims that do not." *Id.* at 724. The former fail as a matter of law, whereas the latter do not.

Like the FDCA, there is no private cause of action under the Poultry Products Inspection Act. *See* 21 U.S.C. § 467c ("All proceedings for the enforcement or to restrain violations of this chapter shall be by and in the name of the United States."). Thus, Plaintiffs may not use the Lanham Act as a disguised attempt to enforce the PPIA. In this case, the USDA indisputably had authority and jurisdiction under the PPIA when it approved Defendant's application to use the term "Raised Without Antibiotics that impact antibiotic resistance in humans" on labels. If Plaintiffs' Amended Complaint had alleged that the Defendant's *labels* were false and misleading under the Lanham Act, the claim would be precluded as an attempt by Plaintiffs to use the Lanham Act as a vehicle to challenge the USDA's primary jurisdiction under the PPIA to determine whether or not a label is false or misleading.

Plaintiffs' Lanham Act claim, however, relates solely to allegedly false and misleading *non-label advertising* and is, therefore, simply not within the authority or jurisdiction of the

USDA. Plaintiffs assert that Defendant's advertisements containing the qualified RWA claim are false or misleading to the consumer public notwithstanding the fact that the USDA has determined that the language in the qualified RWA claim is not "false or misleading" under the PPIA. *See* 21 U.S.C. § 457(b)-(c). As such, Plaintiffs are not trying to enforce the provisions of the PPIA. *Cf. Pediamed Pharms.,* 419 F. Supp. 2d at 726 ("Defendants have not pointed specifically to any portion of the FDCA or to any implementing regulations to support their assertion that Plaintiff's claims are based on the FDCA or its regulations, and therefore are precluded."); *Healthpoint, Ltd.*, 273 F. Supp. 2d at 815-16 (stating that the "the proper judicial approach is for the Court to defer to the FDA for the resolution of issues within its primary jurisdiction and to exercise jurisdiction over Lanham Act and other claims which do not require application or construction of FDA law, regulations or policy").

While FSIS's determination involves a highly technical and scientific review of the proposed label language, it does not involve a review of whether the language is misleading to the consumer when combined with images and promotional slogans.[9] Undoubtedly, language that is technically and scientifically accurate on a label can be manipulated in an advertisement to create a message that is false and misleading to the consumer. The Lanham Act protects against precisely this situation by permitting claims based on language that, although literally

[9] This is true even though, as Defendant stresses, the "false and misleading" text in the PPIA mirrors the requirement under the Lanham Act that the Plaintiffs establish, *inter alia*, "a *false or misleading* description of fact or representation of fact in a commercial advertisement about his own or another's product." *Scotts*, 315 F.3d at 272. As discussed above, although FSIS necessarily determines that language approved for a label is not "false or misleading," it does not and cannot determine whether or not the same language used in an advertisement is false or misleading to the consumer public. That determination is strictly within the province of the Lanham Act.

true, nonetheless misleads or deceives consumers in an advertisement. *See C.B. Fleet*, 131 F.3d at 434. Plaintiffs must therefore show that "Raised Without Antibiotics that impact antibiotic resistance in humans" means something different to the consumer public when viewed as part of Defendant's advertisements than the language did to the experts and scientists at the USDA during the label-approving process. Plaintiffs' Amended Complaint contains this allegation in substance and they have submitted a 600-participant consumer survey that they suggest strongly buttresses their allegation.

In sum, this Court has the obligation to enforce federal statutes that supply private causes of action, such as the Lanham Act. Contrary to Defendant's argument, this Court does not usurp in any way the USDA's authority under the PPIA with respect to labels, nor does it challenge the agency's expert judgment, by allowing Plaintiffs' Lanham Act claim to move forward. The USDA has not and cannot approve Defendant's non-label advertising. Simply put, a non-label false advertising claim brought under the Lanham Act is not precluded because the language on which the claim is based was approved for use on labels by the USDA. The opposite conclusion would extend USDA expertise into an area, *i.e.*, advertising, which the agency has no congressional authority to enter, while at the same time significantly curtailing the congressional protections explicitly accorded to "persons engaged in such commerce" under the Lanham Act. *See* 15 U.S.C. § 1127.

Plaintiffs have stated a cognizable claim that the qualified language approved by the USDA for use on labels, "Raised Without Antibiotics that impact antibiotic resistance in humans," is false and misleading to the consumer when used in advertisements. Therefore, this portion of Plaintiffs' Amended Complaint also survives Defendant's Motion to Dismiss.

CONCLUSION

For the reasons stated in this Memorandum Opinion and on the record at the hearing that concluded on April 10, 2008, Defendant's Motion to Dismiss (Paper No. 50) is DENIED. A separate Order follows.

Dated: April 15, 2008

/s/
Richard D. Bennett
United States District Judge

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

	*	
SANDERSON FARMS, INC. and PERDUE FARMS, INC.,	*	
Plaintiffs,	*	
v.	*	Civil Case No. RDB-08-210
TYSON FOODS, INC.,	*	
Defendant.	*	

* * * * * * * * * * * * *

ORDER

For the reasons stated in the accompanying Memorandum Opinion, it is this 15th day of April, 2008, HEREBY ORDERED that:

1. The Motion to Dismiss filed by Defendant Tyson Foods, Inc. (Paper No. 50) is DENIED;
2. Defendant shall answer the Complaint within 20 days of the date hereof; and
3. The Clerk of the Court transmit copies of this Order and accompanying Memorandum Opinion to counsel for the parties.

/s/
Richard D. Bennett
United States District Judge