UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

Case No. 0:19-cv-62342-UU

BROOK SNYDER, et al.,

Plaintiffs,

v.

GREEN ROADS OF FLORIDA LLC

Defendant.
_____/

ORDER ON MOTION TO DISMISS

This cause is before the Court on Defendant's Motion to Dismiss or, in the Alternative, to Stay (D.E. 15) (the "Motion"). The Motion is fully briefed. For the reasons stated below, the Complaint is dismissed to the extent Plaintiffs have failed to allege facts sufficient to demonstrate their standing to pursue class action claims based on products they did not purchase and for injunctive relief. Also, for reasons explained below, the action is stayed pursuant to the primary jurisdiction doctrine. In all other respects, the Motion is DENIED.

I. Background

Defendant, a Florida limited liability company that maintains its principal place of business in Deerfield Beach, Florida, is a manufacturer, distributor and seller of cannabidiol ("CBD") products including but not limited to CBD Oil, CBD Gummies, CBD capsules, CBD Terpenes, CBD Topicals, CBD Syrups, CBD Tea and CBD Coffee. D.E. 1 ¶¶ 1–2. Plaintiff Snyder, a citizen of Florida, purchased a 250mg version of Defendant's CBD Oil through Defendant's website for a total purchase price of $43.74. *Id.* ¶¶ 34, 43. Plaintiff Terry, a citizen of Ohio, purchased a "Relax Box" through Defendant's website for a total purchase price of $104.14. *Id.* ¶¶ 35, 40. The Relax Box contained CBD Gummies, CBD Tea, and CBD Oil. *Id.* ¶ 40. Each

Plaintiff claims that he relied on the product labels in making his decision to purchase, that the product labels misrepresented the amount of CBD that each product contained and that, as a result, each was over-charged for the products each purchased. *Id.* ¶¶ 12, 41–42.

The Complaint alleges federal subject matter jurisdiction pursuant to the Class Action Fairness Act of 2005, 28 U.S.C. §§ 1332(d)(2) and (6) "because the aggregate sum of the claims of the members of the putative class exceeds $5 million, exclusive of interest and costs, because Plaintiffs bring this action on behalf of a proposed class that is comprised of over one hundred members, and because at least one of the members of the proposed class is a citizen of a different state than Green Roads." *Id.* ¶ 37. It contains two claims: Count I for Unjust Enrichment by both Plaintiffs on behalf of a nationwide class of all purchasers of *all* of Defendant's products within the applicable limitations period; and Count II by Snyder on behalf of the Florida subclass of all Florida purchasers of *all* of Defendant's products for violation of the Florida Deceptive and Unfair Trade Practices Act ("FDUPTA"), FLA. STAT. §§ 501.201, *et. seq.*

The State of Florida Department of Agriculture and Conservation Services ("FDACS") regulates CBD products, including their labelling in respect to the number of milligrams of hemp extract contained in a CBD product. FLA. DEP'T OF AGRIC. AND CONSUMER SERV., DIV. OF FOOD SAFETY, Final Rule 5K-4.034 – Hemp Extract (effective Jan. 1, 2020), https://www.flrules.org/gateway/RuleNo.asp?id=5K-4.034. The Food and Drug Administration ("FDA") is actively considering the regulation of CBD products, including the "manufacturing, product quality, marketing, labeling, and sale of products containing cannabis or cannabis-derived products." *See* U.S. FOOD & DRUG ADMIN., *Scientific Data and Information About Products Containing Cannabis or Cannabis-Derived Compounds; Extension of Comment Period*, 84 Fed. Reg. 28822, 28823 (June 20, 2019).

II. Legal Standards

A. Rule 12(b)(1)

Rule 12(b)(1) of the Federal Rules of Civil Procedure allows for the dismissal of a claim when it is determined that the Court lacks subject-matter jurisdiction. Federal courts are bound by Article III of the United States Constitution to adjudicating only actual "cases" or "controversies." *Allen v. Wright*, 468 U.S. 737, 104 S. Ct. 3315, 82 L. Ed. 2d 556 (1984). Article III standing is a jurisdictional requirement that cannot be waived and, as such, may be brought up at any time in the proceeding. *See Smith v. GTE Corp*., 236 F.3d 1292, 1299 (11th Cir. 2001). "Because standing is jurisdictional, a dismissal for lack of standing has the same effect as a dismissal for lack of subject matter jurisdiction under Fed. R. Civ. P. 12(b)(1)." *Stalley v. Orlando Reg'l Healthcare Sys., Inc*., 524 F.3d 1229, 1232 (11th Cir. 2008) (citation and internal quotation marks omitted). "A dismissal for lack of subject matter jurisdiction is not a judgment on the merits and is entered without prejudice." *Id.* (citation omitted).

B. Rule 12(b)(6)

To state a claim for relief, Federal Rule of Civil Procedure 8(a)(2) requires only "a short and plain statement of the claim showing that the pleader is entitled to relief." While a court, at this stage of the litigation, must consider the allegations contained in the plaintiff's complaint as true, this rule "is inapplicable to legal conclusions." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). In practice, to survive a Rule 12(b)(6) motion to dismiss, "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Id.* (quoting *Twombly*, 550 U.S. at 570). A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. *Id.* The plausibility standard requires more than a sheer possibility that a

defendant has acted unlawfully. *Id.* When a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief. *Id.* Determining whether a complaint states a plausible claim for relief is a context-specific undertaking that requires the court to draw on its judicial experience and common sense. *Id.* at 679.

C. Motion to Stay

It is well-established that a district court has the inherent authority to stay its own proceedings. *See, e.g., Landis v. North Am. Water Works and Elec. Co.*, 299 U.S. 248, 254 (1936) ("[T]he power to stay proceedings is incidental to the power inherent in every court to control the disposition of the causes on its docket with economy of time and effort for itself . . . ."); *see also Ortega Trujillo v. Conover & Co. Commc'ns, Inc.*, 221 F.3d 1262, 1264 (11th Cir. 2000) (evaluating district court's *sua sponte* stay of case pending resolution of a related foreign matter for abuse of discretion). "Stays of proceedings can also promote judicial economy, reduce confusion and prejudice, and prevent possibly inconsistent resolutions." *Lopez v. Miami-Dade Cty.*, 145 F. Supp. 3d 1206, 1208 (S.D. Fla. 2015) (quotations omitted).

III. Analysis

A. Standing

As set forth by the United States Supreme Court in *Spokeo v. Robbins*, 136 S. Ct. 1540 (2016), Article III standing requires a plaintiff to have (1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision. To establish "injury in fact," a plaintiff must show that he or she suffered an "'invasion of a legally protected interest' that is 'concrete and particularized' and 'actual or imminent, not conjectural of hypothetical.'" *Id.* at 1548 (quoting *Lujan v. Defenders of*

Wildlife, 504 U.S. 555, 560 (1992)). For the injury to be "concrete," it must be "real" and not abstract; however, it need not be tangible. *Id.* Dismissal is appropriate under Fed. R. Civ. P. 12 (b)(1) if the plaintiff does not satisfy Article III standing requirements. *See Stalley*, 524 F.3d at 1232.

These principles are applicable in the class action context. "[It] is well-settled that prior to the certification of a class . . . the district court must determine that at least one named class representative has Article III standing to raise each class subclaim." *Prado- Steiman v. Bush*, 221 F.3d 1266, 1279 (11th Cir. 2000). "Only after the court determines the issues for which the named plaintiffs have standing should it address the question whether the named plaintiffs have representative capacity, as defined by Rule 23(a) to assert the rights of others." *Id.* at 1280 (quoting *Griffin v. Dugger*, 823 F.2d 1476, 1482 (11th Cir. 1987)). Thus, district courts have addressed class plaintiff standing early in litigation—prior to a motion for class certification having been filed. *See, e.g., Weiss v. General Motors LLC*, No. 19-cv-21442-RNS, 2019 WL 5394621, at *3 (S.D. Fla. Oct. 22, 2019).

Defendant argues pursuant to Fed. R. Civ. P. 12(b)(1) that Plaintiffs lack standing in respect of the claims pled and that therefore the Complaint should be dismissed. D.E. 15 at 4–7. The Court agrees with Defendant that: (1) Plaintiffs lack standing to sue for products they did not purchase; and (2) they have failed to allege a future injury sufficient to support a claim for injunctive relief.

i. Products Not Purchased

In *Ohio State Troopers Association, Inc. v. Point Blank Enterprises, Inc.*, 347 F. Supp. 3d 1207 (S.D. Fla. 2018), this very Court considered whether in a consumer class action a putative class plaintiff has standing to bring claims on account of products not purchased. After a thorough review of the Eleventh Circuit precedent, this Court held that an unnamed plaintiff in a consumer

class action generally lacks standing to challenge the marketing of a non-purchased product because the plaintiff has suffered no injury-in-fact. *Id.* at 1220–22. In reaching this conclusion, the undersigned considered authority from other jurisdictions allowing that a plaintiff may have standing to assert claims for unnamed class members based on products he or she did not purchase so long as the products and alleged misrepresentations are substantially similar. *Id.* However, the prevailing view in this Circuit seems to be otherwise and to be more in line with Supreme Court precedent. *See Simon v. Eastern Kentucky Welfare Rights Organization*, 426 U.S. 26, 96 S. Ct. 1917, 48 L. Ed. 2d 450 (1976) (representative class plaintiffs must show personal injury); *Wooden v. Bd. Of Regents of Univ. Sys. Of Ga.*, 247 F.3d 1262, 1288 (11th Cir. 2001) ("[J]ust as a plaintiff cannot pursue an individual claim unless he proves standing, a plaintiff cannot represent a class unless he has standing to raise the claims of the class he seeks to represent."); *Prado-Steiman*, 221 F.3d at 1278–83; *Griffin*, 823 F.2d at 1483 ("This individual injury requirement is not met by alleging that injury has been suffered by other, unidentified members of the class to which [the plaintiff] belong[s] and which [he] purport[s] to represent.") (alteration in original) (quotation marks omitted); *Dapeer v. Neutrogena Corp.*, 95 F. Supp. 3d 1366, 1373 (S.D. Fla. 2015) (holding that the plaintiff lacked "standing to bring claims on behalf of the Neutrogena products he did not purchase because he cannot conceivably allege any injuries from products he never purchased or used"); *Garcia v. Kashi Co.*, 43 F. Supp. 3d 1359, 1393–94 (S.D. Fla. 2014) ("[A] named plaintiff in a consumer class action lacks standing to challenge a non-purchased product because there is no injury-in-fact as to that product, even if he purchased a substantially similar product . . . . The Court agrees with *Toback*[*v. GNC Holdings, Inc.*, No. 13-cv-80526-JIC, 2013 U.S. Dist. LEXIS 131135, at *15 (S.D. Fla. Sept. 13, 2014)] that, in the Eleventh Circuit, a named plaintiff in a consumer class action cannot raise claims relating to those other products which he did not

purchase.") (quotation marks omitted). Therefore, without reciting again the reasons explained in *Ohio State Troopers*, 347 F. Supp. 3d at 1218–23, the undersigned finds that Plaintiffs do not have standing to assert claims based on the marketing of products that they did not purchase and that therefore the classes described in the Complaint are overbroad.

ii. Injunctive Relief

Defendant further argues that Plaintiffs have failed to allege a prospective injury which would confer standing to seek injunctive relief. D.E. 15 at 6. Plaintiffs respond by pointing to the following allegations: "[i]f [Plaintiffs] could rely upon the truthfulness of [Defendant's] labeling, [they] would continue to purchase [Defendant's] Products in the future." D.E. 19 at 8 (citing D.E. 1 ¶¶ 42,44).

When a party seeks injunctive relief, he or she must show "that the alleged injury is not too speculative for Article III purposes—that the injury is certainly impending." *Ohio State Troopers*, 347 F. Supp 3d at 1219 (quoting *Clapper v. Amnety Int'l USA*, 568 U.S. 398, 409 (2013)). "The 'injury-in-fact' demanded by Article III requires an additional showing when injunctive relief is sought. 'In addition to past injury, a plaintiff seeking injunctive relief 'must show a sufficient likelihood that [she] will be affected by the allegedly unlawful conduct in the future." *Ohio State Troopers*, 347 F. Supp. 3d at 1223, 1227 (FDUPTA injunctive relief claim barred by lack of standing) (quoting *Houston v. Marod Supermarkets, Inc*. 733 F.3d 1323, 1328 (11th Cir. 2013)); *see also Marty v. Anheuser-Busch Co., LLC*, 43 F. Supp. 3d 1333, 1351–52 (S.D. Fla. 2014) (finding that plaintiffs in a putative class action alleging that brewer of domestic beer made misrepresentations that led consumers to believe the beer was brewed in Germany lacked standing to seek injunctive relief because the complaint contained only allegations of past injury).

Plaintiffs simply have not alleged a likelihood of future injury. In fact, Plaintiffs allegations make clear that they will not purchase more of Defendant's products so long as the labelling does not meet their standards. Accordingly, Plaintiffs lack standing to assert a claim for injunctive relief.

B. Failure to State A Claim

Defendant next argues that the Complaint should be dismissed pursuant to Rule 12(b)(6) as follows: Count I (Unjust Enrichment) fails to state a claim because Plaintiffs acknowledge an express contract with Defendant and because they have an adequate remedy at law; Count II (FDUPTA) fails to state a claim because the Defendant's labelling is protected by FDUPTA's safe harbor, §501.212(1); because Plaintiff Snyder cannot allege deception to a reasonable consumer; and because Plaintiff Snyder has failed to allege actual damages. D.E. 15 at 7–15.

i. Count I: Unjust Enrichment

The Court is not persuaded by Defendant's argument that Plaintiffs cannot state a claim for unjust enrichment and a claim under FDUPTA at the same time. First, the Court rejects Defendant's characterization of Plaintiff's claims as being based on an "express contract." *Id.* at 15. Plaintiffs have not sued based on a contract—which would presume that there was a meeting of the minds when Plaintiffs purchased the subject products. Rather, Plaintiffs claim that they purchased the products as a result of deception and that, as a result, Defendant wrongfully deprived them of their funds. *See, In re Monat Hair Car Prods. Mktg, Sales Practices, & Prods. Liab. Litig.*, MDL No. 2841, 2019 U.S. Dist. LEXIS 184328, at *18 (S.D. Fla. Oct. 23, 2019). Second, the mere existence of the FDUPTA claim does not establish that Plaintiffs have an adequate remedy at law. Whether Plaintiffs prevail on that claim is, at this stage, a speculative possibility. *See In re Horizon Organic Milk Plus DHA Omega-3 Mktg. & Sales Practice Litig.*, 955 F. Supp. 2d 1311, 1337–38 (S.D. Fla. 2013). Accordingly, the Court will not dismiss Count I.

ii. Count II: FDUPTA

1. Safe Harbor

FDUPTA does not apply to "[a]n act or practice required or specifically permitted by federal or state law." FLA. STAT. § 501.212(1). Defendant argues that FDUPTA's safe harbor immunizes it from liability because its labelling adheres to national uniform standards contained in the Nutrition Labeling and Education Act of 1990 (the "NLEA"), 21 U.S.C. § 343-1, which amended the Food Drug and Cosmetic Act of 1938 (the "FDCA"), 21 U.S.C. §§ 301–399i. D.E. 15 at 7–10. In order to make this argument on a 12(b)(6) motion, Defendant must persuade the Court that—taking Plaintiffs' allegations as true—CBD is a dietary supplement within the meaning of 21 U.S.C. §§ 321(ff)(3)(B)(i), that CBD is a naturally-occurring Class II nutrient within the meaning of the pertinent regulation, 21 C.F.R. § 101.9(g)(3), and that the CBD content declared on Defendant's labels is at least equal to 80% of the stated value, 21 C.F.R. § 101.9(g)(4)(ii). *See Fla. v. Tenet Healthcare Corp*, 420 F. Supp. 2d 1288, 1310 (S.D. Fla. 2005) (placing the burden on the defendant on a FDUPTA claim to show "that a specific federal or state law affirmatively authorized it to engage in the conduct alleged"). But the Complaint says little about the characteristics of CBD as incorporated in Defendant's products and about Defendant's manufacturing process. Without these additional facts—and probably others—the Court cannot conclude as a matter of law that the products that Plaintiffs purchased are properly classified as dietary supplements, that they qualify as Class II nutrients, and that Defendant can rely on the 80% standard, 21 C.F.R. § 101.9(g)(4)(ii), to avoid liability.

2. Deception to a Reasonable Consumer

According to Defendant, Plaintiff Snyder's FDUPTA claim does not meet the reasonable consumer standard because: (1) the QR codes on the bottles of CBD oil of the type Plaintiff Snyder

purchased clearly link to a certificate from an independent testing laboratory disclosing the amount of CBD in each batch; and (2) the certificates of the CBD content are available at the point of sale on the website itself. D.E. 15 at 13. However, the Court does not read the Complaint as conceding these facts. Rather, what Plaintiffs allege is that Defendant is in possession of certificates attesting to the percentage of CBD—not that the certificates are available to consumers. D.E. 1 ¶¶ 22, 24, 25. Accordingly, because Defendant relies on facts outside the four corners of the Complaint, its argument fails.

3. Actual Damages

In a related argument, Defendant contends that Plaintiff Snyder has failed to allege, and cannot allege, actual damages as required by FDUPTA because the lab results and QR codes disclosed the specific CBD content of the batch from which Plaintiff Snyder's bottle of CBD oil was produced. D.E. 15 at 14. This argument depends, again, on facts outside the four corners of the Complaint and therefore fails. Nonetheless, the Court notes that Plaintiffs are complaining they each paid a "premium" for the oil in the mistaken belief that it contained amount of CBD represented on the label. D.E. 1 ¶¶ 42, 44. The "premium price theory of damages" has been recognized by multiple courts applying FDUPTA. *See Smith v. Wm. Wrigley Jr. Co.*, 663 F. Supp. 2d 1336, 1339–40 (S.D. Fla. 2009); *Horizon Organic Milk*, 955 F. Supp. 2d at 1333, 1338; *see also Fitzpatrick v. Gen. Mills, Inc.*, 635 F.3d 1279, 1280 (11th Cir. 2011) (appeal of district court's ruling on class certification).

C. Motion to Stay Based on Primary Jurisdiction

Defendant moves, in the alternative, for a stay based on the primary jurisdiction doctrine. D.E. 15 at 16. The primary jurisdiction doctrine applies where a plaintiff's claims implicate a federal agency's expertise with a regulated product. *See United States v. W. Pac. R.R. Co.*, 352

U.S. 59, 64, 77 S. Ct. 161, 1 L. Ed.2d 126 (1956) (explaining that the 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"). Plaintiffs oppose a stay arguing that a court can apply the existing regulations to adjudicate their misrepresentation claims and because when and whether the relevant agencies will act, if at all, with respect to CBD product-content labelling is indefinite. D.E. 19 at 15.

i. Florida CBD Regulation

Effective January 1, 2020, the state of Florida began regulating CBD products, including their labelling with respect to the number of milligrams of hemp extract contained in a product. FLA. DEP'T OF AGRIC. AND CONSUMER SERV., DIV. OF FOOD SAFETY, Final Rule 5K-4.034 – Hemp Extract (effective Jan. 1, 2020), https://www.flrules.org/gateway/RuleNo.asp?id=5K-4.034 ("Hemp or Hemp Extract intended to be ingested is a Food . . . ."). "'Hemp Extract' is defined in Section 581.217(3)(e), F.S. Hemp Extract does not include any material, compound, mixture, or preparation that contains any quantity of Synthetic Cannabinoids as defined in Section 893.03(1)(c)190, F.S." *Id.* § (2)(e). Section 581.217(3)(e) defines "hemp extract" as "a substance or compound intended for ingestion that is derived from or contains hemp and that does not contain other controlled substances."[1] FLA. STAT. § 581.217(3)(e). "Food consisting of or containing Hemp Extract must be labeled as required by Chapter 500, F.S., Section 581.217(7), F.S. and 21 CFR 101, as incorporated by reference in Section 5K-4002(4), F.A.C., and must declare the number of milligrams of Hemp Extract." Rule 5K-4.034 § (6)(a). 21 C.F.R. Part 101 is the FDA's implementing regulations on "food labeling." Part 101 specifically includes the 80% safe harbor

[1] Synthetic cannabinoids, "unless specifically excepted or unless listed in another schedule or contained within a pharmaceutical product approved by the United States Food and Drug Administration," are illicit Schedule I controlled substances. FLA. STAT. § 893.03(1)(c)190.

for Class II nutrients at Section 101.9(g)(4)(ii). *See* 21 C.F.R. § 101.9(g)(4)(ii). "If specific cannabinoids are marketed, the number of milligrams of each cannabinoid per serving must be declared on the label. The serving size shall be displayed on the nutrient facts label of the product." Rule 5K-4.034 § (6)(b).

ii. Federal CBD Regulation

Regulatory oversight of CBD ingestible products, including labelling, is currently the subject of rulemaking at the FDA. The FDA recently has conducted a public hearing and instituted an agency task force on CBD regulation. U.S. FOOD & DRUG ADMIN., *Scientific Data and Information About Products Containing Cannabis or Cannabis-Derived Compounds; Public Hearing; Request for Comments*, 84 Fed. Reg. 12969 (Apr. 3, 2019). In its Notice of Public Hearing, the FDA stated: "Regulatory oversight of products containing cannabis or cannabis derived compounds is complex and involves multiple Federal and State agencies." 84 Fed. Reg. at 12970. It also made clear that it was concerned with labelling of products containing cannabis-derived, including hemp-derived, compounds. 84 Fed. Reg. at 12971–72. Although the FDA rulemaking process is ongoing, the FDA is under considerable pressure from Congress and industry to expedite the publication of regulations and policy guidance regarding CBD products.[2]

[2] S. REP. NO. 116-110, at 108 (2019) ("Within 90 days of enactment of this act, the FDA shall provide the Committee with a report regarding the agency's progress toward obtaining and analyzing data to help determine a policy of enforcement discretion and the process in which CBD meeting the definition of hemp will be evaluated for use in products. Within 120 days of enactment of this act, the FDA shall issue a policy of enforcement discretion with regard to certain products containing CBD meeting the definition of hemp as defined by section 297A of the Agricultural Marketing Act of 1964 (7 U.S.C. 1639)"); Satish Kini, et al., *Cannabis and Hemp: Regulatory Green Light or Still a Pipe Dream?*, A.B.A. (Apr. 15, 2019), https://www.americanbar.org/groups/business_law/publications/blt/2019/05/cannabis/ (reporting that the FDA is under significant political pressure to expedite its policy-making regarding the regulation of hemp-derived products). More recently, Senate Majority Leader Mitch McConnell moved to include report language in the FY2020 appropriations bill requiring the FDA to hasten progress toward regulating the market for CBD products. AIMED ALLIANCE, *Congressional Leaders Pressure FDA to Act Quickly on CBD Regulation*, https://aimedalliance.org/congressional-leaders-pressure-fda-to-act-quickly-on-cbd-regulation/ (last visited Jan. 2, 2020).

iii. Primary Jurisdiction Doctrine Application

State police powers traditionally included the marketing and regulation of food, but the NLEA provides that no state may directly or indirectly establish any requirement for the labelling of food that is not "identical" to the FDCA. 21 U.S.C. § 343-1(a). Thus, the FDCA comprehensively regulates food and beverage labelling. *See id.*; *Pom Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 112 (2014). Florida classifies CBD as a food subject to labelling requirements, and the FDA has not yet promulgated CBD labelling regulations. Rule 5K-4.034 § (1); U.S. FOOD & DRUG ADMIN., *FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD)* (content current as of Dec. 31, 2019), https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd.[3]

In *Greenfield v. Yucatan Foods, L.P.*, 18 F. Supp. 3d 1371 (S.D. Fla. 2014), the Court applied the primary jurisdiction doctrine to stay a putative class action alleging violations of FDUTPA and a Florida state law claim for unjust enrichment. *Id.* at 1375–76. There, the defendant allegedly deceptively labelled its food products with "evaporated cane juice" rather than "sugar." *Id.* at 1373. Although the plaintiff "alleged three state law claims, her complaint turn[ed] on whether the term 'evaporated cane juice' is false and misleading under the FDCA and its implementing regulations," which led the Court to consider the FDA's position on evaporated cane juice. *Id.* at 1374. After analyzing the state of the applicable, not yet final, FDA regulations, the Court stayed the matter under the primary jurisdiction doctrine because of the "unresolved issue of food labeling law that the interpreting agency is actively considering." *Id.* at 1375.

[3] Defendant raises federal preemption as an issue with respect to its argument that Count II should be dismissed under Rule 12(b)(6). D.E. 15 at 8.

Courts consider four factors when applying 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 activity to a comprehensive regulatory scheme that (4) requires expertise or uniformity in administration. *Horizon Organic Milk*, 955 F. Supp. 2d at 1348. The four factors are not exclusive and courts seem heavily influenced by a fifth factor in cases implicating FDA jurisdiction: whether the FDA has shown any interest in the issues presented by the litigants. *See id.* at 1351 (noting that courts have dismissed on primary jurisdiction grounds when "the FDA continues to be actively involved in monitoring and evaluating . . . labeling"); *Greenfield*, 18 F. Supp. 3d at 1376. All of the relevant factors are present in this case as follows:

First, it appears to the Court that the FDA is exercising regulatory authority over ingestible and other CBD products, but there is uncertainty with respect to whether the FDA will conclude that some or all CBD products are food additives, supplements or nutrients that can be safely marketed to the public and, if nutrients, whether the labelling standards and requirements for CBD products will be different or the same as for other nutrients. Thus, there appears to be a need for consistent guidance. Second, the FDA appears to be properly exercising their regulatory authority; the FDA regulates, among other matters, food additives, supplements and nutrients, and because ingestible CBD products could be deemed to fall into any of these categories, they are within the FDA's jurisdiction. Third, the Agriculture Improvement Act of 2018 (the "2018 Farm Bill"), Pub. L. No. 115-334, 132 Stat. 4908–11, explicitly recognized the FDA's authority to regulate products containing cannabis-derived compounds, including hemp-derived products under the FDCA. 7 U.S.C. §§ 1639(o)–(s). Fourth, the exercise of regulatory authority by the FDA over the labelling of ingestible CBD products requires both expertise and uniformity in administration. The need is

well-illustrated by the fact that, among other issues with which the FDA is concerned, are whether CBD products pose safety risks, how the mode of delivery affects safety, whether there are dosage considerations related to safety, whether there is a need for manufacturing standards, and whether there are standardized definitions for the ingredients in, for example, hemp oil. U.S. FOOD & DRUG ADMIN., *FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD)* (content current as of Dec. 31, 2019), https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd. Lastly, the FDA obviously has expressed an active interest in regulating the manufacture and marketing of CBD products. *Id.* ("FDA continues to be concerned at the proliferation of products asserting to contain CBD that are marketed for therapeutic or medical uses although they have not been approved by the FDA."); 84 Fed. Reg. 12969 (notice of public hearing).

In finding that the factors militating in favor of application of the doctrine of primary jurisdiction are present in this case, the undersigned emphasizes that she has nonetheless considered Plaintiffs' arguments that there may be regulatory delays and that further regulation is unnecessary to resolve the labelling dispute at the heart of the case. However, as noted above, the rulemaking processes at the federal level is active. Given that this case is in the nature of public interest litigation, the delay occasioned by a stay under the current circumstances, would not prejudice Plaintiffs to any significant degree.

As for the adequacy of the current regulatory framework to resolve the issue posed by this case, the Court vehemently disagrees. The FDA regulations currently provide little guidance with respect to whether CBD ingestibles, in all their variations are food supplements, nutrients or additives and what labelling standards are applicable to each iteration. Although the newly-enacted Florida Rule 5K-4.034 addresses CBD product labelling, the Court would benefit greatly

from the FDA's regulatory framework. *See Greenfield*, 18 F. Supp. 3d at 1373 ("*If* Yucatan's labeling practice is compliant with FDA standards Plaintiffs very likely cannot state a claim for a *per se* violation of FDUTPA because the Florida food regulations must be identical to the FDA's. And *if* Yucatan's labeling practice is compliant with FDA standards, Plaintiff is much less likely to be able to state a claim for a traditional violation of FDUTPA because FDUTPA exempts from enforcement 'an act or practice required or specifically permitted by federal or state law' . . . the 'safe harbor' provision."). Accordingly, the case will be stayed until the FDA completes its rulemaking regarding the marketing, including labelling, of hemp-derived ingestible products.

IV. Conclusion

Therefore, it is hereby

ORDERED AND ADJUDGED as follows:

1. Plaintiffs lack standing to maintain claims in respect of products that they did not purchase and, therefore, all such claims are hereby DISMISSED;
2. Defendant's motion to the extent based on Rule 12(b)(6), Fed. R. Civ. P., is hereby DENIED; and
3. Defendant's Motion seeking a STAY based on the primary jurisdiction doctrine is GRANTED;
4. The Clerk of Court shall administratively close this case.

DONE AND ORDERED at Miami, Florida this _3d__ day of January, 2020.

THE HONORABLE URSULA UNGARO
UNITED STATES DISTRICT COURT JUDGE

Copies to: counsel of record via CM/ECF