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d/b/a ZOLA ACAI

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

MARY SWEARINGEN and ROBERT FIGY, individually and on behalf of all others similarly situated,

Plaintiffs,

v.

AMAZON PRESERVATION PARTNERS, INC. d/b/a ZOLA ACAI,

Defendant.

Case No. CV13-4402-WHO

NOTICE OF MOTION AND MOTION; MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF DEFENDANT AMAZON PRESERVATION PARTNERS, INC. D/B/A ZOLA ACAI'S MOTION TO DISMISS OR STAY FIRST AMENDED COMPLAINT

Hearing Date:	August 13, 2014
Time:	2:00 p.m.
Judge:	Hon. William H. Orrick
Action Filed:	September 23, 2013

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NOTICE OF MOTION AND MOTION

TO PLAINTIFFS AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE THAT on August 13, 2014 at 2:00 p.m. or as soon thereafter as the matter may be heard, in the United States District Court, Northern District of California, San Francisco Division, located at 450 Golden Gate Avenue, San Francisco, CA 94102, before the Honorable William H. Orrick, defendant Amazon Preservation Partners, Inc. d/b/a Zola Acai ("Zola") will, and hereby does move, to dismiss or stay the First Amended Complaint of Plaintiffs Mary Swearingen and Robert Figy pursuant to Fed. R. Civ. P. 12(b)(6) for failure to state a claim upon which relief can be granted.

This motion is based on this Notice of Motion and Motion, the accompanying Memorandum of Points and Authorities, Request for Judicial Notice, and supporting documents, and on such other written and oral argument as may be presented to the Court.

Dated: May 27, 2014

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CLAUDIA M. VETESI
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By: */s/ William L. Stern*
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D/B/A ZOLA ACAI

STATEMENT OF THE ISSUES TO BE DECIDED

This motion raises the following issues:

1. **Primary Jurisdiction.** Should the Court dismiss or stay the case under the doctrine of primary jurisdiction in light of FDA's March 5, 2014 decision to reopen comments on its non-final *draft* guidance discussing the claim at issue?

2. **Implied Warranty.** Should the Court dismiss Plaintiffs' cause of action for breach of implied warranty of merchantability where Plaintiffs have failed to allege that the product is unfit for its ordinary purpose?

MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION AND SUMMARY OF ARGUMENT

Plaintiffs' entire case is based on an incorrect assumption: that the term Evaporated Cane Juice (ECJ) is "specifically banned" under California and federal law. Judges Gonzalez Rogers, Illston, Henderson, Davila, Armstrong, Seeborg, and Chen all disagree. On March 5, 2014, FDA issued a Notice in the Federal Register reopening the public comment period on its 2009 draft guidance and confirmed that it has "***not*** reached a final decision on the common or usual name" for the ECJ ingredient. (Request for Judicial Notice (RJN) Ex. A (emphasis added).) Despite this, Plaintiffs filed the First Amended Complaint (FAC) without mention of the March 5, 2014 Notice. Instead, they continue to assert that FDA's position on ECJ "is clear," and that FDA has not "wavered from its position" that labels listing ECJ are false and misleading.

Plaintiffs' claims should be dismissed for two reasons.

First, the primary jurisdiction doctrine bars Plaintiffs' claims. The Court should join the seven other judges in this District and dismiss or stay this case pending FDA's determination on the key issue in this litigation: whether ECJ is the common and usual name of the ingredient. To do otherwise would not only run counter to Congress's intent to establish uniform application of FDA's regulatory rules, but would also cause a direct conflict with numerous other federal courts that have considered the same issue.

Second, Plaintiffs' newly added implied warranty claims fail for additional reasons. Rather than allege facts as to how Defendant Amazon Preservation Partners d/b/a Zola Acai's (Zola) juice drinks are unfit for their ordinary use as a beverage, Plaintiffs simply repeat their allegation that the products are "illegal." This Court and others have rejected similarly deficient allegations of a breach of implied warranty.

For these reasons, the Court should dismiss Plaintiffs' FAC or, in the alternative, stay the litigation pending FDA's action on its ECJ guidance.

II. FACTUAL BACKGROUND

A. Procedural History.

In their original complaint, Plaintiffs Mary Swearingen and Robert Figy alleged that Zola's use of the term ECJ on its products' ingredient lists did not comply with FDA's labeling requirements. (Complaint (Compl.) ¶ 2.) They alleged that Zola sold them a "worthless, illegal product that could not be legally sold or possessed," and that this regulatory infraction violated California's "Sherman Law" (Compl. ¶¶ 29-38), which they hoped to redress through two state law claims: (i) the "unlawful" prong of California's unfair competition law (Cal. Bus. & Prof. Code § 17200) (UCL), and (ii) the Consumer Legal Remedies Act (Cal. Civ. Code § 1750 *et seq.*) (CLRA).

Zola moved to dismiss Plaintiffs' Complaint on the grounds that Plaintiffs lacked standing, their claims were barred by the doctrine of primary jurisdiction and expressly preempted, and for failure to satisfy Rule 9(b). (Dkt. No. 14). The Court granted Zola's motion to dismiss. (Dkt No. 33.) It agreed that Plaintiffs lacked standing for failure to allege reliance on the challenged label statements, but declined to reach Zola's other arguments, including primary jurisdiction. The Court acknowledged, however, that Zola filed a notice of supplemental authority indicating that FDA had reopened the comment period for its 2009 draft ECJ guidance and expressed concern as to "when or if the FDA will conclusively resolve this issue." (*Id.* at 6 n.3.) Plaintiffs then filed a First Amended Complaint. (Dkt. No. 35.)

B. The Gravamen of the FAC.

Plaintiffs seek certification of a nationwide class of buyers of four Zola products. (FAC ¶ 127.) The crux of their grievance has not changed: Zola's use of the term ECJ—they claim—violates FDA regulations. (*Id.* ¶ 9.) But Plaintiffs now allege that, in addition to being unlawful, Zola's use of ECJ on its labels "deceived [them] into purchasing the product" and "misled [them] to believe that the product did not contain added sugars." (*Id.* ¶ 10). In addition to violations of UCL's unlawful prong and the CLRA, Plaintiffs contend that Zola's actions also violate: (i) the "unfair" and "fraudulent" prongs of the UCL; (ii) California's False Advertising Law (Cal. Bus. & Prof. Code § 17500 *et. seq.*) (FAL); and (iii) the implied warranty of merchantability. They

seek restitution, damages, punitive damages, injunctive relief, attorneys' fees, costs, and interests. (*Id.* at 52:17-53:4).

C. Recent FDA Action

On March 5, 2014, FDA published a Notice in the Federal Register that reopened the comment period on its 2009 draft guidance, and specifically requested comments, data, and information on ECJ. The Notice stated, in part:

> We have not reached a final decision on the common or usual name for this ingredient and are reopening the comment period to request further comments, data, and information about the basic nature and characterizing properties of the ingredient sometimes declared as "evaporated cane juice," how this ingredient is produced, and how it compared with other sweeteners.

(RJN Ex. A at 12507.) The 60-day comment period ended May 5, 2014. Among the questions FDA posed in the Notice are: "How is 'evaporated cane juice' manufactured? Specifically, how is the method of manufacture different from that of other sweeteners made from sugar cane (such as cane sugar, cane syrup, etc.)?" and "Does the name 'evaporated cane juice' adequately convey the basic nature of the food and its characterizing properties or ingredients, consistent with the principles in 102.5(a) ("common and usual name" of a food)?"

The Notice further states that "[a]fter reviewing the comments received, [FDA] intends to revise the draft guidance, if appropriate, and issue it in final form, in accordance with FDA's good guidance practice regulations in 21 C.F.R. 10.115." (*Id.*)

III. LEGAL STANDARD

A court must accept all factual allegations pleaded in the complaint as true, *Cahill v. Liberty Mutual Insurance Co.*, 80 F.3d 336, 337-38 (9th Cir. 1996), but it need not accept unreasonable inferences or legal conclusions cast in the form of factual allegations. *See Ashcroft v. Iqbal*, 556 U.S. 662, 681 (2009) ("[B]are assertions…amount[ing] to nothing more than a 'formulaic recitation of the elements' of a constitutional discrimination claim" are not entitled to an assumption of truth) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)).

Because Plaintiffs allege that Zola engaged in a scheme of false advertising, using "the term ECJ to make its products appear healthier than a product that contains 'sugar' as an ingredient" (Compl. ¶ 14), the entire Complaint must be pled with particularity. *See Kearns v. Ford Motor Co.*, 567 F.3d 1120, 1126-27 (9th Cir. 2009); *see also Brazil v. Dole Food Co.*, 935 F. Supp. 2d 947, 963-64 (N.D. Cal. 2013).

IV. ARGUMENT

A. The Primary Jurisdiction Doctrine Bars Plaintiffs' Claims.

1. The Four Elements of Primary Jurisdiction.

The primary jurisdiction doctrine applies where a plaintiff's claims implicate a federal agency's expertise for a regulated product. *United States v. W. Pac. R.R. Co.*, 352 U.S. 59, 63-64 (1956) (primary jurisdiction doctrine applies "whenever enforcement of [a] claim requires the resolution of issues which, under a regulatory scheme, have been placed within the special competence of an administrative body"). The doctrine is based on the need for agency expertise and a uniform interpretation of a statute or regulation. *See Syntek Semiconductor Co. v. Microchip Tech. Inc.*, 307 F.3d 775, 780-81 (9th Cir. 2002); *see also Clark v. Time Warner Cable*, 523 F.3d 1110, 1115 (9th Cir. 2008).

Courts traditionally consider four factors when deciding whether to apply the primary jurisdiction doctrine: (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. Dismissal on primary jurisdiction grounds is especially appropriate where an agency is actively considering how to regulate industries or activities under its authority. *See Clark*, 523 F.3d at 1115.

All four elements are met.

2. Element #1: There Is A Need to "Resolve" Whether the Term "ECJ" Is Consistent with FDA Regulations.

As for the first element, the Court cannot adjudicate Plaintiffs' claims *without* determining whether ECJ is the "common and usual name" of any ingredient or if use of that ingredient name

is misleading and prohibited under the FDCA. (*See* FAC ¶¶ 27, 42, 96-98; *see also Reese v. Odwalla, Inc.*, No. 13-CV-00947-YGR, 2014 WL 1244940, at *4 (N.D. Cal. Mar. 25, 2014) (Gonzalez Rogers, J.) (finding the first *Syntek* factor met in nearly identical ECJ case because the parties dispute the same issues FDA is addressing in its guidance).) As such, whether ECJ may properly be included on food labels "fit[s] squarely within Congress' delegation of authority to the FDA." *See Figy v. Amy's Kitchen, Inc.*, No. C 13-03816-SI, 2014 WL 1379915, at *2 (N.D. Cal. Apr. 9, 2014) (Illston, J.) (citing *Clark*, 523 F.3d at 1115).

The first element of primary jurisdiction is met.

3. Element #2: The Proper Declaration of Ingredients on Food Labels Is Within FDA's Core Expertise.

Whether Zola can lawfully include ECJ on its product labels is a question committed to FDA's expertise. This Court specifically noted that "food regulation is undoubtedly in the purview of, and an area of 'special competence' for, the FDA." *Morgan v. Wallaby Yogurt Co., Inc.*, No. 13-CV-00296-WHO, 2013 WL 5514563 at *4 (N.D. Cal. Oct. 4, 2013); s*ee also Reese*, 2014 WL 1244940, at *4 ("[t]he issue of proper declaration of ingredients on food labels is one as to which Congress vested the FDA with comprehensive regulatory authority:' "this determination is a matter that is not only within the expertise and authority of the agency, it is before the agency at this moment.").

Not only is food labeling generally committed to FDA's authority, but the specific issue in this case—whether ECJ is the "common or usual name" of the ingredient—entirely depends on FDA's interpretation of its own regulations. FDA requires manufacturers to list ingredients "on the label or labeling of a food . . . by [it's] common or usual name." 21 C.F.R. § 101.4(a)(1). According to the regulations, the "common or usual name of a food may be established by common usage or by establishment of a regulation . . ." 21 C.F.R. § 102.5(d).

The second element of primary jurisdiction is met.

4. Element #3: A Dismissal Or Stay Would Enhance Court Efficiency.

Deferring to FDA for resolution of the ECJ issue "'will enhance decision-making and efficiency by allowing the court to take advantage of administrative expertise.'" *See, e.g., Amy's*

Kitchen, 2014 WL 1379915, at *3 (citation omitted). FDA's decision as to what name should appear on product labels for the ingredient, and how it must appear, will inform the Court's position. And as discussed further below, FDA's determination could expressly preempt state law claims seeking to impose different requirements. (*See* Section A.5.) Given that FDA is actively considering this issue, there is no reason for the Court to rush towards a judgment in this case.

First, both FDA's 2009 draft guidance and its March 5, 2014 Notice make clear that the agency has not reached a final decision on the common or usual name for ECJ. Indeed, FDA's 2009 draft guidance specifically states: "[t]his guidance is being distributed for comment purposes only," and "*when finalized*, will represent [FDA's] current thinking" on whether ECJ is the common or usual name of the ingredient. *See* FDA, Guidance of Industry: Ingredients Declared as Evaporated Cane Juice, Draft Guidance at 1 (Oct. 2009) (emphasis added).[1] Given these explicit "words of caution," *Figy v. Lifeway Foods, Inc.*, No. 13-cv-04282-THE, 2014 WL 1779251 at *3 (N.D. Cal. May 5, 2014), FDA's 2009 draft guidance shows that the agency was *formulating* a position on ECJ labeling requirements—it had *not* reached a definitive conclusion. *Id.*

FDA's recent decision to reopen the comment period on ECJ labeling guidance further confirms that its position is in flux. In its March 5, 2014 Notice, FDA specifically stated that it has "*not* reached a final decision on the common or usual name for this ingredient." (RJN Ex. A at 12507 (emphasis added).) The Notice also clarifies that the 2009 draft guidance represented the agency's "preliminary thinking" on ECJ labels, and that after reviewing the comments, data, and other information on ECJ, FDA "intend[s] to revise the draft guidance, if appropriate, and issue it in final form." (*Id.* at 12508.) FDA received 81 comments during the 60-day comment

[1] *Available at* http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/labelingnutrition/ucm181491.htm (last visted May 27, 2014).

period ending May 5, 2014.[2] Accordingly, the Court should defer moving forward on Plaintiffs' claims until FDA has the opportunity to fully consider these comments and other data.

Plaintiffs are likely to disagree, but have yet to address the effect of the March 5, 2014 Notice on their claims. The FAC ignores the Notice completely, focusing only on FDA's comments regarding ECJ through the 2009 draft guidance. In fact, they continue to assert that "FDA's position is clear: labels listing 'Evaporated Cane Juice' are 'false and misleading,'" and that "FDA has not wavered from its position." (FAC ¶¶ 45, 50.) As Judge Henderson held in *Lifeway Foods*, such a position is belied by FDA's explicit statements in both the 2009 draft guidance and March 5, 2014 Notice. *See* 2014 WL 1779251, at *5 ("contrary to Plaintiff's position, the FDA has not definitively announced that listing ECJ as an ingredient is misleading or improper in light of the preliminary nature of the 2009 ECJ Draft Guidance and the subsequent 2014 FDA Notice"); *accord Swearingen v. Attune Foods, Inc.*, No. 13-cv-04541-SBA 2014 WL 2094016, at *3 (N.D. Cal. May 19, 2014) (rejecting Plaintiffs' argument that FDA has consistently considered the term ECJ to be unlawful in light of FDA's Notice). Plaintiffs' silence regarding FDA's recent action is telling. In the face of FDA's active consideration of the subject of this case, Plaintiffs' case should not proceed.

Indeed, nearly every court to consider FDA's March 5, 2014 Notice has found that it requires dismissal or stay of identical ECJ claims on primary jurisdiction grounds.[3] *See e.g.*, *Swearingen v. Santa Cruz Natural Inc.*, No. C 13-04291 SI, 2014 WL 1339775 at *4 (N.D. Cal. Apr. 2, 2014) (Illston, J.) (dismissal on primary jurisdiction grounds given FDA's active

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[2] *See, e.g.*, FDA, Ingredients Declared as Evaporated Cane Juice; Draft Guidance for Industry, Docket Folder Summary (Docket ID: FDA-2009-D-0430), Regulations.Gov, http://www.regulations.gov./#!docketDetail;D=FDA-2009-D-0430 (last visited May 27, 2014).

[3] As discussed further below, this Court referred to FDA's March 5, 2014 Notice in its orders in *Morgan v. Wallaby Yogurt Co.*, No. 13-CV-00296-WHO, 2014 WL 1017879, at *3 n.2 (N.D. Cal. Mar. 13, 2014) and here. *Swearingen v. Amazon Preservation Partners, Inc.*, No. 13-CV-04402-WHO, 2014 WL 1100944, at *4 n.3 (N.D. Cal. Mar. 18, 2013). But in both cases, FDA's Notice was issued after briefing was complete. As such, the parties did not have the opportunity to brief the significance of the Notice with regard to primary jurisdiction. Moreover, the Court here dismissed Plaintiffs' claims based on standing, and did not rule on primary jurisdiction. 2014 WL 1100944, at *4 ([b]ecause the Plaintiffs have not pleaded actual reliance, their complaint fails and I need not reach Zola's other arguments.").

consideration of ECJ requirements); *Amy's Kitchen*, 2014 WL 1379915 at *4 (Illston, J.) (same); *Attune Foods, Inc.*, 2014 WL 2094016, at *3 (Armstrong, J.) (same); *Avila v. Redwood Hill Farm & Creamery, Inc.*, No. 13-CV-00335-EJD, 2014 WL 2090045, at *3 (N.D. May 19, 2014) (Davila, J.) (same); *Reese*, 2014 WL 1244940 at *5 (Gonzalez Rogers, J.) (stay in light of FDA's active consideration of ECJ requirements); *Lifeway Foods, Inc.*, 2014 WL 1779251 at *5 (same); *Swearingen v. Late July Snacks LLC*, No. 3:13-cv-04324-EMC (N.D. Cal. May 22, 2014) (Civ. Minutes) (Dkt. No. 68) (same); *Greenfield v. Yucatan Foods, L.P.*, No. 1:13-cv-21610-KMW, 2014 WL 1891140, at *4-6 (S.D. Fla. May 7, 2014) (FDA's active consideration of ECJ requirements satisfied "unofficial fifth factor"—whether FDA has shown *any* interest in the issues presented by the litigants).[4] Indeed, Judge Seeborg had initially refused to grant a stay, but changed his mind following FDA's March 5, 2014 Notice. *Swearingen v. Yucatan Foods, L.P.*, No. C 13-3544 RS, 2014 WL 2115790, at *2-3 (N.D. May 20, 2014) (Seeborg, J.) (granting motion for reconsideration and dismissing action on primary jurisdiction grounds given FDA's decision to "engage in active consideration of the issue presented by plaintiffs' claims").

And even before FDA's recent Notice, other courts in this district have dismissed or stayed misbranding cases "where determination of a plaintiff's claim would require a court to decide an issue committed to the FDA's expertise without a clear indication of how FDA would view the issue." *See, e.g., Hood v. Wholesoy & Co.*, No. 12–CV–5550–YGR, 2013 WL 3553979, at *5 (N.D. Cal. Jul. 12, 2013) (dismissing plaintiff's ECJ claim because FDA regulates ECJ requirements and its position on the issue is unclear); *Ivie v. Kraft Foods Global, Inc.*, No. C-12-02554-RMW, 2013 WL 685372, at *7 (N.D. Cal. Feb. 25, 2013) (dismissing state law claim because "the FDA is currently engaged in rulemaking procedures to *change* existing requirements").[5]

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[4] Similarly, the parties in *Bennett v. Amy's Kitchen, Inc.*, No. 60CV-13-4924 (Cir. Ct. of Pulaski Cnty. Ark. Apr. 23, 1014), stipulated to stay all proceedings in light of the 2014 FDA Notice (*available at* https://contexte.aoc.arkansas.gov/imaging/IMAGES/DMS/CK Image.Present2?DMS_ID=U5ZRMFGALCFBLQKOGDAW5KBWYX3Q4R).

[5] *See also Gordon v. Church & Dwight Co.*, No. C 09–5585 PJH, 2010 WL 1341184, at *2 (N.D. Cal. Apr. 2, 2010) (dismissing mislabeling claims where FDA was "still considering public comments and other data in connection with warnings similar to those that plaintiffs seek

(Footnote continues on next page.)

Second, whether ECJ is the "common or usual name" of the ingredient within the meaning of 21 C.F.R. § 101.4 (a)(1) raises a host of technical and policy issues that FDA, rather than courts, is best positioned to first address. *See Swearingen v. Yucatan Foods*, 2014 WL 2115790, at *2 (noting that "[t]he question of [ECJ] labeling presents a host of technical issues uniquely within the agency's expertise."). The FAC confirms this. Plaintiffs have added a lengthy discussion of why they believe ECJ is the same as "sugar," including a description from a website called "Processed Free America" of the scientific process of making ECJ. (FAC ¶ 109 n.6.) They admit that this is a complex scientific issue. But rather than submit their arguments to FDA as the agency considers these exact issues, Plaintiffs are hoping to leapfrog past FDA's rigorous technical analysis. Instead they cite blogs and health food stores' magazines to try to convince the Court that the term ECJ is improper. Such difficult questions are best left to the experts—FDA—rather than the Court.

Indeed, courts have applied primary jurisdiction in situations like this, where a plaintiff's claim falls within the specialized knowledge of an agency. *See W. Pac. R.R.. Co.*, 352 U.S. at 66-68 (applying primary jurisdiction where agency, and not the court, originally determined the regulation at issue, and resolution of the issue required the review of "voluminous and conflicting evidence . . . [and] an acquaintance with many intricate facts" known only to the Commission); *Gordon*, 2010 WL 1341184, at *2 (dismissing false advertising claims under primary jurisdiction where it "would be inappropriate for [the] court to assume the FDA's regulatory role, and to interpret scientific studies or other evidence to determine whether the labeling [of a product] should be changed to include an additional warning").

The third element of primary jurisdiction is met.

(Footnote continued from previous page.)

to have the court impose."); *Taradejna v. Gen. Mills, Inc.*, 909 F. Supp. 2d 1128, 1135 (D. Minn. 2012) (applying the doctrine because, "given that the FDA has issued its 2009 Proposed Rule on the standard of identity for yogurt, it would be imprudent for the Court, at this juncture, to substitute its judgment for that of the Agency's while revision of the standard of identity is pending").

5. Element #4: A Dismissal Or Stay Would Advance Federal Policies of Uniformity.

Finally, a dismissal or stay pending FDA's consideration of its ECJ guidance would enable uniform application of regulatory law. There are several ways in which a dismissal or stay would further uniformity.

First, there is the law. Congress intended for FDA to regulate issues of food labeling and safety in order to achieve uniformity across the states. The FDCA empowers FDA to protect the public health by ensuring that "foods are safe, wholesome, sanitary, and properly labeled." 21 U.S.C. § 393(b)(2)(A). The agency promulgates regulations implementing the statute and enforces regulations through the administrative process. 21 C.F.R. § 7.1. "The FDCA deems a food 'misbranded' if its labeling is 'false or misleading in any particular.'" 21 U.S.C. § 343(a)(1). Congress also passed the Nutrition Labeling and Education Act (NLEA), which was intended to "clarify and to strengthen [FDA's] legal authority to require nutrition labeling on foods." H.R. Rep. No. 101-538, at 7 (1990), *reprinted in* 1990 U.S.C.C.A.N. 3336, 3337. Together, these statutes ensure that uniform requirements will not devolve into a state-by-state patchwork of labeling schemes that would impede federal objectives. *See, e.g.*, *Pom Wonderful LLC v. Coca-Cola Co.*, 679 F.3d 1170, 1178 (9th Cir. 2012) (Congress "entrust[ed] matters of . . . beverage labeling to the FDA"), *cert. granted*, 130 S. Ct. 895 (Jan. 10, 2014); *Turek v. Gen. Mills, Inc.*, 662 F.3d 423, 426 (7th Cir. 2011) ("Congress would not want to allow states to impose disclosure requirements of their own on packaged food products, most of which are sold nationwide.").

Second, uniformity is particularly important here given the surge of ECJ claims within the past two years. Fifty ECJ cases have been filed in district courts across the country—27 of which were filed by Plaintiffs' counsel. (*See* RJN Ex. B.). These cases all hinge on the same technical interpretation of 21 C.F.R. § 101.4(a)(1): whether ECJ is the common and usual name of the ingredient. FDA's final guidance will provide a uniform response to these identical, nationwide claims. For this reason (among others), nearly every court to consider FDA's March 5, 2014 Notice has found that it requires dismissal or stay of identical ECJ claims on primary jurisdiction

grounds, as described above.[6] To do otherwise would not only result in a direct conflict with other federal courts, but could also require manufacturers to produce different labels for different jurisdictions—precisely what the uniform regulatory scheme under FDCA was designed to prevent. *See, e.g., Santa Cruz Natural*, 2014 WL 1339775 at *3 ("'[t]he primary jurisdiction doctrine rests ... on a concern for uniform outcomes (which may be defeated if disparate courts resolve regulatory issues inconsistently)....'").

Third, deferring to FDA will prevent this Court from issuing a decision in conflict with FDA's ultimate position, which "would usurp the FDA's interpretive authority." *Pom Wonderful*, 679 F.3d at 1176. Courts and juries may not evaluate food labeling issues the same way as FDA. *See, e.g., Meaunrit v. Pinnacle Foods Grp., LLC*, No. C 09–04555 CW, 2010 U.S. Dist. LEXIS 43858, at *19-20 (N.D. Cal. May 5, 2010) (plaintiff's false advertising claims preempted where United States Department of Agriculture had already approved the food labels because "it does not follow that a jury would evaluate Defendant's labels in the same fashion as the USDA. [ ] To allow a jury to pass judgment on Defendant's labels, notwithstanding the USDA's approval would disrupt the federal regulatory scheme.") (internal citation omitted).

The regulatory posture of this case raises the potential for the exact type of conflict that Congress intended to avoid. What if this Court found that use of the term ECJ was unlawful and misleading, and several months later FDA found that the term is consistent with FDA regulations? The Court should be particularly wary of this prospect here, where state food

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[6] Some courts (including this one) previously declined to apply the doctrine prior to the March 5, 2014 Notice on the grounds that the 2009 draft guidance alone was insufficient to demonstrate that FDA's ECJ position was unsettled. *See, e.g., Morgan*, 2013 WL 5514563 at *4 (noting that "'the FDA has issued guidance (albeit informal guidance) regarding whether ECJ is consistent with FDA requirement. Thus, *at this stage*, the Court is not persuaded that the Court will be required to resolve an issue of 'first impression' without the benefit of the FDA's opinion.'"); *Kane v. Chobani, Inc.*, No. 12-CV-02425-LHK, 2013 WL 3703981 at *17 (N.D. Cal. July 12, 2013), *vacated*, 2013 WL 5529723 (N.D. Cal. July 25, 2013) (declining to apply primary jurisdiction based on 2009 draft guidance alone). Several courts have changed their position since FDA's March 5, 2014 Notice. *See, e.g., Avila*, 2014 WL 2090045, at *3 (finding application of primary jurisdiction doctrine appropriate "[a]t this juncture" in light of FDA's Notice although"[i]n the past, this Court . . . found that the primary jurisdiction doctrine did not bar adjudication of ECJ claims."); *Swearingen v. Yucatan Foods*, 2014 WL 2115790, at *3 (granting motion for reconsideration and dismissing action on primary jurisdiction grounds "[i]n light of the FDA's recent decision").

labeling requirements not identical to federal law are expressly preempted. *See Reese*, 2014 WL 1244940, at *4 (noting that a "state requirement is preempted if it is not identical to the federal provision, meaning that the state provision differs from the federal or that the state provision 'imposes obligations **or contains provisions ... that ... are not imposed** by or contained in the applicable [federal statute or regulation].'"); *see also Avila*, 2014 WL 2090045, at *3 ("[i]f the Court proceeds with this action and issues a decision that is contrary to the FDA's formal position on ECJ, it would disrupt the uniform application of the FDA's regulatory rules.").

Fourth, deference to FDA will save time and money by avoiding duplication. Moving forward on Plaintiffs' claims will require the Court to complete much of the same assessment FDA is conducting now. For example, the parties will need to designate experts to testify about the scientific reasons for naming the ingredient ECJ. The Court should await FDA's determination and preserve the parties and the Court's resources.

The fourth element is met.

6. The Court's Concerns Regarding "When Or If" FDA Will Take Action Are Not A Proper Basis to Decline Application of Primary Jurisdiction.

FDA issued its March 5, 2014 Notice after briefing was complete on Zola's motion to dismiss Plaintiffs' original complaint. While the Court did not reach Zola's primary jurisdiction argument, it noted that Zola submitted a notice of supplemental authority attaching the Notice. *Amazon Preservation Partners*, 2014 WL 1100944, at *4 n.3 (referring to Dkt. No. 31). The Court concluded that because "[i]t remains unclear when or if the FDA will conclusively resolve this issue," this case "will proceed apace." *Id.* *See also Morgan*, 2014 WL 1017879, at *3 n.2 (same). The Court's concerns regarding "when or if" FDA will resolve the issue are not a proper basis for declining to apply primary jurisdiction.

First, FDA announced in the Notice that it intends to finalize its guidance. Given that the comment period ended May 5, 2014, FDA is poised to make a final pronouncement shortly. *See Lifeways Foods*, 2014 WL 1779251, at *4 ("the Court concludes that the FDA is likely to make a final pronouncement with respect to whether ECJ is the common or usual name for the ingredient at issue"); *accord Swearingen v. Yucatan Foods*, 2014 WL 2115790, at *2 ("FDA has signaled

that it intends to issue final guidance after the comment period closes in May 2014"). However, formulating guidance can be a time consuming task,[7] and should not be rushed at the expense of agency expertise. Moreover, if delay alone were reason enough to deny application of a stay, few cases, if any, would ever qualify for the primary jurisdiction doctrine.

Second, concerns regarding "when and if" FDA will resolve an issue are not a proper basis to decline to apply primary jurisdiction where the elements are otherwise met. The purpose of primary jurisdiction is to provide the agency with the ***opportunity*** to act on an issue within its expertise. *See All One God Faith v. Hain Celestial Grp.*, No. C 09-3517 SI, 2012 U.S. Dist. LEXIS 111553, at *31 (N.D. Cal. Aug. 8, 2012) ("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.") (quotations omitted); *Schering-Plough Healthcare Prods., Inc. v. Schwartz Pharma, Inc.*, 586 F.3d 500, 510 (7th Cir. 2009) (primary jurisdiction applied where plaintiff "jumped the gun by suing before the FDA addressed [a] misbranding issue" for drug).

Courts routinely apply the doctrine where FDA is investigating an issue, even if the agency's timeline is unknown. *See, e.g.*, *Reese*, 2014 WL 1244940, at *5; *Taradejna*, 909 F. Supp. 2d at 1135; *accord All One God Faith*, 2012 U.S. Dist. LEXIS 111553, at *29 ("[t]he fact that the USDA has not acted quickly enough [] to develop and promulgate [relevant] regulations [] does not mean that the Court may adjudicate plaintiff's [] claim without impermissibly intruding on the USDA's jurisdiction."). Moreover, courts have applied primary jurisdiction *before* FDA even initiated an investigation, or took other action on an issue. *See, e.g.*, *Cox v. Gruma Corp.*, No. 12-CV-6502 YGR, 2013 U.S. Dist. LEXIS 97207, at *5 (N.D. Cal. July 11, 2013) (applying primary jurisdiction before FDA expressed any interest in GMOs and its "natural" policy).

[7] This is especially true here given that FDA must review 81 comments along with supplemental data submitted in response to its Notice. (*See* Section A.4 7:5.)

Furthermore, application of the primary jurisdiction doctrine does not turn on FDA's final action. Even if FDA simply "confirmed its preliminary position on ECJ," it would enhance the Court's ultimate decision-making efficiency by allowing the Court to benefit from FDA's definitive guidance on the issue. *See Lifeway Foods*, 2014 WL 1779251, at *5. At least the Court could proceed knowing that it would not run afoul of Congress's intent for uniform application of regulatory laws.

Third, if the Court has concerns about the potential for delay, it can stay the litigation rather than dismiss. Several courts have done exactly that. Both Judges Gonzalez Rogers and Henderson stayed their cases and set a compliance hearing a few months out. *See Reese*, 2014 WL 1244940, at *5; *Lifeway Foods*, 2014 WL 1779251, at *5. The parties are also to file a joint statement updating the courts on the status of FDA's action and the parties' position as to whether further briefing concerning the effects of any action or inaction is necessary. *Id.* The Court can therefore avoid potential delay by staying the case and monitoring FDA action. *Accord Greenfield*, 2014 WL 1891190, at *6 ("[w]hile it seems unlikely that the Parties would be unfairly disadvantaged by a dismissal without prejudice,[8] staying this case appears to be the more prudent course.")

For these reasons, the Court should apply the doctrine of primary jurisdiction and dismiss or stay the litigation pending FDA's final announcement regarding its ECJ guidance.

B. The Court Should Dismiss Plaintiffs' Implied Warranty Claim.

Plaintiffs' newly added implied warranty cause of action also fails for independent reasons. If nothing else, this claim should be dismissed with prejudice.

First, Plaintiffs have failed to allege a breach of warranty. "A plaintiff who claims a breach of the implied warranty of merchantability must show that the product 'did not possess

[8] Indeed, several courts have dismissed ECJ cases rather than stay precisely because any potential delay will not disadvantage Plaintiffs. *Cf. Swearingen v. Yucatan Foods*, 2014 WL 2115790, at *2 (noting that, because plaintiffs primarily seek injunctive relief on behalf of a putative class for products purchased four years prior to the litigation, plaintiffs will not be particularly disadvantaged "[s]hould some amount of time elapse before the FDA issues final guidance on this issue").

even the most basic degree of fitness for ordinary use.'" *Bohac v. Gen. Mills, Inc.*, No. 12-cv-05280-WHO, 2014 U.S. Dist. LEXIS 41454, at *31 (N.D. Cal. Mar. 26, 2014) (quoting *Mocek v. Alfa Leisure, Inc.*, 114 Cal. App. 4th 402, 406 (2003)). "The Commercial Code does not 'impose a general requirement that goods precisely fulfill the expectation of the buyer. Instead, it provides for a minimum level of quality." *Id.* (quoting *Hauter v. Zogarts*, 14 Cal. 3d 104, 117-18 (1975); *see also Birdsong v. Apple, Inc.*, 590 F.3d 955, 958 (9th Cir. 2009); *Stearns v. Select Comfort Retail Corp.*, 2009 WL 1635931, at *8 (N.D. Cal. June 5, 2009) (plaintiff must allege a "fundamental defect that renders the product unfit for its ordinary purpose").

Plaintiffs fail to meet this standard. They merely conclude that a breach occurred based on the alleged "warranty that the Purchased Product is legal and can be lawfully resold." (FAC ¶ 196.) They claim the "Product was unfit for the ordinary purpose for which Plaintiffs and the Class purchased them," yet they fail to allege any facts as to how the "ordinary purpose" of a juice drink was not met. (FAC ¶ 202.) Conclusory allegations that the products were "not legal" fall far short of the pleading standard. Plaintiffs instead needed to allege that the products were not fit for *consumption*—the ordinary purpose of food and beverages.

This Court has found similar allegations insufficient. In *Bohac*, the Court dismissed implied warranty claims relating to the "100% natural" label on granola bars because the plaintiff failed to allege "that the products lack 'even the most basic degree of fitness for ordinary use' … [or] that the granola bars are not merchantable or fit for consumption; he has not, for example, alleged that the products were not edible or contaminated." 2014 U.S. Dist. LEXIS 41454, at *30-32 (quoting *Mocek*, 114 Cal. App. 4th at 406). Other courts agree. In *Viggiano v. Hansen Natural Corp.*, 944 F. Supp. 2d 877, 890 (C.D. Cal. 2013), the court dismissed the plaintiff's implied warranty claim that was based on a soda drink's labeling as a "premium" diet soda with "all natural flavors." The court concluded that plaintiff "misapprehended the nature of implied warranty claims" because he failed to allege "that the drink is not suitable for use as a diet soda,"

such as that it "was not drinkable, that it was contaminated or contained foreign objects." *Id.*[9] This case is no different.

Second, Plaintiffs' claim fails for lack of privity. "The general rule is that privity of contract is required in an action for breach of either express or implied warranty and that there is no privity between the original seller and a subsequent purchaser who is in no way a party to the original sale." *Blanco v. Baxter Healthcare Corp.*, 158 Cal. App. 4th 1039, 1058-59 (2008) (quoting *All West Elecs., Inc. v. M-B-W, Inc.*, 64 Cal. App. 4th 717, 725 (1998)). Here, Defendant sells its products directly to retailers—not consumers. As such, no privity exists.

Third, Plaintiffs improperly failed to give notice of their warranty claim, as required by the California Commercial Code Section 2607(3)(A). *See Pollard v. Saxe & Yolles Dev. Co.*, 12 Cal. 3d 374, 380 (1974) (dismissal for failure to give timely notice); *In re iPhone 4S Consumer Litig.*, No. C 12-1127 CW, 2014 WL 589388, at *8 (N.D. Cal. Feb. 14, 2014) (dismissing express warranty claim with prejudice for failure to give reasonable notice). This alone is enough to defeat the claim.

The Court should dismiss Plaintiffs' newly added claim for breach of implied warranty with prejudice, as amendment would be futile.

V. CONCLUSION

For the foregoing reasons, Zola respectfully requests that this Court dismiss Plaintiffs' implied warranty claims with prejudice and the remaining claims without prejudice. In the alternative, it requests that the Court stay Plaintiffs' claims pending FDA's final guidance on ECJ labeling requirements.

[9] *Compare Chateau des Charmes Wines Ltd. v. Sabate USA, Inc.*, No. 01-cv-4203 MMC, 2005 WL 1528703, at *1 (N.D. Cal. June 29, 2005) (alleging that "the corks damaged the smell, character and drinkability" of the wines).

Dated: May 27, 2014

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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

MARY SWEARINGEN and ROBERT FIGY, individually and on behalf of all others similarly situated,

Plaintiffs,

v.

AMAZON PRESERVATION PARTNERS, INC. d/b/a ZOLA ACAI,

Defendant.

Case No. CV13-4402-WHO

[PROPOSED] ORDER GRANTING DEFENDANT AMAZON PRESERVATION PARTNERS, INC. D/B/A ZOLA ACAI'S MOTION TO DISMISS OR STAY FIRST AMENDED COMPLAINT

Hearing Date: August 13, 2014
Time: 2:00 p.m.
Judge: Hon. William H. Orrick
Action Filed: September 23, 2013

The motion of Defendant Amazon Preservation Partners, Inc. d/b/a Zola Acai ("Zola" or "Defendant") to dismiss or stay Plaintiffs Mary Swearingen and Robert Figy's First Amended Complaint pursuant to the primary jurisdiction doctrine and Rule 12(b)(6) of the Federal Rules of Civil Procedure came on for hearing on August 13, 2014. Counsel for both parties appeared.

Based on the supporting and opposing papers, the exhibits attached to the Request for Judicial Notice (filed May 27, 2014), other related documents filed with the Court in connection with this motion (including the Declaration of Claudia M. Vetesi, filed on May 27, 2014), and the papers and records on file in this action, Defendant's Motion to Dismiss Plaintiffs' First Amended Complaint is GRANTED.

IT IS SO ORDERED.

DATED:

HONORABLE WILLIAM H. ORRICK
United States District Court Judge