IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

ALL ONE GOD FAITH, INC.,

Plaintiff,

v.

THE HAIN CELESTIAL GROUP, INC., et al.,

Defendants.
_____/

No. C 09-3517 SI

ORDER GRANTING DEFENDANTS' MOTIONS TO DISMISS AND DENYING PLAINTIFF'S MOTION FOR LEAVE TO AMEND THE COMPLAINT

On June 15, 2012, the Court held a hearing on defendants' motions to dismiss the complaint and plaintiff's motion for leave to file a fourth amended complaint. For the reasons set forth below, the Court GRANTS defendants' motions to dismiss the complaint without leave to amend and DENIES plaintiff's motion. The Third Amended Complaint is DISMISSED WITHOUT PREJUDICE.

BACKGROUND

Plaintiff All One God Faith, doing business as Dr. Bronner's Magic Soaps, makes and sells personal care and cosmetic products ("personal care products") labeled as "organic." Plaintiff filed this lawsuit in 2008 against a number of companies that manufacture, sell and/or distribute personal care products labeled as "organic." Plaintiff claims that defendants' products are not "organic" as that term is understood by consumers because the products are made from conventional agricultural material rather than organic material, contain ingredients made from petrochemicals or petrochemical compounds, and/or contain synthetics. Plaintiff also sued defendant Ecocert, which certifies products,

including some of defendants' products, as "organic" based on its own, privately-determined standards.

I. Regulatory background[1]

A. Organic Food Products Act and the National Organic Program

The Organic Food Products Act of 1990 ("OFPA"), 7 U.S.C. §§ 6501 *et seq*., authorized the United States Department of Agriculture ("USDA") to implement the regulatory National Organic Program ("NOP"), providing for the establishment and enforcement of national standards for labeling agriculture and food products as "organic." The purpose of the statute is "(1) to establish national standards governing the marketing of certain agricultural products as organically produced products; (2) to assure consumers that organically produced products meet a consistent standard; and (3) to facilitate interstate commerce in fresh and processed food that is organically produced." 7 U.S.C. § 6501. The USDA established the NOP in 2000. *See* National Organic Program, 65 Fed. Reg. 80,548 (Dec. 21, 2000) (codified at 7 C.F.R. Pt. 205) ("the Final Rule"). The NOP includes standards for growing and producing organic agricultural products, including grains, fruits, vegetables and livestock. *See* 7 C.F.R. Pt. 205, Subpt. C. Among other things, the regulations govern use of the term "organic" in the labeling and marketing of agricultural and food products. *See* 7 C.F.R. Pt. 205, Subpt. D. The OFPA defines the term "agricultural product" as "any agricultural commodity or product, whether raw or processed, including any commodity or product derived from livestock that is marketed in the United States for human or livestock consumption." 7 U.S.C. § 6502(1). The statute provides further that "no person may affix the label to, or provide other market information concerning, an agricultural product if such label or information implies, directly or indirectly, that such product is produced and handled using organic methods, except in accordance with this chapter." *Id*. at § 6505(a)(1)(B).

In order to create consistent national standards for organic products, Congress authorized the USDA to create a "National List" of approved and prohibited ingredients that may or may not be

[1] Much of this background has been set forth in Judge Fogel's previous orders. Because the regulatory framework is important to this Court's determination that plaintiff's Lanham Act claim is barred, the Court repeats Judge Fogel's discussion of this framework. The Court also GRANTS defendant's unopposed request for judicial notice of public government records. Docket No. 208. Judge Fogel previously granted defendants' requests for judicial notice of similar public government records, and this order cites those documents as well as the agency documents submitted at Docket No. 208.

permitted in the production, handling, and processing of organic products. *See* 7 U.S.C. § 6517. To develop that National List, Congress created the National Organic Standards Board ("NOSB") to advise the Secretary of Agriculture on crafting organic standards and regarding what materials should be included on the National List of approved organic ingredients. *See* 7 U.S.C. § 6518. Congress vested the NOSB with the exclusive authority to recommend materials for placement on the National List. *Id*. § 6518(k). Congress also mandated that the NOSB "establish procedures under which persons may petition the [NOSB] for the purpose of evaluating substances for inclusion on the National List." *Id*. § 6518(n). Relying on the NOSB, the USDA has created specific lists of synthetic materials for several product classes. *See, e.g.*, 7 C.F.R. § 205.601 (crop production); *id*. § 205.603 (livestock production); *id*. § 205.605 (processed products). The USDA reserved Section 205.608-619 of 7 C.F.R. for the purpose of future product classes.

Congress expressly declined to create a private right of action to enforce the OFPA or its implementing regulations. *See* 7 U.S.C. §§ 6519, 6520(a). Only the federal government can initiate enforcement of the OFPA, and the government can impose a $10,000 civil penalty on "any person who knowingly sells or labels a product as organic, except in accordance with this chapter . . . ." *Id*. § 6519(a). The statute requires the USDA to establish an "expedited administrative appeals procedure" that allows a person to appeal any action taken under the federal program by the USDA or its certifying agents if that action "(1) adversely affects such person; or (2) is inconsistent with the organic certification program established under this chapter." *Id*. § 6520(a). A person may file an appeal of a final agency decision to federal district court. *Id*. § 6520(b).

The Final Rule provides that "[t]he NOP is ultimately responsible for the oversight and enforcement of the program, including . . . cases of fraudulent or misleading labeling." Final Rule at 80,557. The USDA has indicated that it accepts all consumer and business complaints regarding alleged misuse of the word "organic," and it has rejected private enforcement actions. According to the Final Rule,

> [a]nyone may file a complaint, with USDA, an [State Organic Program's] SOP's governing State official, or certifying agent, alleging violation of the Act or these regulations. Certifying agents, SOP's governing State officials, and USDA will receive, review, investigate complaints alleging violations of the Act or these regulations . . . Citizens have no authority under the NOP to investigate complaints

> alleging violation of the Act or these regulations . . . Only USDA may bring an action under 7 U.S.C. § 6519.

Id. at 80,627; *see also id*. at 80,556 (noting, in a discussion of common-law nuisance claims for pesticide drift onto organic farms, that the OFPA "itself does not provide for the right to bring suit as a Federal cause of action, and [the USDA] could not grant it through this regulation").

B. NOP's labeling standards and rules

The NOP contains a "comprehensive labeling and certification scheme." *Harvey v. Veneman*, 396 F.3d 28, 36 (1st Cir. 2005). The First Circuit described the regime as follows:

> This scheme provides for four different types of product labels and for two different types of certification, all depending on the percentage of organic ingredients in the labeled product. The labeling scheme distinguishes (1) products containing 100% organic ingredients, which may be labeled "100 percent organic," *see* [7 C.F.R.] § 205.301(a); (2) products containing 94 to 100% organic ingredients, which may be labeled "organic," *see id.* § 205.301(b); (3) products containing 70 to 94% organic ingredients, which may be labeled "made with organic (specified ingredients or food group(s))," *see id.* § 205.301(c), and (4) products containing less than 70% percent organic ingredients, which may identify each such ingredient on the label or ingredient statement with the word "organic," *see id.* §§ 205.301(d), 205.305(a)(1).
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> This scheme allows (1) products in the first two labeling categories, containing 95% or more organic ingredients, to bear both a USDA seal and the seal of a private certifying agent, *see* 7 C.F.R. §§ 205.303(b)(4)-(5), 205.311(a); (2) products containing 70 to 94% organic ingredients to bear a notice of private certification and the seal of a private certifying agent, *see id.* 205.304(a)(3), (b)(2); and (3) products containing less than 70% organic ingredients to bear neither a USDA seal nor that of a private certifier, *see id.* § 205.305(b).

Id. at 36-37; *see also* 7 U.S.C. §§ 6505(a)-(c), 6510 (forbidding labeling of products as organically produced unless produced in accordance with the Act and providing that no more than 5% nonorganic ingredients may be added to processed foods handled in accordance with the Act, but also permitting labeling of ingredients as organic in processed foods containing less than 94% organic ingredients).

The Regulatory Impact Assessment of the Final Rule states that,

> [t]he primary benefits from implementation of USDA's National Organic Program (NOP) are standardizing the definitions in the manner in which organic product information is presented to consumers, which may reduce the costs associated with enforcement actions and consumer fraud cases . . . [and] harmonizing the various State and private organic standards . . . .

Docket No. 26, Ex. D.

C. Personal care products

Since the Final Rule was published in 2000, the USDA's approach to "organic" claims on personal care products has evolved. During deliberations on the regulations, comments were received asking "that the NOP include in the final rule certification standards for cosmetics, body care products, and dietary supplements." Final Rule at 80,557. The USDA concluded, however, that "[t]he ultimate labeling of cosmetics, body care products, and dietary supplements . . . is outside the scope of these regulations." *Id*.

In May 2002, USDA issued a "Policy Statement on National Organic Program Scope" indicating that because cosmetics and body care products may "contain agricultural products the producers and handlers of such products, classes of products and production systems are eligible to seek certification under the NOP." Docket No. 26, Ex. H. At the same time, it clarified that NOP labeling standards were not mandatory for personal care and cosmetic products, but that manufacturers of such products voluntarily could seek USDA certification and only then would be subject to complying with the NOP standards for organic labeling. *Id*.

In April 2004, USDA changed its position, declaring that producers of personal care and cosmetic products could not seek even voluntary participation in the NOP. In a Guidance Statement, the USDA stated that the "OFPA does not extend" to products over which "USDA has no regulatory authority," including such products as "personal care products." *Id*., Ex. I.

In August 2005, the USDA issued a memorandum changing its position once again. The August 2005 memorandum stated,

> There are agricultural products, including personal care products, that, by virtue of their organic agricultural product content, may meet the NOP standards and be labeled as "100 percent organic," "organic" or "made with organic" pursuant to the NOP regulations. Businesses that manufacture and distribute such products may be certified under the NOP, and such products may be labeled as "100 percent organic," "organic" or "made with organic" so long as they meet NOP requirements. Additionally, products that may be labeled "100 percent organic" or "organic" may also carry the USDA organic seal. If additional rulemaking is required for such products to address additional labeling issues or the use of synthetics in such products, the NOP will pursue such rulemaking as expeditiously as possible.

Id., Ex. A.

In April 2008, the USDA issued another guidance statement on the application of NOP standards to personal care products. *Id.*, Ex. B. This Guidance Statement confirmed again that producers and handlers of personal care products may seek USDA certification:

> [I]f a cosmetic body care product or personal care product contains or is made up of agricultural ingredients, and can meet the USDA/NOP organic production, handling, processing and labeling standards, it may be eligible to be certified under the NOP regulations . . . Any cosmetic, body care product or personal care product that does not meet the production, handling, processing, labeling and certification standards described above, may not state, imply or convey in any way that the product is USDA -certified organic or meets the USDA organic standards.

Id. At the same time, the USDA again made clear that the NOP regulatory regime does not govern the labeling of personal care products unless the labeling itself implies certification under the specific NOP standards:

> USDA has no authority over the production and labeling of cosmetics, body care products and personal care products that are not made up of agricultural ingredients or do not make any claims to meeting USDA organic standards. Cosmetics, body care products, and personal care products may be certified to the other, private standards and may be marketed to those private standards in the United States. These standards might include foreign organic standards, eco–labels, Earth friendly, etc. USDA's NOP does not regulate these labels at this time.

Id.

In March 2009, the NOSB adopted a discussion draft recommendation urging the USDA to amend its existing regulations to (1) "assur[e] consumers that the federal government is policing [organic personal care product] claims"; and (2) "allow[] for the development of a complete federal organic cosmetic program." *Id.*, Ex. K. These recommendations were to be considered for final adoption at the NOSB's November 2009 meeting.

In July 2009, the NOP issued draft guidance on the certification and labeling of soap products made from organic agricultural ingredients. *Id.*, Ex. C. The draft guidance stated, *inter alia*, that "[t]he NOP regulations describe the inputs and processing which take place in the formulation and manufacturing of a finished product; they do not prescribe the nature of the finished product itself. This allows agricultural products and allowed synthetics to be used to create a wide variety of products which may be eligible for certification, regardless of end use." *Id.* at 2.

On December 10, 2009, the NOSB formally recommended to the Secretary of Agriculture that the existing rules be amended to provide that NOP standards for labeling a product as "organic" or "made with organic [ingredient]" apply to personal care products. Docket No. 208, Ex. A.

On April 23, 2010, the NOP issued a Memorandum to the Chair of the NOSB. Docket No. 117, Ex. A. The memorandum stated that the NOP will: (1) communicate with the Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) regarding the use of the term "organic" in personal care products in order to achieve a "comprehensive approach" across agencies; (2) obtain information regarding organic labeling of personal care products in the marketplace; and (3) "consider the recommendations of the NOSB on rulemaking and take them under advisement for future incorporation." *Id.*

II. Procedural background

Plaintiff originally filed this lawsuit in state court. The first amended complaint alleged a single claim under California Business & Professions Code Section 17200. *See* Notice of Removal, Ex. B. The first amended complaint alleged that plaintiff labels and markets its products as USDA certified "organic" or "Made with Organic [ingredients]" in compliance with NOP standards. First Amended Compl. ("FAC") ¶¶ 71-78, Docket No. 1, Ex. B. Plaintiff claimed that defendants violated consumer expectations by using the word "organic" to describe their products, and specifically that the federal "[NOP] criteria [under which a personal care product may be voluntarily labeled 'organic'] reflects basic organic consumer expectations and criteria." *Id.* ¶ 53. The state court dismissed the Section 17200 claim for lack of standing. *Id.*, Ex. E. Plaintiff filed a second amended complaint alleging a claim for false advertising under Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), and defendants removed to federal court based on federal question jurisdiction. *Id.*, Ex. F.

This case was initially assigned to Judge Fogel. In an order filed December 14, 2009, Judge Fogel dismissed the Lanham Act claim based on plaintiff's failure to exhaust administrative remedies within the USDA and the primary jurisdiction of the USDA in interpreting and applying its own standards. *See* Docket No. 76 at 10-14. Judge Fogel granted plaintiff leave to amend the complaint, holding that removing reliance on NOP organic standards could possibly state a "'valid (if hard to prove) complaint' in which the Lanham Act claim could survive." *Id.* at 14.

On January 14, 2010, plaintiff filed a Third Amended Complaint ("TAC"), alleging that defendants had deliberately and willfully engaged in "false, misleading, deceptive, and confusing labeling, promoting, and advertising" and that consumer expectations could be established through

survey results. TAC ¶¶ 34, 118. The TAC eliminated reliance on the NOP definition of "organic." For example, the TAC alleges,

> Survey research of consumers and other evidence of consumer beliefs demonstrate that a substantial segment of consumers of organic skin, body and hair care products understands, expects and believes that such a product labeled, advertised and promoted as "Organic," "Organics," "100% Organic Active Ingredients" "Pure Organic Technology" or "Made with Organic Ingredients" do not contain any petrochemicals or petrochemical compounds in ingredients whatsoever, and are thus entirely free of petrochemical contaminants. Survey research of consumers and other evidence of consumer beliefs demonstrate that a substantial segment of consumers of organic skin, body and hair care products understands, expects and believes that a product labeled, advertise, or promoted as "Organic," "Organics," "100% Organic Active Ingredients" "Pure Organic Technology" or "Made with Organic Ingredients" does not contain synthetic compounds including preservatives.

Id. ¶ 34. The TAC alleges that because defendants' products do not meet the alleged consumer expectations, "the labeling and advertising [of] such products as 'Organic' is literally false by necessary implication and/or has misled, confused and/or deceived the consuming public" and none of the products are truly "organic." *Id*. ¶¶ 67-70. The TAC alleges that defendants have engaged in false advertising under the Lanham Act, and seeks damages and injunctive relief enjoining defendants from selling products that use the word "organic" in any way with regard to "any product which contains any cleansing or moisturizing ingredient made in any part from any petrochemical or petrochemical compound, and/or which contains any cleansing or moisturizing ingredient not made exclusively from organic rather than conventional agricultural material." *Id*., Prayer for Relief ¶ 1.

The same day that plaintiff filed the TAC, plaintiff filed an administrative complaint with the USDA, in which plaintiff requested that the USDA take action, including the imposition of money penalties, against defendants for their alleged failure to comply with NOP regulations in the labeling of their personal care products. *See* Docket No. 95, Ex. A.

Defendants moved to dismiss the TAC. Rather than dismissing, Judge Fogel stayed the case pending developments in the USDA proceeding. In an order filed on May 24, 2010, Judge Fogel stated that "where a pending administrative proceeding might render the relief sought in district court unnecessary, it is proper for the district court to stay the case before it pending the outcome of the administrative proceeding." Docket No. 118 at 11 (quoting *Shipley v. United States*, 608 F.2d 770, 775 (9th Cir. 1979)). Judge Fogel also noted that although the TAC does not explicitly invoke the NOP regulations, "the TAC necessarily would require the Court to interpret and apply the NOP regulatory

framework when determining questions such as what 'organically produced,' 'nonagricultural,' or 'synthetic' mean. . . . Because the USDA's enforcement of NOP standards governing personal care products has been recommended formally by the [NOSB] and currently is under the NOP's review, and because Plaintiff has an active administrative action pending before the USDA, it would be inappropriate for this Court to adjudicate Plaintiff's Lanham Act claim and impose a potentially conflicting set of standards." *Id.* Judge Fogel decided to exercise his discretion to stay the case rather than dismiss because "without knowing how the USDA will proceed regarding the NOSB's recommendation and Plaintiff's administrative complaint, the Court cannot presume that there will be nothing left for it to decide." *Id.* at 12.

In a letter dated February 2, 2011, Judge Fogel wrote to Miles McEvoy, Deputy Administrator of the Agricultural Service and manager of the NOP, inquiring whether the "USDA now has additional information relevant to this case that the Court does not." Docket No. 137 at 1-2. In his letter, Judge Fogel noted that the record in this case contained plaintiff's administrative complaint that was pending before the USDA, as well as NOP materials indicating the NOP's intent to engage in rulemaking regarding application of the NOP standards to personal care products. In a May 5, 2011 letter, Mr. McEvoy responded that "after considerable research, we do not have any additional information relevant to this case." Docket No. 141 at 1.

On September 22, 2011, Judge Fogel extended the stay, stating, "[g]iven that the Court twice has found that this case is within the USDA's primary jurisdiction and that the agency seems to making progress, albeit slowly, towards resolving the relevant issues, it is premature to lift the stay at this time." Docket No. 174 at 11.

This case was reassigned to this Court on September 28, 2011. On April 6, 2012, defendant Hain filed a motion to dismiss the complaint, and all of the other defendants have joined in Hain's motion. Defendant Ecocert has moved to dismiss plaintiff's Lanham Act claim on the additional ground that Ecocert is not in competition with plaintiff. Finally, plaintiff seeks leave to amend its complaint as against Ecocert, proposing to drop its Lanham Act claim against Ecocert and alleging a new state claim for false advertising and unfair competition under Section 17200.

LEGAL STANDARD

Dismissal under Fed. R. Civ. P. 12(b)(6) "is appropriate only where the complaint lacks a cognizable legal theory or sufficient facts to support a cognizable legal theory." *Mendiondo v. Centinela Hosp. Medical Center*, 521 F.3d 1097, 1104 (9th Cir. 2008). For purposes of a motion to dismiss, the plaintiff's allegations are taken as true, and the court must construe the complaint in the light most favorable to the plaintiff. *Jenkins v. McKeithen*, 395 U.S. 411, 421 (1969). At the same time, "[w]hile a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (internal citations omitted). Thus, a court need not accept as true conclusory allegations, unreasonable inferences, legal characterizations, or unwarranted deductions of fact contained in the complaint. *Clegg v. Cult Awareness Network*, 18 F.3d 752, 754-55 (9th Cir. 1994). "[W]here the well pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged-but it has not 'show[n]'- 'that the pleader is entitled to relief.'" *Ashcroft v. Iqbal*, 129 S. Ct. 1949, 1590 (2009) (quoting Fed. R. Civ. P. 8(a)(2)).

Leave to amend must be granted unless it is clear that the complaint's deficiencies cannot be cured by amendment. *Lucas v. Department of Corrections*, 66 F.3d 245, 248 (9th Cir. 1995). When amendment would be futile, however, dismissal may be ordered with prejudice. *Dumas v. Kipp*, 90 F.3d 386, 393 (9th Cir. 1996).

DISCUSSION

I. Hain's motion to dismiss

Hain moves to dismiss the TAC pursuant to the primary jurisdiction doctrine. Hain contends that the development and enforcement of production, processing and labeling standards for personal care products remains within the USDA's primary jurisdiction, and that resolution of plaintiff's Lanham Act claim would impermissibly require the Court to interpret and apply those standards.

In the September 22, 2011 order, Judge Fogel set forth the legal framework regarding the primary jurisdiction doctrine:

> The primary jurisdiction doctrine allows the Court, "under appropriate circumstances, [to] determine that the initial decisionmaking responsibility should be performed by the relevant agency rather than the courts." *Syntek Semiconductor Co., Ltd v. Microchip Technology, Inc.*, 307 F.3d 775, 780 (9th Cir. 2002). The application of the doctrine does not imply that the court lacks subject-matter jurisdiction, but rather that the case "requires resolution of an issue of first impression, or of a particularly complicated issue that Congress has committed to a regulatory agency." *Brown v. MCI WorldCom Network Servs., Inc.*, 277 F.3d 1166, 1172 (9th Cir. 2002). Although it is a discretionary question, courts applying the doctrine traditionally have [considered] "(1) the need to resolve an issue that (2) has been placed by Congress within the jurisdiction of an administrative body having regulatory authority (3) pursuant to a statute that subjects an industry or activity to a comprehensive regulatory authority that (4) requires expertise or uniformity in administration." *Syntek*, 307 F.3d at 781. Where primary jurisdiction lies with an agency, the court may stay the case pending administrative action or dismiss it without prejudice. *Davel Commc'n, Inc. v. Qwest Corp.*, 460 F.3d 1075, 1091 (9th Cir. 2006).

Docket No. 174 at 8.

The Court agrees with defendants that plaintiff's Lanham Act claim is barred because the allegations of the TAC would necessarily require the Court to interpret and apply federal standards regarding what constitutes an "organic" personal care product or ingredient. In reaching this decision, the Court is guided by a recent Ninth Circuit decision issued after Judge Fogel's September 2011 order, *Pom Wonderful LLC v. Coca-Cola Co.*, 679 F.3d 1170 (9th Cir. 2012), and the cases cited therein. *Pom* sets forth the framework for evaluating whether a Lanham Act claim is barred by an agency's primary jurisdiction, and underscores the importance of deferring to a federal agency's primary jurisdiction where, in order to determine the falsity or misleading nature of a defendant's representations about its products, the court would be required to interpret and apply federal standards governing those products.

In *Pom*, the plaintiff juice manufacturer alleged a Lanham Act false advertising claim against another juice manufacturer. The plaintiff alleged that defendant's juice product, which was named and labeled as "Pomegranate Blueberry," violated consumer expectations because it consisted primarily of cheaper juices and contained only 0.3% pomegranate juice and 0.2% blueberry juice. *Id*. at 1173. The district court ruled that the plaintiff's Lanham Act challenge to the defendant's name and labeling was barred because the suit "'may be construed as impermissibly challenging' Food and Drug Administration (FDA) regulations permitting the name and labeling that Coca-Cola uses and because Pom's claim could improperly require the court to interpret and apply FDA regulations on juice beverage labeling." *Id*. at 1174 (quoting district court opinion).

The Ninth Circuit affirmed this ruling. The Ninth Circuit noted that the Lanham Act "broadly prohibits false advertising," while the Federal Food, Drug, and Cosmetic Act "comprehensively regulates food and beverage labeling," and that "[t]hough a private plaintiff may sue under the Lanham Act's false advertising provision, the FDCA may be enforced only by the FDA or the Department of Justice." *Id*. at 1175. The *Pom* court then stated,

> As sometimes happens with two broad federal statutes, the Lanham Act and the FDCA can conflict with each other. When faced with a potential conflict, "[c]ourts try to give as much effect to both statutes as possible." *Scherina-Plough Healthcare Prods., Inc. v. Schwarz Pharma, Inc.*, 586 F.3d 500, 508 (7th Cir. 2009). In that effort, courts have focused on Congress's decision to entrust to the FDA the task of interpreting and enforcing the FDCA.
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> In light of that focus, courts have agreed that the FDCA limits claims under the Lanham Act. A plaintiff may not, for example, sue under the Lanham Act to enforce the FDCA or its regulations because allowing such a suit would undermine Congress's decision to limit enforcement of the FDCA to the federal government. *See, e.g., Mylan Labs., Inc. v. Maktari*, 7 F.3d 1130, 1149 (4th Cir. 1993). Nor may a plaintiff maintain a Lanham Act claim that would require a court originally to interpret ambiguous FDA regulations, because rendering such an interpretation would usurp the FDA's interpretive authority. *See, e.g., Sandoz Pharms. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 231-32 (3d Cir. 1990) (claim that drug label falsely described ingredient as "inactive" was barred because FDA had not decided whether ingredient was active or inactive.).
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> Where the FDA has not concluded that particular conduct violates the FDCA, we have even held that a Lanham Act claim may not be pursued if the claim would require litigating whether that conduct violates the FDCA. *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919, 924 (9th Cir. 2010). . . .

Id. at 1175-76. The Ninth Circuit concluded that the plaintiff's name and labeling claim was barred because the FDA had regulated extensively regarding the naming and labeling of drinks, and "as best we can tell, FDA regulations authorize the name Coca-Cola has chosen. . . . Thus, Pom's challenge to the name . . . would create a conflict with FDA regulations and would require us to undermine the FDA's apparent determination that so naming the product is not misleading." *Id*. at 1176-77.

Here, as in *Pom*, there is no private right of action to enforce the OFPA or the NOP regulations. Plaintiff argues that this Court and the USDA both have jurisdiction over the issues presented by its false advertising Lanham Act claim.[2] Plaintiff asserts the USDA has failed to exercise jurisdiction over

[2] Plaintiff asserts that Judge Fogel previously held that the Court has jurisdiction over plaintiff's Lanham Act claim. *See* Opp'n at 2:1-6. The Court disagrees with plaintiff's interpretation of Judge Fogel's orders. Judge Fogel's May 2010 order held that the TAC "necessarily would require the Court to interpret and apply the NOP regulatory framework when determining questions such as what 'organically produced,' 'nonagricultural,' or 'synthetic' mean" and that "it would be inappropriate for this Court to adjudicate Plaintiff's Lanham Act claim and impose a potentially conflicting set of

the labeling of personal care products, and thus that there is no conflict with the USDA's jurisdiction. Further, plaintiff argues that "there are no NOP regulations to interpret or apply because no NOP regulations exist that are applicable to the labeling of personal care products." Opp'n at 11:22-23. Plaintiff asserts that it can establish the falsity or misleading nature of defendants' labeling of their products as "organic" "based on consumer survey research without reference to any agency regulations or rules, including NOP." *Id*. at 12:22-23.

The Court is unpersuaded by plaintiff's arguments. The fact that the USDA has not acted quickly enough, in plaintiff's view, to develop and promulgate regulations regarding the labeling of personal care products does not mean that the Court may adjudicate plaintiff's Lanham Act claim without impermissibly intruding on the USDA's jurisdiction. Although there are no NOP regulations specific to personal care products, since 2005 the NOP has stated that personal care products may use any of the organic labeling claims (based on percentage of organic content) authorized by the federal organic rules "so long as they meet NOP requirements." Docket No. 26, Ex. A at 1 (August 23, 2005 NOP Guidance). Moreover, plaintiff's administrative complaint is pending before the USDA, the NOSB has recommended rulemaking regarding personal care products, *see* Docket No. 208, Ex. A (NOSB Recommendation), and the USDA has taken pre-rulemaking steps to assess the scope of what it might need to do. *See* Docket No. 117, Ex. A (NOP Memorandum to NOP Chair).

The Court finds instructive *Sandoz Pharmaceuticals*, which was cited with approval in *Pom*. In *Sandoz Pharmaceuticals*, a drug company brought a Lanham Act false advertising claim challenging a competitor's labeling of an ingredient as "inactive." The Third Circuit held that the Lanham Act claim was barred because "[t]he FDA has not found conclusively that demulcents must be labeled as active or inactive ingredients within the meaning [of a regulation]. . . We decline to find and do not believe that the district court had to find, either 'as a matter of common sense' or 'normal English,' that which the FDA, with all of its scientific expertise, has yet to determine. Because 'agency decisions are frequently of a discretionary nature or frequently require expertise, the agency should be given the first chance to exercise that discretion or to apply that expertise.'" *Sandoz Pharms.*, 902 F.2d at 230-31 (quoting

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standards." Docket No. 118 at 11:1-3, 9-11. Judge Fogel exercised his discretion to stay the case rather than dismiss out of an abundance of caution because the Court could not "presume that there will be nothing left to decide" following the USDA's resolution of the administrative complaint. Judge Fogel did not hold that the Court had jurisdiction to adjudicate plaintiff's Lanham Act claim.

McKart v. United States, 395 U.S. 185, 194 (1969); *see also Schering-Plough*, 586 F.3d at 508-09, 510 (holding that "Schering jumped the gun by suing before the FDA addressed the misbranding issue" because "[t]he FDA should be given the chance to opine on the proper labeling before a Lanham Act suit is filed, since it has more experience with consumers' understanding of drug labels than judges do.") (internal citations omitted); *Summit Tech., Inc. v. High-Line Med. Instruments, Co.*, 933 F. Supp. 918, 934 (C.D. Cal. 1996) (dismissing Lanham Act claim because "in order for this Court to test the truth of Defendant's apparent claim that it can legally import the Summit lasers, the Court would be required to perform an 'original interpretation' of the FDA regulations governing this area").

Plaintiff also argues that the Court would not be required to apply the federal organic rules because defendants market products as "organic" that no reasonable consumer would believe are "organic," and that plaintiff can establish this consumer expectation through consumer surveys. However, the Court would be required to evaluate how the alleged consumer expectations compare and/or conflict with federal organic standards. For example, plaintiff alleges that consumers expect that organic products have no "synthetic" ingredients or "petrochemical compounds." TAC ¶¶ 34-44. However, federal organic standards permit the use of synthetic ingredients in "organic" products. *See* 7 U.S.C. § 6510(a)(1); 7 C.F.R. § 205.301(b). The USDA has also acknowledged that "petrochemicals," like other synthetics, are eligible for use in organic products if the material appears on the National List. Docket No. 85, Ex. D (Q & A regarding petrochemicals). Similarly, plaintiff claims that consumers expect that personal care products containing "cleansing and moisturizing agents" are comprised solely of organic agricultural ingredients, *see* TAC ¶ 35, and yet the OFPA and the NOP permit the inclusion of some percentage of non-organic ingredients. *See* 7 U.S.C. § 6510(a)(4) (allowing up to 5 percent non-organic content in an "organic" product); 7 C.F.R. § 205.301(b)(same); 7 C.F.R. § 201.301(c) (products labeled "made with organic ingredients" may contain up to 30 percent non-organic agricultural content); 76 Fed. Reg. 2328, 2329 (Jan. 13, 2011) ("[t]he remaining 30 percent may include [a]gricultural ingredients which are conventionally produced."); *see also* Docket No. 208, Ex. B (NOSB's September 9, 2009 Recommendation on Classification of Materials, addressing how the NOSB determines whether a substance is "synthetic" or not); Docket No. 208, Ex. C (November 15, 2011 "Request for Clarification of 'Other Ingredients' in Organic Processed Products"; NOP document directing NOSB to consider the "other ingredients" that may be included in substances appearing on the

National List). Plaintiff's challenge to defendants' labeling would inevitably require the Court to interpret and apply federal organic standards, potentially create a conflict with those standards, and would intrude upon and undermine the USDA's authority to determine how organic products should be produced, handled, processed and labeled. This Court lacks the USDA's expertise in deciding what products and ingredients may be labeled as "organic," and "[i]n the circumstances here, 'the appropriate forum for [plaintiff's] complaint is the [USDA].'" *Pom*, 679 F.3d at 1178 (quoting *PhotoMedex*, 601 F.3d at 929).

"Normally, if the court concludes that the dispute which forms the basis of the action is within the agency's primary jurisdiction, the case should be dismissed without prejudice so that the parties may pursue their administrative remedies." *Syntek*, 307 F.3d at 783. "The factor most often considered in determining whether a party will be disadvantaged by dismissal is whether there is a risk that the statute of limitations may run on the claims pending agency resolution of threshold issues." *Davel Communications, Inc. v. Qwest Corp.*, 460 F.3d 1075, 1091 (9th Cir. 2006). Although the Lanham Act contains no explicit statute of limitations, *see Jarrow Formulas, Inc. v. Nutrition Now, Inc.*, 304 F.3d 829, 836 (9th Cir. 2002), a three year laches defense may bar plaintiff's claims. *See id.* (holding that a laches defense to a Lanham Act claim is available after three years). The Court believes that a laches defense it is unlikely to be argued or found meritorious in light of plaintiff's administrative complaint filed with the USDA, plaintiff's vigorous opposition to the dismissal of this case, and the emerging regulations in this area.[3] Accordingly, the Court GRANTS defendant's motion and DISMISSES this case without prejudice.

II. Ecocert

Defendant Ecocert moves to dismiss plaintiff's Lanham Act claim on the ground that it fails to allege a requisite element of false advertising, specifically that "the plaintiff has been or is likely to be injured as a result of the false statement, either by direct diversion of sales from itself to the defendant, or by a lessening of goodwill associated with plaintiff's product." *Newcal Industries, Inc., v. Ikon Office*

[3] At the hearing on defendant's motion, counsel for Hain Celestial stated that his client is not contemplating asserting a laches defense if the Court dismissed this case and plaintiff pursued its claims against Hain after the resolution of plaintiff's administrative complaint.

Solution, 513 F.3d 1038, 1052 (9th Cir. 2008) (quoting *Jarrow Formulas, Inc. v. Nutrition Now, Inc.*, 304 F.3d 829, 835 n.4 (9th Cir. 2002)). As Ecocert is a certifying agency and does not produce consumer products, it argues that plaintiff has failed to adequately allege competition. In response, plaintiff seeks to amend the complaint by deleting the Lanham Act claim and alleging a Section 17200 claim against Ecocert.

The Court GRANTS Ecocert's motion to dismiss plaintiff's Lanham Act claim and DENIES plaintiff's motion to amend. As the Court has dismissed the Lanham Act claim against all defendants, the Court declines supplemental jurisdiction over the proposed state law claim. *See* 28 U.S.C. § 1367(c)(3).

CONCLUSION

For the foregoing reasons, the Court GRANTS defendants' motions to dismiss and DISMISSES the complaint without prejudice. The Court DENIES plaintiff's motion to amend the complaint. This order resolves Docket Nos. 205, 207, 209, 212, 213 & 217.

IT IS SO ORDERED.

Dated: August 8, 2012

SUSAN ILLSTON
United States District Judge