UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

LAUREN SOUTER, individually, and on behalf of others similarly situated,, Plaintiff, v. EDGEWELL PERSONAL CARE COMPANY, EDGEWELL PERSONAL CARE BRANDS, LLC, and EDGEWELL PERSONAL CARE, LLC,, Defendants.	Case No.: 20-CV-1486 TWR (BLM) **ORDER GRANTING DEFENDANTS' MOTION TO DISMISS** **(ECF No. 22)**

Defendants Edgewell Personal Care Company, Edgewell Personal Care Brands, LLC, and Edgewell Personal Care, LLC ("Defendants") have moved to dismiss Plaintiff Lauren Souter's Complaint. ("Mot. to Dismiss" (ECF No. 22).) For the reasons set forth below, the Court **GRANTS** the motion.

BACKGROUND

This case is about a false and deceptive product label. Plaintiff brings this putative class action against the Defendants for making misleading representations about their antibacterial hand wipes known as "Wet Ones." (Compl. (ECF No. 1) ¶ 2.) Plaintiff takes issue with two representations in particular: (1) that the hand wipes kill 99.99 percent of germs (the "Efficacy Representations"); and (2) that the hand wipes are "hypoallergenic"

and gentle" ("the Skin Safety Representations"). (*Id.* ¶¶ 22, 61.) Both are allegedly misleading. (*See generally* Compl.)

A. The Efficacy Representations

With respect to the Efficacy Representations, Plaintiff argues that Defendants' hand wipes do not kill 99.99 percent of germs, as stated on the product label. (*Id.* ¶ 23–24.) According to Plaintiff, the active ingredient in these hand wipes, benzalkonium chloride ("BAC"), is ineffective against certain viruses, bacteria, and spores, which comprise more than 0.01 percent of germs and can cause serious diseases. (*Id.* ¶¶ 35, 41, 47.) Some of those diseases include polio, norovirus, human papillomavirus, picornavirus, crypotosporidium, and C. difficile. (*Id.* ¶¶ 35, 47.) Plaintiff also claims that the hand wipes are ineffective against COVID-19. (*Id.* ¶ 44–45)

B. The Skin Safety Representations

In addition, Plaintiff takes issue with Defendants' product label for stating that the hand wipes are "hypoallergenic" and "specifically formulated to be tough on dirt and germs, yet gentle on the skin." (*Id.* ¶ 62.) Contrary to this representation, the hand wipes allegedly contain ingredients that are "known allergens or skin irritants." (*Id.* ¶ 63.)

Plaintiff purchased the hand wipes multiple times during the class period. (*Id.* ¶ 81.) In buying the hand wipes, Plaintiff relied on the Efficacy and Skin Safety Representations on the product label. (*Id.* ¶ 82.) According to Plaintiff, these representations were false and misleading and likely to deceive reasonable consumers. (*Id.* ¶ 83.) If she had known the truth, Plaintiff claims, she would not have bought the hand wipes or would have bought them on different terms. (*Id.* ¶ 84.)

Plaintiff files suit under California's Unfair Competition Law ("UCL"), False Advertising Law ("FAL"), and the Consumer Legal Remedies Act ("CLRA"). (*Id.* ¶¶ 99–143.) Plaintiff also asserts claims for breach of express warranty and quasi-contract. (*Id.* ¶¶ 144–58.) In response, Defendants have moved to dismiss under Fed. R. Civ. P. 12(b)(1), 12(b)(6), and 9(b). For the reasons set forth below, the Court **GRANTS** the motion to dismiss **WITHOUT PREJUDICE**.

LEGAL STANDARD

A. Federal Rule of Civil Procedure 12(b)(6)

Rule 12(b)(6) allows a court to dismiss a complaint for "failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). To survive a motion to dismiss, the complaint must contain a "short and plain statement showing that the pleader is entitled to relief," backed by sufficient facts that make the claim "plausible on its face." Fed. R. Civ. P. 8(a)(2); *Ashcroft v. Iqbal*, 556 U.S. 662, 678, (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 547 (2007)). Plausibility requires "more than a sheer possibility that a defendant has acted unlawfully." *Iqbal*, 566 U.S. at 678. Rather, it demands enough factual content for the court to "draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (citing *Twombly*, 550 U.S. at 556). The court must accept as true "all factual allegations in the complaint" and "construe the pleadings in the light most favorable to the nonmoving party." *Manzarek v. St. Paul Fire & Marine Ins. Co.*, 519 F.3d 1025, 1031 (9th Cir. 2008). This presumption does not extend to conclusory allegations, "unwarranted deductions of fact, or unreasonable inferences." *See In re Gilead Scis. Sec. Litig.*, 536 F.3d 1049, 1055 (9th Cir. 2008).

B. Leave to Amend

Federal Rule of Civil Procedure 15(a) states that "the court should freely give leave [to amend] when justice so requires." In exercising this discretion, the court must keep in mind the "underlying purpose of Rule 15," which is to "facilitate decision on the merits, rather than on the pleadings or technicalities." *United States v. Webb*, 655 F.2d 977, 979 (9th Cir. 1981). The Ninth Circuit has repeatedly held that "a district court should grant leave to amend even if no request to amend the pleading was made, unless it determines that the pleading could not possibly be cured by the allegation of other facts." *Lopez v. Smith*, 203 F.3d 1122, 1130 (9th Cir. 2000) (internal quotation marks and citation omitted).

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ANALYSIS

Defendants move to dismiss on five grounds: (1) lack of constitutional and statutory standing; (2) failure to satisfy the heightened pleading standard under Rule 9(b); (3) failure to satisfy the reasonable consumer test; (4) primary jurisdiction; and (5) preemption. The Court addresses each in turn.

A. Constitutional and Statutory Standing

Defendants claim that Plaintiff lacks constitutional and statutory standing because she fails to allege a cognizable injury. Under Fed. R. Civ. P. 12(b)(1), a court may dismiss a case for lack of subject matter jurisdiction when a party does not have Article III standing. *Maya v. Centex Corp.*, 658 F.3d 1060, 1067 (9th Cir. 2011). "Standing to sue is a doctrine rooted in the traditional understanding of a case or controversy." *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547, 194 L. Ed. 2d 635 (2016). To have constitutional standing, the plaintiff must 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." *Id.* (*citing Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560–61 (1992)).

Statutory standing under the UCL, FAL, and CLRA has similar requirements but is assessed under the Rule 12(b)(6) standard. *See Vaughn v. Bay Env't Mgmt., Inc.*, 567 F.3d 1021, 1024 (9th Cir. 2009) ("[A] dismissal for lack of statutory standing is properly viewed as a dismissal for failure to state a claim rather than a dismissal for lack of subject matter jurisdiction."). For those claiming an economic harm, like the case here, plaintiffs must meet an economic injury-in-fact requirement, which "demands no more than the corresponding requirement under Article III of the U.S. Constitution." *Reid v. Johnson & Johnson*, 780 F.3d 952, 958 (9th Cir. 2015). "In a false advertising case, plaintiffs meet this requirement if they show that, by relying on a misrepresentation on a product label, they paid more for a product than they otherwise would have paid, or bought it when they otherwise would not have done so." *Id.* To establish standing under the UCL and FAL, Plaintiff must "(1) establish a loss or deprivation of money or property sufficient to qualify as injury in fact, i.e., *economic injury*, and (2) show that that economic injury was the result

of, i.e., *caused by*, the unfair business practice or false advertising that is the gravamen of the claim." *Van Patten v. Vertical Fitness Grp., LLC*, 847 F.3d 1037, 1048 (9th Cir. 2017) (emphasis in original) (quoting *Kwikset Corp. v. Superior Court*, 51 Cal.4th 310, 120 Cal.Rptr.3d 741, 246 P.3d 877, 885 (2011)). A "plaintiff must allege actual reliance in order to have standing to pursue UCL and FAL claims." *Moore v. Mars Petcare US, Inc.*, 966 F.3d 1007, 1020 (9th Cir. 2020) (citation omitted). "[A]ny plaintiff who has standing under the UCL's and FAL's 'lost money or property' requirement will, *a fortiori,* have suffered 'any damage' for purposes of establishing CLRA standing." *Id.* (quoting *Hinojos v. Kohl's Corp.*, 718 F.3d 1098, 1108 (9th Cir. 2013)). And "[r]eliance is alleged where the misrepresentation or nondisclosure was an immediate cause of the plaintiff's injury-producing conduct, such as where the plaintiff in all reasonable probability would not have engaged in [that] conduct in the absence of the fraud." *Beyer v. Symantec Corp.*, 333 F. Supp. 3d 966, 980 (N.D. Cal. 2018) (internal quotation marks omitted).

Here, Plaintiff has both constitutional and statutory standing. First, Plaintiff alleges an economic harm, or in other words, the loss of money. Plaintiff claims that she would not have bought the hand wipes or would have bought them on different terms if she had known the truth about their efficacy. (*Id.* ¶ 84.) That is enough for standing.[1] *See Hawkins v. Kroger Co.*, 906 F.3d 763, 769 (9th Cir. 2018) ("Because Hawkins adequately alleged that she relied on the label's misrepresentations and *would not have purchased the product without those misrepresentations*, she has adequately alleged standing for her labeling claim.") (emphasis added).

Second, Plaintiff alleges reliance. The Complaint states that, "[i]n purchasing the Products, Plaintiff relied on Defendants' Representations, including that the Products 'Kill[] 99.99% of Germs' and that they are hypoallergenic and/or gentle on skin." (Compl.

[1] The other two standing requirements—traceability and redressability—are not at issue here.

¶ 82.) Although Defendants argue that this is conclusory (Mot. to Dismiss at 21), in *Moore v. Mars Petcare US, Inc.*, 966 F.3d 1007 (9th Cir. 2020), the Ninth Circuit held that a similar statement sufficed to show reliance. There, the Ninth Circuit observed that although the plaintiffs did "not provide much detail in their individual allegations," they still alleged that "as a result of the false and fraudulent prescription requirement, each Plaintiff paid more for [the product] than each Plaintiff would have paid in the absence of the requirement, or would never have purchased [the product]" at all. 966 F.3d at 1020. Here, since Plaintiff's claim is similar to the statement in *Moore*, the Court finds that reliance has been sufficiently alleged.

Defendants make two arguments to show that Plaintiff lacks standing, neither of which is convincing. First, Defendants claim that Plaintiff never suffered an injury due to the hand wipes, such as the diseases and illnesses listed in the Complaint. (ECF No. 39 at 7.) But that misses the point. Despite the appeal of that argument, the Ninth Circuit has found economic harms like Plaintiff's cognizable *independent* of whether the product has caused her actual harm. *See Reid*, 780 F.3d at 958. In other words, "[t]he harm was not that the product was somehow inferiorly made, but simply that the consumer would not have purchased it at the price he paid, but for the misrepresentations." *Stanwood v. Mary Kay, Inc.*, 941 F. Supp. 2d 1212, 1218 (C.D. Cal. 2012). Second, Defendants argue that Plaintiff's economic harm does not suffice for statutory standing because she did not pay a premium price for a product that she would not have otherwise paid but for the misrepresentation. (Mot. to Dismiss at 15–16.) To that end, Defendants cite *Davidson v. Kimberly-Clark Corp.*, 889 F.3d 956, 966 (9th Cir. 2018). But in that case, the Ninth Circuit stated that "a consumer's allegation that 'she would not have bought the product but for the misrepresentation ... is sufficient to allege causation ... [and] to allege economic injury.'" *Davidson*, 889 F.3d at 965–66 (citing *Kwikset Corp. v. Superior Court*, 246 P.3d 877, 890 (2011)). And that is what Plaintiff has alleged here. Further, the Ninth Circuit has recently affirmed this theory of economic harm by stating that a "consumer who relies on a product label and challenges a misrepresentation contained therein can satisfy the

standing requirement of [the UCL] by alleging ... that he or she *would not have bought the product* but for the misrepresentation." *Moore,* 966 F.3d at 1020. (emphasis added) (citation omitted). Thus, the Court **DENIES** Defendants' motion to dismiss on this ground.

B. Federal Rule of Civil Procedure Rule 9(b)

For claims based on fraud, Rule 9(b) applies and imposes a heightened pleading standard. *See Davidson v. Kimberly-Clark Corp.*, 889 F.3d 956, 964 (9th Cir. 2018). Under Rule 9(b), the plaintiff must state with "particularity the circumstances constituting the fraud or mistake." Fed. R. Civ. P. 9(b). Thus, the plaintiff must state the "who, what, when, where, and how' of the misconduct charged." *Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097, 1106 (9th Cir. 2003) (citation omitted). In addition, the plaintiff must also state "what is false or misleading about the purportedly fraudulent statement, and why it is false." *Davidson*, 889 F.3d at 964 (citations omitted).

Here, since Plaintiff's claims are rooted in fraud, Rule 9(b) applies. And based on the factual allegations in the Complaint, Plaintiff has met this standard. Plaintiff claims that the Defendants (the "who") made misleading statements on the product labels of the hand wipes (the "what") during the class period and "in or about March of 2020" (the "when")[2] in San Diego ("the where).[3] The representations are misleading because it says

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[2] Defendants claim that "in or about March of 2020" does not satisfy Rule 9(b), but the Court disagrees. *See Astiana v. Ben & Jerry's Homemade, Inc.*, No. C 10-4387 PJH, 2011 WL 2111796, at *6 (N.D. Cal. May 26, 2011) (finding that "since at least 2006" and "throughout the class period" satisfies the "when" under Rule 9(b)); *see also Werdebaugh v. Blue Diamond Growers*, No. 12-CV-02724-LHK, 2013 WL 5487236, at *14 (N.D. Cal. Oct. 2, 2013) (finding that "[d]uring the Class Period [April 11, 2008 to present]" satisfies the "when" under Rule 9(b), especially since the defendant did not argue that "any of the Purchased Product labels changed during the class period").

[3] In other cases where plaintiffs have satisfied Rule 9(b), they have specifically alleged the exact place or store in which they purchased the products. *See Nathan v. Vitamin Shoppe, Inc.*, No. 317CV01590BENKSC, 2019 WL 1200554, at *7 (S.D. Cal. Mar. 14, 2019) (finding that the plaintiff had alleged her claims "with sufficient particularity" when she stated that "in approximately February 2017 in San Diego, she purchased a 180-caplet bottle of [the Product] for approximately $20 from Vitamin Shoppe."); *see also Fernandez v. Atkins Nutritionals, Inc.*, No. 317CV01628GPCWVG, 2018 WL 280028, at *11 (S.D. Cal. Jan. 3, 2018) (plaintiff alleged that she purchased the products at Wal-Mart and Target). And although this seems insignificant on the surface, the "where" serves a critical

that it kills 99.99 percent of germs, when it does not (the "how"). (Compl. ¶ 27.) Plaintiff identifies the specific misrepresentations at issue and alleges that she relied on them in purchasing the hand wipes. (*Id.* ¶ 82.) That is all that Rule 9(b) requires. *See Kosta v. Del Monte Corp.*, No. 12-CV-01722-YGR, 2013 WL 2147413, at *14–15 (N.D. Cal. May 15, 2013) (finding Rule 9(b) satisfied because plaintiff alleged the "who" (the defendant company), the "what" (the defendant's "allegedly unlawful and deceptive claims in its labeling, packaging and website"); the "where" (the defendant's package labels and website), the "when" ("since 2008 and through the class period"), and the "how" (the defendant "violated the Sherman law in nine specific ways" and the plaintiffs "purchased products while reasonably relying on [the defendant's] misrepresentations" and were "deceived by [the defendant's] product labels and website.").

C. UCL, FAL, CLRA, and the Reasonable Consumer Test

Still, even though Plaintiff satisfies Rule 9(b), her claims fall short under the reasonable consumer test. Courts often analyze claims under the UCL, FAL, and CLRA together "because they share similar attributes." *In re Sony Gaming Networks & Customer Data Sec. Breach Litig.*, 996 F. Supp. 2d 942, 985 (S.D. Cal. 2014). California's UCL prohibits any "unlawful, unfair or fraudulent business act or practice." Cal. Bus. & Prof. Code § 17200. California's FAL prohibits any "unfair, deceptive, untrue or misleading advertising." Cal. Bus. & Prof. Code § 17500. Any FAL violation amounts to a UCL

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part under Rule 9(b) in providing notice. The "where" does not serve to establish venue or jurisdiction but is rather part of a pleading standard aimed to give Defendants notice of their misconduct. *See Kearns v. Ford Motor Co.*, 567 F.3d 1120, 1125 (9th Cir. 2009) (listing the three purposes of Rule 9(b), one of which is to "provide defendants with adequate notice to allow them to defend the charge and deter plaintiffs from the filing of complaints as a pretext for the discovery of unknown wrongs") (internal quotation marks and citation omitted). Still, since Plaintiff has alleged enough details here to satisfy the "purpose behind Rule 9(b)," *Openwave Messaging, Inc. v. Open-Xchange, Inc.*, No. 16-CV-00253-WHO, 2016 WL 2621872, at *9 (N.D. Cal. May 9, 2016), the Court declines to dismiss on this ground. The level of specificity already provided "enables defendants to prepare an adequate answer from the allegations." *Stathakos v. Columbia Sportswear Co.*, No. 15-CV-04543-YGR, 2016 WL 1730001, at *3 (N.D. Cal. May 2, 2016).

violation. *See Williams v. Gerber Prod. Co.*, 552 F.3d 934, 938 (9th Cir. 2008) (quoting *Kasky v. Nike, Inc.*, 45 P.3d 243, 250 (2002)). California's CLRA prohibits "unfair methods of competition and unfair or deceptive acts or practices." Cal. Civ. Code § 1770. Claims under all three of these statutes are subject to the "reasonable consumer test." *Williams*, 552 F.3d at 938 (9th Cir. 2008) (citing *Freeman v. Time, Inc.*, 68 F.3d 285, 289 (9th Cir. 1995)). The reasonable consumer test requires a probability that a "significant portion of the general consuming public or of targeted consumers, acting reasonably in the circumstances, could be misled." *Ebner v. Fresh, Inc.*, 838 F.3d 958, 965 (9th Cir. 2016) (internal quotation marks omitted). Courts have dismissed cases under the reasonable consumer test only in select circumstances, particularly where the "alleged violations of the UCL, FAL, and CLRA are simply not plausible." *Ham v. Hain Celestial Grp., Inc.*, 70 F. Supp. 3d 1188, 1193 (N.D. Cal. 2014). "[I]f common sense would not lead anyone to be misled, then the claim may be disposed of at a motion to dismiss stage." *Moore v. Mars Petcare US, Inc.*, 966 F.3d 1007, 1018 (9th Cir. 2020).

Here, Defendants argue that this Court should dismiss Plaintiff's claims because they do not pass the reasonable consumer test. According to Defendants, no reasonable consumer would be misled by the Efficacy and Skin Safety Representations in the way that Plaintiff alleges. The Court agrees.

1. Efficacy Representations

Plaintiff argues that the Efficacy Representations are misleading because the hand wipes do not kill 99.99 percent of germs. (Compl. ¶ 4.) Plaintiff claims that the hand wipes are ineffective against a variety of diseases and viruses, including the norovirus, poliovirus, polyomavirus, human papillomavirus ("HPV"), picornavirus, and other gram-negative bacteria like pseudomonas aeruginosa, and mycobacteria. (*Id.* ¶¶ 35, 41.) Taken together, these disease-causing microorganisms comprise more than 0.01 percent of germs. (*Id.* ¶ 27.)

But here, Plaintiff has not set forth a plausible theory under the reasonable consumer test. No reasonable consumer would believe that a hand wipe advertised to kill 99.99

percent of germs would be effective against the bacteria and viruses that Plaintiff names. For example, Plaintiff does not explain how or why a reasonable consumer would take a hand wipe's representation that it kills 99.99 percent of germs to mean that it would also be effective against HPV, a sexually transmitted disease, or the norovirus and polyomavirus, which are food-borne illnesses. (Mot. to Dismiss at 23.) It also seems implausible that a reasonable consumer would believe that a hand wipe would be effective against polio, a virus that has not had an active case in the United States since 1979. *See Moreno v. Vi-Jon, Inc.*, No. 20CV1446 JM(BGS), 2021 WL 807683, at *6 (S.D. Cal. Mar. 3, 2021) (citation omitted). In addition, Plaintiff claims that the hand wipes are ineffective against gram-negative bacteria such as pseudomonas aeruginosa and mycobacteria, which can cause blood infections, pneumonia, and tuberculosis, respectively (Compl. ¶¶ 42–43), and also certain spores that can cause diseases like C. Difficile and cryptosporidium. (*Id.* ¶¶ 41, 47.) But again, Plaintiff does not explain how or why a reasonable consumer would believe that a hand wipe would protect against these viruses or diseases. If anything, a reasonable consumer would likely suspect that a hand wipe would be effective against bacteria often found on hands, and Plaintiff has not alleged how likely these strains of bacteria appear on hands. The same reasoning applies to certain spores like C. difficile and cryptosporidium, the latter of which includes a pathogen that is "commonly found in cat litter and undercooked food." (*Id.* ¶¶ 47, 52.) And what is more, the product label explicitly states that the hand wipes should be used to "keep hands fresh and clean *when soap and water are not available*." (*Id.* ¶ 21) (emphasis added). These kinds of "qualifiers," though not explicit, can "ameliorate any tendency of the label to mislead." *Moore v. Mars Petcare US, Inc.*, 966 F.3d 1007, 1017 (9th Cir. 2020).

In short, simply listing all kinds of germs that the hand wipes cannot kill misses the mark. The relevant question is whether a reasonable consumer would believe that, based on Defendants' representations, the hand wipes would be effective against the named germs and diseases. And even then, it must be "a *significant portion* of the general consuming public or of targeted consumers." *Ebner v. Fresh, Inc.*, 838 F.3d 958, 965 (9th

Cir. 2016) (emphasis added). Here, Plaintiff has not met her burden, so the Court **DISMISSES** this claim accordingly.

2. Skin Efficacy Representations

Plaintiff's claims about the Skin Safety Representations fare no better. According to Plaintiff, although Defendants label the hand wipes as "hypoallergenic" and "gentle," the hand wipes contain various ingredients that are "known allergens or skin irritants." (Compl. ¶ 13.) But here again, Plaintiff does not explain how or why a reasonable consumer would take "hypoallergenic" and "gentle" to mean that the hand wipe is *entirely free* of allergens or skin irritants. This case is like *Rugg v. Johnson & Johnson*, No. 17-CV-05010-BLF, 2018 WL 3023493, at *1 (N.D. Cal. June 18, 2018), where the plaintiffs challenged Johnson & Johnson's use of the word "hypoallergenic" on the product labels of its baby products. There, the plaintiffs argued that using the word "hypoallergenic" was misleading because the products contained "known skin sensitizers, known skin or eye irritants, carcinogens, teratogens, mutagens, or pollutants, and substances that have not been adequately assessed for safety or skin sensitization potential." *Id.* at 2. (internal quotation marks omitted). The court rejected that argument. Noting that "hypoallergenic" had the dictionary definition of "having little likelihood of causing an allergic response," the court found it "completely implausible" that a reasonable consumer would take "hypoallergenic" on a product's label to mean that the product does not contain "*any* ingredients, in any concentration, which could 'sensitize' the skin, cause cancer, or have *any* other negative effect, regardless of whether such effect constitutes an allergic reaction." *Id.* at 3. (emphasis in original). The court dismissed the claim accordingly.

The same reasoning applies here. No reasonable consumer would read "hypoallergenic" and "gentle" to mean that it is completely free of ingredients that can cause an allergic reaction. Indeed, it seems implausible to argue that a reasonable consumer would take "hypoallergenic" and "gentle" to mean that the hand wipes pose *no possible risk* of skin irritation (*see id.* ¶¶ 72, 75–78) as opposed to posing a *lower* risk. And what is more, a reasonable consumer may not even think those words suggest anything about the

hand wipes' *ingredients* as opposed to the hand wipes' *performance.* In other words, a reasonable consumer may take "hypoallergenic" and "gentle" to mean something about the *effect* of the hand wipes when applied on the skin—*i.e.*, that it would not cause skin irritation and be smooth and gentle—*regardless* of its ingredients, such as whether they contain skin irritants. Either way, "hypoallergenic" and "gentle" do not suggest anything about how the hand wipes may affect the central nervous system, lungs, eyes, kidneys, or the liver, as Plaintiff argues here. (*Id.* ¶¶ 70, 72–73.) Without explaining how or why a reasonable consumer would believe this, the Court finds this theory implausible. The Court **DISMISSES** this claim accordingly.

D. Primary Jurisdiction and Preemption

Lastly, Defendants argue that this Court should dismiss this case because primary jurisdiction and preemption apply. First, Defendants argue that the nature of Plaintiff's claims, which are based on the safety and efficacy of the hand wipes, fall under the primary jurisdiction of the Food and Drug Administration ("FDA"). (Mot. to Dismiss at 4–10.) Second, Defendants argue that Plaintiff's claims under the UCL, FAL, and CLRA are preempted—both expressly and impliedly—by federal law. Neither argument is convincing.

1. Primary Jurisdiction

"Primary jurisdiction applies in a limited set of circumstances." *Clark v. Time Warner Cable,* 523 F.3d 1110, 1114 (9th Cir. 2008). The doctrine applies if the claim at issue "requires resolution of an issue of first impression, or of a particularly complicated issue that Congress has committed to a regulatory agency and if protection of the integrity of a regulatory scheme dictates preliminary resort to the agency which administers the scheme." *Id.* (internal quotation marks and citations omitted). And while the matter is ultimately one of discretion, courts have given due weight to "(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 Semiconductor Co. v. Microchip Tech. Inc.*, 307 F.3d 775, 781 (9th Cir. 2002). If primary jurisdiction applies, the district court either "stays proceedings or dismisses the case without prejudice, so that the parties may seek an administrative ruling." *Clark*, 523 F.3d at 1115 (citation omitted).

Here, primary jurisdiction does not apply. Contrary to Defendants' claims, Plaintiff is not arguing that the hand wipes are misbranded or that they should be subject to a different classification under the FDA. (Mot. to Dismiss at 5–6.) Rather, Plaintiff is arguing that the hand wipes' product labels are *misleading*, which is "not a technical area in which the FDA [has] greater technical expertise than the courts." *Jovel v. Boiron Inc.*, No. 2:11-CV-10803-SVW-SH, 2013 WL 12164622, at *12 (C.D. Cal. Aug. 16, 2013) (quoting *Lockwood v. Conagra Foods, Inc.*, 597 F. Supp. 2d 1028, 1035 (N.D. Cal. 2009)). "[E]very day courts decide whether conduct is misleading." *Id.* (citation omitted). Thus, Defendants' motion to dismiss on this ground is **DENIED**.[4]

2. Preemption

In addition, Defendants argue that Plaintiffs' claims are preempted by federal law. Relevant here, Defendants point to the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, which Congress passed due to increased concerns about "unsafe drugs and fraudulent marketing." *Delarosa v. Boiron, Inc.*, 818 F. Supp. 2d 1177, 1181 (C.D. Cal. 2011) (quoting *Wyeth v. Levine,* 555 U.S. 555, 129 S.Ct. 1187, 1198–99, 173 L.Ed.2d 51 (2009)). As Defendants note, under the FDCA, the FDA has the power to regulate the "ingredients and labeling of nonprescription [over the counter] drugs" like the hand wipes at issue here. (Mot. to Dismiss at 8.) (citing 21 U.S.C. §§ 321, 352; 21 C.F.R. § 201, *et seq.*). Some over-the-counter drugs are subject to FDA "monographs," which are

[4] In arguing for primary jurisdiction, Defendants mischaracterize Plaintiff's arguments. This case is not about whether the hand wipes are safe, effective, or misclassified, per se. (Mot. to Dismiss at 4–5; ECF No. 39 at 1–3.) Rather, this case is about whether Defendants' representations about the hand wipes are misleading to a *reasonable consumer*. As noted above, courts routinely handle these kinds of claims. *See Jovel*, 2013 WL 12164622, at *12.

detailed regulations that establish "conditions under which OTC (over-the-counter) drugs are generally recognized as safe and effective and not misbranded." 21 C.F.R. § 330.10. Monographs "provide[] the FDA-approved active ingredients for a given therapeutic class of OTC drugs and sets forth the conditions under which each active ingredient is [generally regarded as safe and effective]." *Moreno v. Vi-Jon, Inc.*, No. 20CV1446 JM(BGS), 2021 WL 807683, at *10 (S.D. Cal. Mar. 3, 2021). Products that contain non-monograph active ingredients "cannot be marketed to the public without an approved [New Drug Application], which requires, *inter alia*, that Defendant present evidence that the products are safe and effective for their represented uses." *Borchenko v. L'Oreal USA, Inc.*, 389 F. Supp. 3d 769, 771–72 (C.D. Cal. 2019). Relevant here, the FDA has deferred making a final monograph for BAC, the active ingredient in Defendants' hand wipes. 84 Fed. Reg. 71 14847-01 at 14848. Still, Defendants argue, the 1994 tentative final monograph ("TFM") applies and regulates the hand wipes. (Mot. to Dismiss at 10.) Plaintiff disagrees and argues that the FDA's deferral means that the hand wipes are not subject to any FDA regulation. (Compl. ¶ 60.) Either way, the Court finds that preemption does not apply.

Defendants argue that Plaintiff is using state law to "impose alternative labeling requirements" for the hand wipes that are governed exclusively by federal law. (Mot. to Dismiss at 11.) As a result, Defendants argue, Plaintiff's arguments are preempted. "Federal preemption occurs when: (1) Congress enacts a statute that explicitly pre-empts state law; (2) state law actually conflicts with federal law; or (3) federal law occupies a legislative field to such an extent that it is reasonable to conclude that Congress left no room for state regulation in that field." *Chae v. SLM Corp*., 593 F.3d 936, 941 (9th Cir. 2010). Here, Defendants argue that Plaintiff's state claw claims seek to impose additional labeling requirements on the hand wipes, which is explicitly prohibited under § 379(r) of the FDCA. That provision specifically prohibits states from establishing "any requirement … (1) that relates to the regulation of a [nonprescription drug]; and (2) that is *different from or in addition to, or that is otherwise not identical with*, a requirement under the [FDCA] …" 21 U.S.C. § 379r(a) (emphasis added). Defendants go on to state that the FDA

regulates the hand wipes' labeling requirements under 21 C.F.R. 201.66 and the 1994 TFM, both of which provide labeling requirements on "directions and use, intended purpose, ingredients, disclosures, safety warnings, potential allergic reactions and when to discontinue use." (Mot. to Dismiss at 11.)

These arguments are unconvincing. Plaintiff's allegation is that Defendants' product labels are deceptive or misleading under state law—and "[t]hese state laws "exist[] independently of [the FDCA]" and provide a "valid state cause of action even if the FDA ceased to exist."[5] *Morgan v. Wallaby Yogurt Co., Inc.*, No. 13-CV-00296-WHO, 2013 WL 5514563, at *6 (N.D. Cal. Oct. 4, 2013) (internal quotation marks and citation omitted). Contrary to Defendants' claim, Plaintiff is not asking this Court to impose additional labeling requirements under state law that are "different from or in addition to" the ones that the FDCA imposes. Rather, Plaintiff is merely saying that Defendants' product labeling, as it currently stands, is *misleading*. This is a different argument, since "[t]he FDCA is not focused on the truth or falsity of advertising claims but is instead directed to protect the public by ensuring that drugs sold in the marketplace are safe, effective and not misbranded." *In re Epogen & Aranesp Off-Label Mktg. & Sales Pracs. Litig.*, 590 F. Supp. 2d 1282, 1290 (C.D. Cal. 2008) (citation omitted). This case is about Defendants' advertising and not about whether the products are safe or misbranded, per se. Indeed "to the extent that Plaintiffs have alleged that Defendants made statements that were fraudulent (i.e., literally false, misleading, or omitted material facts), their claims are actionable." *In re Epogen*, 590 F. Supp. 2d at 1291 (citation omitted); *see also Moreno v. Vi-Jon, Inc.*, No. 20CV1446 JM(BGS), 2021 WL 807683, at *11 (S.D. Cal. Mar. 3, 2021) ("To the extent that Plaintiff's claims simply require the court to make factual determinations as to whether the statements are false, such claims do not give rise to preemption.") (citing cases). Thus, preemption does not apply. *See Corra v. Energizer Holdings, Inc.*, 962 F. Supp. 2d 1207,

[5] For this reason, Defendants' argument that Plaintiff is bringing a private right of action under the FDCA fails. (Mot. to Dismiss at 13.)

1215 (E.D. Cal. 2013) (finding that 379(r) preemption provision does not bar the plaintiff's UCL and CLRA claims because even if successful, "Defendants' [] labeling duties would remain unchanged.").

In arguing for preemption, Defendants mischaracterize Plaintiff's claims. (ECF No. 39 at 4–5.) Just because Plaintiff points out that Defendants omitted certain information in advertising their product does not mean that if Plaintiff prevails, Defendants will have to include that information on the product labels for their hand wipes. Indeed, even if Plaintiff were to win this case, Defendants would not be required as a matter of law to include the omitted information to correct the alleged misrepresentation. Nothing in the UCL, FAL, or CLRA requires this—let alone impose any labeling requirements.[6] Rather, if proven, Plaintiff's claims would "simply require Defendant[s] to truthfully state [their products'] efficacy or not sell its products; such relief would not impose a state requirement that is different from or in addition to, or that is otherwise not identical with that of the FDCA." *See Jovel v. Boiron Inc.*, No. 2:11-CV-10803-SVW-SH, 2013 WL 12164622, at *11 (C.D. Cal. Aug. 16, 2013) (internal quotation marks omitted). After all, federal law did not require Defendants to represent that their hand wipes kill 99.99 percent of germs or that they are "hypoallergenic" and "gentle." Instead, these were advertising choices that Defendants made, and Plaintiff is simply challenging those choices. *See id.* (noting that just because federal law may require certain information on product labels does not mean

[6] Defendants cite *Webb v. Trader Joe's Co.*, 418 F. Supp. 3d 524, 528 (S.D. Cal. 2019), but that case is inapposite. There, the Food Safety and Inspection Service approved the defendant's product label and the representation contained in it. Thus, the court found that the plaintiff's claim failed as a matter of law. *See id.* at 529. But here, the FDA has not reviewed and approved Defendants' product label. Rather, Defendants' argument is that their product labels and representations are presumptively valid because it complies with existing federal guidelines, namely the 1994 TFM. That is a different argument—and one that makes all the difference. Unlike *Webb*, because the federal government has not specifically approved Defendants' representations, Plaintiff's claims that they are misleading remain viable and are not preempted.

that "federal law [] mandates, or approves of, the specific indications selected for the [product] label" at issue).

Lastly, to the extent Defendants base their preemption argument on a tentative final monograph, that argument fails. "The legal status of each tentative final monograph … is that of a proposed rule." Fed. Reg. 31403. Since a TFM is not law, it has no preemptive force. *See Won Kyung Hwang v. Ohso Clean, Inc.*, No. C-12-06355 JCS, 2013 WL 1632697, at *17 (N.D. Cal. Apr. 16, 2013) (declining to find preemption based on the 1994 Tentative Final Monograph because it was "never adopted and ha[s] only the legal status of a proposed rule."). Further, and as explained above, because these state law claims exist independently of federal law, it would not make a difference if the FDA issued a final monograph anytime soon. Here, Plaintiff's claims only require the court to determine whether Defendants' product labels are false or misleading to a reasonable consumer, and those kinds of claims do not give rise to preemption. *See id.* (finding that preemption does not apply because "Plaintiff's claims only require the court to make a factual determination as to whether the statements on the labels of Defendants[']sanitizing products are false" and "such claims do not give rise to implied preemption."). Defendants' motion to dismiss on this ground is **DENIED**.

E. Remaining State Law Claims

Plaintiff also sues for (1) breach of express warranty and (2) quasi-contract. For the reasons stated below, the Court **DISMISSES** both claims.

1. Breach of Express Warranty

"To state a claim for breach of express warranty under California law, a plaintiff must allege: (1) the seller's statements constitute an affirmation of fact or promise or a description of the goods; (2) the statement was part of the basis of the bargain; and (3) the warranty was breached." *Portelli v. WWS Acquisition, LLC*, No. 17-CV-2367 DMS (BLM), 2018 WL 9539773, at *5 (S.D. Cal. July 6, 2018) (internal quotation marks and citation omitted). Here, Plaintiff's claim fails. As discussed above, Defendants never promised that the hand wipes would kill 99.99 percent of *all* germs as Plaintiff suggests,

or even the ones identified in the Complaint. Thus, since Defendants have not breached an express warranty, the Court **DISMISSES** this claim accordingly. *See Myers-Taylor v. Ornua Foods N. Am., Inc.*, No. 3:18-CV-01538-H-MDD, 2019 WL 424703, at *6 (S.D. Cal. Feb. 4, 2019) (finding that the defendants did not breach an express warranty because it did not promise what the plaintiffs alleged).

2. Quasi-Contract

For similar reasons, Plaintiff's claim for quasi-contract, or unjust enrichment, also fails. (Compl. ¶¶ 153–58.) A quasi-contract claim typically involves a plaintiff seeking a return of a benefit that the defendant had unjustly gained through "mistake, fraud, coercion, or request." *Astiana v. Hain Celestial Grp., Inc.*, 783 F.3d 753, 762 (9th Cir. 2015) (citation omitted). Here, and as explained above, there was no fraudulent conduct. Both the Efficacy and Skin Efficacy Representations were not fraudulent and misleading in the way that Plaintiff alleges. Absent fraud, Plaintiff has no claim for unjust enrichment. *See Myers-Taylor v. Ornua Foods N. Am., Inc.*, No. 3:18-CV-01538-H-MDD, 2019 WL 424703, at *6 (S.D. Cal. Feb. 4, 2019) ("in order to succeed in an unjust enrichment claim, a plaintiff must show some fraud."). Thus, the Court **DISMISSES** the quasi-contract claim accordingly.

CONCLUSION

For the foregoing reasons, the Court **GRANTS** Defendants' motion to dismiss **WITH LEAVE TO AMEND**. Plaintiff will have 30 days from the date of this Order to file an amended complaint.

IT IS SO ORDERED.

Dated: June 7, 2021

Honorable Todd W. Robinson
United States District Judge