STINSON LLP
John Moticka, MOSB 31760 (pro hac vice pending)
john.moticka@stinson.com
7700 Forsyth Blvd, Suite 1100,
St. Louis, Missouri 63105
Telephone: 314.259.4562 Facsimile: 314. 259-4467

Megan McCurdy, MOSB 60071 (pro hac vice pending)
megan.mccurdy@stinson.com
1201 Walnut, Suite 2900
Kansas City, Missouri 64106
Telephone: 816.691.2649 Facsimile: 816.412.9733

Ashley Crisafulli, MOSB, 71852 (pro hac vice pending)
ashley.crisafulli@stinson.com
1201 Walnut, Suite 2900
Kansas City, Missouri 64106
Telephone: 816.691.2676 Facsimile: 816.412.9733

SELTZER CAPLAN MCMAHON VITEK
Daniel Eaton, CASB 144663
eaton@scmv.com
750 B Street, Suite 2100
San Diego, California 92101
Telephone: 619.685.3052 Facsimile: 619.702.6880

Attorneys for Defendants EDGEWELL PERSONAL CARE COMPANY, EDGEWELL PERSONAL CARE BRANDS, LLC and EDGEWELL PERSONAL CARE, LLC

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.: 20CV1486 TWR BLM *The Honorable Todd W. Robinson* **DEFENDANTS' MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF MOTION TO DISMISS PLAINTIFF'S CLASS ACTION COMPLAINT** Hearing Date: December 2, 2020 Hearing Time: 1:30 P.M. Courtroom 3A

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MEMORANDUM OF POINTS AND AUTHORITIES

Defendants Edgewell Personal Care Company, Edgewell Personal Care Brands, LLC, and Edgewell Personal Care, LLC ("Defendants"), respectfully submit this Memorandum of Points and Authorities in Support of their Motion to Dismiss the putative Class Action Complaint ("Complaint") pursuant to Federal Rules of Civil Procedure 8, 9(b), 12(b)(1), and 12(b)(6). For all of the reasons set forth below, this Court should dismiss the Plaintiff's Complaint with prejudice, as the defects in the Plaintiff's Complaint – including that the FDA has primary jurisdiction, that Plaintiff's claims are preempted by federal law, that Plaintiff lacks standing, and plaintiff fails to state a claim for relief – are fatal to Plaintiff's claims.

INTRODUCTION

Plaintiff Lauren Souter ("Plaintiff") challenges the marketing of Wet Ones® Antibacterial Hand Wipes sold by Defendants.[1] Plaintiff directly challenges, *inter alia*, the truth of the claim that Wet Ones® Antibacterial Hand Wipes "[k]ills 99.99% of [g]erms." *See* Plaintiff's Class Action Complaint, Dkt. #1 ("Plaintiff's Compl."), ¶¶ 1-6.

The Court should dismiss Plaintiff's Complaint for the following reasons,

First, the Court should dismiss Plaintiff's state law false advertising claims as they are subject to the primary jurisdiction of the U.S. Food and Drug Administration ("FDA"). Whether Wet Ones® Antibacterial Hand Wipes' labeling claims and use of the active ingredient and antimicrobial agent, benzalkonium chloride 0.13% ("BAC"), is "generally recognized as safe and effective and is not misbranded . . .", falls squarely within the FDA's primary jurisdiction. *See* 21 C.F.R. § 330.1.

Second, Plaintiff's claims are preempted by the Federal Food Drug and Cosmetics Act ("FDCA".) The FDA heavily regulates the ingredients and labeling of nonprescription,

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[1] Not all Defendants are involved in the manufacture and sale of Wet Ones® Antibacterial Hand Wipes. Defendants reserve the right to challenge, if necessary, the real party in interest.

over-the-counter ("OTC") drugs, such as the antiseptic hand wipe products at issue here. 21 U.S.C. §§ 321, 352; 21 C.F.R.§ 201, *et seq*. Wet Ones® Antibacterial Hand Wipes comply with the applicable OTC drug monograph. *See* Tentative Final Monograph for Health-Care Antiseptic Drug Products, 59 Fed. Reg. 116, 31402 (June 17, 1994) ("1994 TFM"); *see also* Final Rule: Safety and Effectiveness of Consumer Antiseptics: Topical Antimicrobial Drug Products for Over-the-Counter Human Use (Consumer Antiseptic Rubs); Final Monograph, 84 Fed. Reg. 71, 14847 (Apr. 12, 2019) ("2019 Final Topical Antimicrobial Rule"). In compliance with the 1994 TFM, Wet Ones® Antibacterial Hand Wipes clearly communicate "product use" as to "decrease bacteria on skin." Tobias Decl., ¶ 6(a). Plaintiff seeks to enforce labeling requirements "different from or in addition to" the applicable monograph by requiring pathogen-specific claims which would likely cause the FDA to classify the product as a "new drug" triggering different regulatory requirements. The Court should also dismiss this action because the FDCA prohibits private enforcement actions.

Third, Plaintiff lacks standing. Plaintiff has no "concrete and particularized injury" and thus, fails to allege an injury-in-fact. Plaintiff's purported economic injury does not satisfy the injury-in-fact requirement. Plaintiff also lacks CLRA, UCL, and FAL statutory standing because she fails to allege reliance on any "advertising" or "marketing."

Fourth, Plaintiff fails to meet in the heightened pleading requirement of Rule 9(b). Plaintiff fails to articulate the who, what, when, where, and how surrounding her purchase of the product and any pre-purchase reliance on any "advertising" or "marketing" of the product. Plaintiff also fails to allege how a "reasonable consumer" would understand "[k]ills 99.99% of [g]erms" or "keep hands fresh and clean when soap and water are not available" to mean the product kills chlamydiae, parvoviruses, tuberculosis, coccidian (causing infection in dogs), norovirus, poliovirus, polyomavirus, human papillomavirus ("HPV"), picornavirus, coronavirus ("COVID-19"), severe acute respiratory syndrome ("SARS") coronavirus, middle east respiratory syndrome ("MERS") coronavirus, and C. difficile to name a few. *See* Plaintiff's Compl., ¶¶ 33, 35, 44, 46, 48.

Finally, Plaintiff fails to allege she lacks an adequate remedy at law to secure restitution and/or injunctive relief warranting dismissal of Plaintiff's claims for equitable relief.

BACKGROUND

Plaintiff filed this putative class action complaint alleging purported violations of California's Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code §§ 17200, *et seq.*; California's False Advertising Law ("FAL"), Cal. Bus. & Prof. Code §§ 17500, *et seq.*; Consumer Legal Remedies Act ("CLRA"), Cal. Civ. Code §§ 1750 *et seq.*; and breach of express warranty and quasi-contract.

Plaintiff alleges that Wet Ones® Antibacterial Hand Wipes contain the following "false and misleading" misrepresentations:

- "Kills 99.99% of Germs" and "Wet Ones® Antibacterial Hand Wipes kill 99.99% of germs and wipe away dirt, providing a better clean than hand sanitizers. They are specially formulated to be tough on dirt and germs, yet gentle on skin, so you can confidently keep your hands fresh and clean when soap and water are not available." Plaintiff deems the foregoing "*Efficacy* Representations."
- "Directions . . . adults and children 2 years and over" should "apply to hands" and "allow skin to dry without wiping."
- "Hypoallergenic," "Pediatrician Tested," and "specially formulated to be tough on dirt and germs, yet gentle on skin." Plaintiff defines the forgoing as "Skin *Safety* Representations."

Plaintiff's Compl. ¶¶ 23-24, 62 (emphasis added).

Plaintiff states that she "would not have purchased the Products, or would have purchased them on different terms, if she had known the truth." Plaintiff's Compl. ¶ 84. Plaintiff, however, does not explain the who, what, when, where, and how surrounding her purchase, whether she used the product, and whether the product failed to work as intended.

I. PLAINTIFF'S CLAIMS ARE SUBJECT TO THE FDA'S PRIMARY JURISDICTION AND FURTHER PREEMPTED BY FEDERAL LAW.

The doctrine of primary jurisdiction is designed to ensure a proper working relationship between federal agencies and the courts. The doctrine permits a court to dismiss a party's claim that falls within the jurisdiction of a federal agency. *See infra*, § I.A. Federal preemption requires the dismissal of any state law claims which conflict with federal law. *See infra*, § I.C. Dismissal is warranted on both grounds.

A. WET ONES® ANTIBACTERIAL HAND WIPES ARE SUBJECT TO THE FDA'S PRIMARY JURISDICTION.

Federal law bars Plaintiff's claims, as they are subject to the primary jurisdiction of the FDA. The primary jurisdiction doctrine ensures the proper working relationship between federal agencies and courts. *See United States. v. W. Pac. R. R. Co*., 352 U.S. 59, 62 (1956); *Far East Conference v. United States*, 342 U.S. 570, 575 (1952). The doctrine "applies where a claim is originally cognizable in the courts, and comes into play whenever enforcement of the claim requires the resolution of issues which, under a regulatory scheme, have been placed within the special competence of an administrative body." *W. Pac. R. R. Co.*, 352 U.S. at 64. The Ninth Circuit applies the doctrine of primary jurisdiction when the following facts are present: "(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) (citations omitted). Those factors clearly exist here.

Plaintiffs seek to enforce claims based on safety and efficacy, both of which fall under the primary jurisdiction of the FDA. Congress enacted the FDCA, and in doing so, authorized the FDA to regulate, *inter alia*, the ingredients and labeling of nonprescription, over-the-counter ("OTC") drugs, such as the antiseptic hand wipe products at issue here. 21 U.S.C. §§ 321, 352; 21 C.F.R.§ 201, *et seq*. Whether Wet Ones® Antibacterial Hand Wipes' use of BAC is "generally recognized as safe and effective and is not misbranded . . .", and whether the efficacy claims and labeling associated with the active ingredient are

appropriate, falls squarely within the FDA's primary jurisdiction. *See* 21 C.F.R. § 330.1. Historically, the FDA has regulated topical consumer antiseptic and hand wipe products through a comprehensive set of proposed rules and tentative and final monographs.[2] In the 2019 Final Topical Antimicrobial Rule, the FDA stated its intent to issue new regulations regarding the use of "BAC, ethyl alcohol, and isopropyl alcohol." 84 F.R. 14847. The FDA clearly intends to update its regulation of BAC. *Id*. Any safety and efficacy ruling here might easily conflict with that rulemaking and the 1994 TFM.

Further, classification of a product is within the primary jurisdiction of the FDA. *Weinberger v. Bentex Pharm., Inc*., 412 U.S. 645, 653 (1973); *see also Mollicone v. Universal Handicraft, Inc*., No. 216CV07322CASMRWX, 2017 WL 440257, at *13 (C.D. Cal. Jan. 30, 2017) (granting defendants' motion to dismiss because the FDA has primary jurisdiction on whether defendants are selling new drugs unlawfully); *Imagenetix, Inc. v. Frutarom USA, Inc*., No. 12CV2823-GPC WMC, 2013 WL 6419674, at *4 (S.D. Cal. Dec. 9, 2013) (granting defendant's summary judgment because the FDA had primary jurisdiction over whether the product should be classified as a new drug). Plaintiff will argue that Wet Ones® Antibacterial Hand Wipes do not have monograph status and thus, require new product approval from the FDA and/or are subject to Plaintiff's claims because there is no applicable OTC monograph. In addition to improperly stepping into the shoes of the federal agency which is actively enforcing in this area, Plaintiff seeks a different classification for Wet Ones® Antibacterial Hand Wipes. Both of the foregoing questions

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[2] *See e.g*. Topical Antimicrobial Drug Products: Consumer Antiseptic Tentative Final Monograph, 43 Fed. Reg. 4, 1210 (Jan. 6, 1978) ("1978 TFM"); 1994 TFM; Safety and Effectiveness of Consumer Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Proposed Amendment of the Tentative Final Monograph; Reopening of Administrative Record, 78 Fed. Reg. 242, 76444 (December 17, 2013); Safety and Effectiveness of Consumer Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Proposed Amendment of the Tentative Final Monograph; Reopening of Administrative Record, 81 Fed. Reg. 126, 42912 (June 29, 2016); 2019 Final Topical Antimicrobial Rule.

– whether Defendants' claims are outside of the currently applicable TFM and whether Defendants' products are a new product – are subject to the FDA's primary jurisdiction.

The FDA is actively regulating and enforcing its regulations as it relates to hand antiseptics and rubs. *See e.g. United States v. Innovative Biodefense, Inc.*, No. 8:18-cv-0996, 2020 LEXIS 155959 (C.D. Cal. May 4, 2020). In a case brought by the FDA, the California District Court recently enjoined the distribution of the hand-sanitizer, Zylast, until its maker obtains new drug approval or removes product claims that do not conform to final or tentative final OTC drug monographs and 21 C.F.R. Part 201. *Id.*

In *Zylast*, the California District Court found that "the 1994 tentative final monographs applies to Zylast" products containing the active ingredients ethyl alcohol[3] and benzethonium chloride. *United States v. Innovative Biodefense, Inc.*, No. 8:18-cv-0996, 2019 WL 2428670, at *9 (C.D. Cal. Feb. 22, 2019). The "[1994] TFM requires that the labeling describe the indicated use as 'handwashing to decrease bacteria on the skin,' and contains the same provision permitting other truthful statements, but only if they describe that indication for use." *Id.* at *7.

But unlike Defendants here, Zylast did not limit its product use claims to "decrease bacteria on skin," rather Zylast claimed "efficacy at killing specific pathogens, preventing specific diseases, and preventing the spread of certain illnesses among people." *Id.* at *8 ("These claims go beyond 'only the indications for use that have been established and listed' in the monograph."). The district court ultimately gave Zylast two choices: (1) seek new product approval as a "new drug," or (2) "remove from Defendants' [l]abeling all claims that do not conform to applicable final or tentative final OTC drug monographs relating to effectiveness against specific diseases or pathogens (such as, but not limited to,

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[3] The use of BAC and ethyl alcohol are similar in that they are both regulated by the 1994 TFM, *see e.g. Innovative Biodefense*, 2019 WL 2428670, at *9; and the FDA is currently seeking manufacturer data for the purpose of issuing further rulemakings on both those active ingredients, *see* 2019 Final Topical Antimicrobial Rule.

Methicillin-Resistant Staphylococcus Aureus ("MRSA"), Ebola, norovirus, diarrhea, rhinovirus, cold viruses, rotavirus, E. coli, H1N1, flu viruses, the stomach flu, HIV, Herpes viruses, or Vancomycin-resistant enterococci), including express or implied claims of effectiveness, extended efficacy claims, and infection reduction or prevention claims." *See e.g. Innovative Biodefense, Inc.*, 2020 LEXIS 155959 at *4 (C.D. Cal. May 4, 2020).

Importantly and unlike the claims involving Zylast, Wet Ones® Antibacterial Hand Wipes do not make pathogen-specific claims, rather Defendants' product clearly communicates the product's use, to "decrease bacteria on skin" in compliance with the 1994 TFM. Tobias Decl., ¶ 6(a). Plaintiff, on the other hand, by attempting to define "germs" to encompass pathogens, would bait Defendants into making pathogen-specific claims to draw it out of the confines of the 1994 TFM.[4] Plaintiff defines "germs" to encompass chlamydiae, parvoviruses, tuberculosis, coccidian (causing infection in dogs), norovirus, poliovirus, polyomavirus, human papillomavirus ("HPV"), picornavirus, coronavirus ("COVID-19"), severe acute respiratory syndrome ("SARS") coronavirus, middle east respiratory syndrome ("MERS") coronavirus, and C. difficile to name a few. *See* Plaintiff's Compl., ¶¶ 33, 35, 44, 46, 48. The 1994 TFM does not allow pathogen specific claims. Here, it is clearly within the FDA's primary jurisdiction to determine whether "[k]ills 99.99% of [g]erms" complies with the 1994 TFM's requirement to describe the use "to decrease bacteria on skin." Plaintiff also admits that the FDA "was deferring a ruling on whether the ingredients, including BAC, are generally recognized as safe and effective" Plaintiff's Compl., ¶ 59, further proof that BAC's safety and efficacy determination rests squarely with the FDA. As outlined in the 2019 Final Topical Antimicrobial Rule, the FDA is working with interested stakeholders—including

[4] Requiring label changes consistent with Plaintiff's demand would result in labeling requirements that are "different from or in addition to, or that is otherwise not identical with, a requirement under [the FDCA]...." further running afoul of the FDA's authority to regulate OTC FDCA labels. *See* 21 U.S.C. § 379r(a); *see also infra*, section I.B.

Defendants—to collect additional available data to determine what testing requirements may be needed to support a generally recognized as safe/generally recognized as effective ("GRAS/GRAE") determination for BAC, ethyl alcohol, and isopropyl alcohol. 84 Fed. Reg. 14847-01 at 14859-14860.[5] The question of the safety and effectiveness of BAC is clearly a question for the FDA. *Israel v. Baxter Labs*., Inc., 466 F.2d 272, 280 (D.C. Cir. 1972) (deferring to FDA because the question of whether a drug is safe and effective was "most properly for the FDA"). The Court should deny Plaintiff's attempt to litigate questions subject to the primary jurisdiction of the FDA.

B. THE FDA REGULATES WET ONES® ANTIBACTERIAL HAND WIPES PURSUANT TO THE 1994 TFM.

The FDCA authorizes the FDA to regulate, *inter alia*, the ingredients and labeling of nonprescription OTC drugs, including the hand wipe products at issue here. *See* 21 U.S.C. §§ 321, 352; 21 C.F.R. § 201, *et seq*.[6] Products do not require new drug application

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[5] The 2019 Final Topical Antimicrobial Rule made a final determination that 28 active ingredients that are not eligible for evaluation under the OTC drug review for use in a consumer antiseptic rub and would require an NDA or ANDA before further marketing after the effective date of the rule. *See* 2019 Final Topical Antimicrobial Rule. On the other hand, BAC was one of three ingredients deemed eligible for continued use in antiseptic products while the agency evaluated relevant safety and efficacy data. *Id*

[6] The FDA's overview of the "Over-the-Counter (OTC) Drug Monograph Process" provides:

> In 1972, FDA established the OTC Drug Review to evaluate the safety and effectiveness of hundreds of thousands of OTC drug products that were on the market at that time. Under the OTC Drug Review, FDA regulates certain nonprescription drugs using a system that groups products by therapeutic category. For each category, FDA issues an OTC drug monograph (OTC monograph).
>
> An OTC monograph is a "rule book" for each therapeutic category establishing conditions, such as active ingredients, uses (indications), doses, labeling, and testing, under which an OTC drug is generally recognized as safe and effective (GRASE) and can be marketed without a New Drug Application and FDA pre-market approval.

("NDA") or abbreviated new drug application ("ANDA") approval if they conform to the applicable OTC drug monograph. Title 21 of Code of Regulations § 330.1 provides:

> An over-the-counter (OTC) drug listed in this subchapter is generally recognized as safe and effective and is not misbranded if it meets each of the conditions contained in this part and each of the conditions contained in any applicable monograph. Any product which fails to conform to each of the conditions contained in this part and in an applicable monograph is liable to regulatory action.

21 C.F.R. § 330.1.

Here, Defendant Edgewell Personal Care Brands, LLC markets Wet Ones® Antibacterial Hand Wipes in compliance with the FDA's 1994 TFM. *See* 59 Fed. Reg. 31402.[7] The 1994 TFM addressed, *inter alia*, labeling for antiseptic hand washes for consumer use, and discussed their intended use, decreasing or helping to reduce bacteria on skin. *Id*. at 31,442.[8] The 1994 TFM provides exemplar claims for designated product

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FDA, Over-the-Counter (OTC) Drug Monograph Process, (9/03/2020) available at https://www.fda.gov/drugs/over-counter-otc-drug-monograph-process (last visited on September 19, 2020).

[7] Historically, the FDA has regulated Wet Ones® Antibacterial Hand Wipes through a patchwork of proposed rules and tentative and final monographs. The 1994 TFM was predated by a 1978 TFM for OTC topical antimicrobial products, in which it was proposed that BAC was safe and effective as a skin wound cleanser at a concentration of not greater than 1/750 in water. 43 Fed. Reg. 1210 at 1246. The agency also determined in the tentative final monograph for OTC first aid antiseptic drug products that the safe and effective concentration range for using benzalkonium chloride as a first aid antiseptic has been established as 0.1 percent to 0.13 percent. *See* 56 Fed. Reg. 33644 and 33663. First aid, however, was broken off prior to the 1994 TFM and is not part of our product's regulatory history. For Rulemaking History for OTC Topical Antimicrobial Drug Products, *see* Rulemaking History for OTC Topical Antimicrobial Drug Products, available at https://www.fda.gov/drugs/status-otc-rulemakings/rulemaking-history-otc-topical-antimicrobial-drug-products#Consumer_Antiseptic (last visited on September 19, 2020).

[8] The 1994 TFM notably did not address intended uses to reduce or prevent infection or illness from disease-related pathogens such as norovirus, rhinovirus, flu virus, MRSA and/or Ebola virus. *See* 1994 TFM. Here, Plaintiff seeks pathogen-specific labeling

uses, labeling content requirements and guidance for verification testing for "germ" kill tests. 59 Fed. Reg. 31402. Wet Ones® Antibacterial Hand Wipes comply with the 1994 TFM with respect to label claims, warnings, and verification and the 1978 TFM with respect to active ingredient concentration. Proposed monographs and TFMs have the effect of law, as not complying with them can result in regulatory action. 21 C.F.R 330.1; 21 C.F.R. 330.13(b)(2).

In its 2019 Final Topical Antimicrobial Rule, the FDA issued a final rule on the safety and effectiveness of consumer antiseptic rubs. *See* 84 Fed. Reg. 71, 14847. In doing so, the FDA deferred rulemaking on three active ingredients, including BAC, in order to allow for the development of additional safety and effectiveness data. 84 Fed. Reg. 71, 14847-01 at 14848. The FDA determined that BAC was an active ingredient eligible – not ineligible – for evaluation under the OTC Drug Review for use in consumer antiseptic rubs, but deferred final decision regarding BAC GRASE status. Recognizing the public health benefit provided by this class of products, FDA determined it would exercise enforcement discretion and permit OTC drug products containing those certain active ingredients to be marketed provided certain conditions are met. 68 Fed. Reg. 75585-01. As a result, the FDA continues to regulate Wet Ones® Antibacterial Hand Wipes pursuant to its 1994 TFM. "OTC drugs covered by ongoing OTC monograph proceedings may remain on the market as provided in current enforcement policies (*see, e.g.*, CPG section 450.300, 450.300, 21 C.F.R part 330)." DRAFT GUIDANCE MARKETED UNAPPROVED DRUGS – COMPLIANCE POLICY GUIDE, 2003 WL 24014273, at *8 (October 15, 2003). Thus, contrary to Plaintiff's allegations, BAC is not "nonmonograph." The foregoing clearly demonstrates the depth to which the FDA has regulated Wet Ones® Antibacterial Hand Wipes and its ongoing intention to continue to do so.

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changes "different from or in addition to, or that is otherwise not identical with, a requirement under" the 1994 TFM. *See* 21 U.S.C. § 379r(a); *see also infra*, section I.C.1.

C. PLAINTIFF'S CLAIMS ARE PREEMPTED BY THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.

Federal law preempts Plaintiff's attempt to use state law claims based on safety and efficacy to impose alternative labeling requirements for the Wet Ones® Antibacterial Hand Wipes. "The Supremacy Clause provides a clear rule that federal law 'shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, anything in the Constitution or Laws of any State to the Contrary notwithstanding.'" *Arizona v. United States*, 567 U.S. 387, 399 (2012) (quoting U.S. const. art. VI, cl. 2). "[S]tate law that conflicts with federal law is 'without effect.'" *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516 (1992) (citations omitted). "Federal preemption occurs when: (1) Congress enacts a statute that explicitly preempts 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); *Webb v. Trader Joe's Co.*, 418 F. Supp.3d 524, 527 (S.D. Cal. 2019). Preemption may be either express or implied. *Atay v. Cty. of Maui*, 842 F.3d 688, 699 (9th Cir. 2016). Here, Congress has unambiguously intended to expressly and impliedly preempt state law claims imposing labeling requirements differing from or in addition to those required by federal regulations.

1. Plaintiff's claims are expressly preempted.

Plaintiff's state law claims, if successful, would impose state law "requirements" that are expressly preempted under § 379r of the FDCA. Section 379r(a) provides that states may not establish "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).

The FDA regulates the labeling requirements of Wet Ones® Antibacterial Hand Wipes through 21 C.F.R. 201.66 in conjunction with the 1994 TFM and provides labeling requirements related to directions and use, intended purpose, ingredients, disclosures, safety warnings, potential allergic reactions and when to discontinue use. *See* 21 C.F.R.

201.66(c); 1994 TFM, at 116, 333.450(c). "The content and format requirements [of 21 C.F.R. 201.66] must be followed unless otherwise specifically provided in the applicable monograph or regulation." 21 C.F.R. 201.66(a). "An OTC drug product that is not in compliance with the format and content requirements in this section is subject to regulatory action." 21 C.F.R. § 201.66(g). Defendants make no claims outside of the 1994 TFM. If they did, the FDA would require new drug approval. Plaintiff plainly seeks to impose labeling requirements beyond the 1994 TFM's requirement to describe the use "to decrease bacteria on skin," evading the FDA's regulatory authority. *See e.g.* Plaintiff's Compl. ¶¶ 29, 30, 105, 119. Plaintiff also seeks to impose testing requirements that conflict with the 1994 TFM. *See e.g.* Plaintiff's Compl. ¶ 33. As such, Plaintiff's claims are expressly preempted.

2. Plaintiff's Claims are Impliedly Preempted.

Even though the FDCA contains an express preemption provision, such a provision does not foreclose the applicability of implied preemption as well. *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287-89 (1995). "[A] federal statute implicitly overrides state law either when the scope of a statute indicates that Congress intended federal law to occupy a field exclusively, or when state law is in actual conflict with federal law." *Id.* at 287 (internal citation omitted). Implied or conflict preemption arises when a state-law claim "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" or a federal agency acting within the scope of its congressionally delegated authority. *Capital Cities Cable, Inc. v. Crisp*, 467 U.S. 691, 698-99, (1984) (citation omitted).

"[C]laims seeking to enforce the FDCA must thread a 'narrow gap' to escape preemption." *Somers v. Beiersdorf, Inc.*, No. 14CV2241-LAB (AGS), 2020 WL 1890575, at *3 (S.D. Cal. Apr. 15, 2020). "The plaintiff must be suing for conduct that violates the FDCA (or else [the] claim is expressly preempted . . . but the plaintiff must not be suing because the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman [Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 353 (2001)]." *Id.* (citations

omitted). In *Somers*, the plaintiff did not thread that narrow gap because she alleged that product purported misrepresentations deemed the product a "new drug" under FDA regulations (resulting in a finding of implied preemption). *Id*. The Court further characterized plaintiff's effort "as an attempt to privately enforce the FDCA." *Id*. Here, Plaintiff is either seeking to enforce labeling requirements "different from or in addition to" the 1994 TFM or to enforce the 1994 TFM via the FDCA. Both approaches are preempted.

3. The FDCA bars private enforcement actions.

Plaintiff does not have a private right to allege FDCA violations. "[A]ll proceedings for the enforcement, or to restrain violations of [the Act] shall be by and in the name of the United States." 21 U.S.C.A. § 337. Courts have interpreted this provision to "mean that no private right of action exists to redress alleged violations of the FDCA." *Summit Tech., Inc. v. High-Line Med. Instruments Co., Inc*., 922 F. Supp. 299, 305 (C.D. Cal. 1996); *see also Gile v. Optical Radiation Corp*., 22 F.3d 540, 544 (3d Cir. 1994), *cert. denied*, 513 U.S. 965 (1994) ("violations of the FDCA do not create private rights of action"); *In re Epogen & Aranesp Off-Label Mktg. & Sales Practices Litig*., 590 F. Supp.2d 1282, 1290-91 (C.D. Cal. 2009) (The absence of a private right of action also prohibits use of "state unfair competition laws" "as a vehicle to bring a private cause of action that is based on violations of the FDCA.")

Here, Plaintiff tries to sidestep the applicability of multiple tentative and final monographs that have regulated and currently regulate Wet Ones® Antibacterial Hand Wipes by arguing that FDA regulations simply do not apply. *See* Plaintiff's Compl., ¶¶ 58-60. Any such holding would be in direct contradiction to the arguments advanced by the FDA in its regulatory action against *Innovative Biodefense, Inc*. and that district court's holding that the 1994 TFM applies to Zylast products that similarly contain one of the three deferred active ingredients, ethyl alcohol. *See Innovative Biodefense, Inc*., 2019 WL 2428670, at *9. Should Plaintiff pivot to suggest she is seeking to enforce the FDCA, that enforcement action is barred.

II. PLAINTIFF LACKS STANDING REQUIRING DISMISSAL.

A. PLAINTIFF LACKS ARTICLE III STANDING.

The Court also should dismiss Plaintiff's claims because the Court lacks subject matter jurisdiction. Fed. R. Civ. P. 12(b)(1). Article III of the United States Constitution dictates that jurisdiction of the federal courts extends only to actual cases or controversies. U.S. Const. art. III; *see also Lujan v. Defs. of Wildlife*, 504 U.S. 555, 590, (1992). To satisfy standing under Article III of the U.S. Constitution, a plaintiff has the burden to show: (1) an injury-in-fact; (2) that the injury is traceable to the challenged action of the defendant; and (3) that the injury is redressable by a favorable ruling. *Lujan*, 504 U.S. at 560–61. *See also Monsanto Co. v. Geertson Seed Farms*, 130 S. Ct. 2743, 2752 (2010); *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs*. (TOC), Inc., 528 U.S. 167, 180-81 (2000). When the face of a complaint fails to demonstrate a basis for standing, the court should dismiss the action.

1. Plaintiff fails to allege an injury-in-fact.

Plaintiff fails to allege an injury-in-fact required for standing under Article III. The Supreme Court has held that a plaintiff must suffer an injury that is "concrete and particularized" and "actual or imminent, not conjectural or hypothetical." *Lujan*, 504 U.S. at 560; *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1545 (2016); *Friends of the Earth*, 528 U.S. at 180 (2000). Where a complaint makes allegations of potential future injury, the threat of future harm must be "certainly impending" as opposed to a mere possibility. *Whitmore v. Arkansas*, 495 U.S. 149, 158 (1990); *Lujan*, 504 U.S.at 564.

Here, Plaintiff fails to allege that she suffered from any disease resulting from exposure to the microbes that she alleges Wet Ones® Antibacterial Hand Wipes are ineffective at killing. *See generally* Plaintiff's Compl. Plaintiff also fails to allege that she suffered any kind of allergic reaction. *Id*. Plaintiff does not even allege that she used Wet Ones® Antibacterial Hand Wipes. *Id*. Instead, Plaintiff's claims are entirely premised on conjectural and hypothetical risks of diseases and allergic reactions that she fails to allege occurred. *See Birdsong v. Apple, Inc*., 590 F.3d 955, 961 (9th Cir. 2009) ("the alleged loss

in value does not constitute a distinct and palpable injury that is actual or imminent because it rests on a hypothetical risk"). Therefore, this Court should reject Plaintiff's "attempt[s] to recast no-injury products-liability claims (which are not cognizable) as consumer fraud claims for contract-like economic damages." *See Lassen v. Nissan N. Am., Inc*., 211 F.Supp. 3d 1267, 1281 (C.D. Cal. 2016).

2. Plaintiff's alleged economic injury does not satisfy injury-in-fact.

Plaintiff also fails to allege that any economic injury—there isn't one—satisfies injury-in-fact. "To properly plead an economic injury, a consumer must allege that she was exposed to false information about the product purchased, which caused the product to be sold at a higher price, and that she 'would not have purchased the goods in question absent this misrepresentation.'" *Davidson v. Kimberly-Clark Corp*., 889 F.3d 956, 966 (9th Cir. 2018), *cert. denied*, 139 S. Ct. 640, 202 (2018) (quoting *Hinojos v. Kohl's Corp*., 718 F.3d 1098, 1105 (9th Cir. 2013), *as amended on denial of reh'g and reh'g en banc* (July 8, 2013)). In *Davidson v. Kimberly-Clark*, the plaintiff sufficiently pled an economic injury because she paid a premium for the falsely-advertised product. *Id*. at 965-966. Here, Plaintiff merely alleges that she "would not have purchased the Products, or would have purchased them on different terms, if she had known the truth." Plaintiff's Compl., ¶ 84. That allegation is fatally defective, requiring dismissal.

Courts have found that a plaintiff's allegation that they would not have purchased a product had they known of some misrepresentation is insufficient to establish injury-in-fact on its own. *See e.g. Contreras v. Toyota Motor Sales U.S.A. Inc*., 484 F. App'x. 116, 118 (9th Cir. 2012) (affirming dismissal because plaintiffs' allegation "that they would not have purchased the vehicles had they known of the defect" did not meet the standing requirement); *Degelmann v. Advanced Medical Optics, Inc*., No. C 07-3107 PJH, 2010 WL 55874, at *3-4 (N.D. Cal., Jan. 4, 2010) (granting defendants' motion to dismiss for lack of standing, finding plaintiffs' allegations that they would not have purchased a contact lens solution had they known that the solution was less effective against a certain disease, insufficient); *Herrington v. Johnson & Johnson Consumer Companies, Inc*., C 09-1597

CW, 2010 WL 3448531, at *4-5 (N.D. Cal. Sept. 1, 2010) (granting defendants' motion to dismiss, finding plaintiffs' allegation that "they would have never purchased these products had they known of the presence of these contaminants" insufficient to establish injury-in-fact).

As plead, Plaintiff fails to allege an economic injury sufficient to establish injury-in-fact, as required for standing under Article III. Accordingly, the Court should grant Defendants' Motion to Dismiss.

B. PLAINTIFF LACKS STATUTORY STANDING UNDER THE CLRA, UCL AND FAL.

Plaintiff fails to plead reliance as required for standing under the CLRA, UCL, and FAL. *See In re Sony Gaming Networks & Customer Data Sec. Breach Litig*., 903 F. Supp.2d 942 at 969 (S.D. Cal. 2012) ("For fraud-based claims under all three consumer statutes the named Class members must allege actual reliance to have standing."); *Bronson v. Johnson & Johnson, Inc*., No. C 12–04184 CRB, 2013 WL 1629191, at *2 (N.D. Cal. Apr. 16, 2013); *Hall v. Sea World Entm't, Inc*., 3:15-CV-660-CAB-RBB, 2015 WL 9659911, at *3 (S.D. Cal. Dec. 23, 2015). When proceeding on a claim of misrepresentation, a plaintiff "must demonstrate actual reliance on the allegedly deceptive or misleading statements." *Graham v. VCA Animal Hosps., Inc*., 729 Fed. Appx. 537, 539 (9th Cir. 2018) (quoting *In re Tobacco II Cases*, 207 P.3d 20, 25–26 (2009). *See* also *Kwikset Corp. v. Superior Court*, 246 P.3d 877, 888 (Cal. 2011). A plaintiff "must demonstrate actual reliance…in accordance with well-settled principles regarding the element of reliance in ordinary fraud actions." *Kwikset Corp*., 246 P.3d at 888. Consequently, "a plaintiff must show that the misrepresentation was an immediate cause of the injury-producing conduct." *Id*.

1. Plaintiff lacks standing to challenge Wet Ones® Antibacterial Hand Wipes' marketing and advertising.

Plaintiff fails to plead reliance on marketing and advertising of Wet Ones® Antibacterial Hand Wipes. In order to have standing to challenge marketing and

advertising, a plaintiff must allege reliance on such marketing and advertising. *See Fisher v. Monster Beverage Corp*., 656 Fed. Appx. 819, 822 (9th Cir. 2016) (citing to *Kwikset* and affirming that plaintiff lacked standing when he failed to rely on any specific misrepresentations); *Bronson v. Johnson & Johnson, Inc*., 2013 WL 1629191, at *2 (holding that plaintiffs lacked standing to challenge advertising when plaintiffs failed to allege they relied on advertisements beyond one vague reference to commercial marketing*); In re Sony Gaming Networks & Customer Data Sec. Breach Litig.*, 903 F. Supp.2d at 970 (dismissing claims under the UCL, FAL, and CLRA "because Plaintiffs have not plead actual reliance, cannot rely on an inference of reliance, and have not alleged a long-term advertising campaign such that reliance is unnecessary").

Here, Plaintiff seeks to enjoin Defendants from marketing and advertising Wet Ones® Antibacterial Hand Wipes. Plaintiff's Compl. ¶ 28. However, Plaintiff only makes vague references to "advertising" and "marketing." *See e.g*., Plaintiff's Compl. ¶¶ 15, 19, 107. Plaintiff fails to plead any information regarding what was contained in the "advertising" and "marketing" that she seeks to challenge and fails to allege that she even relied on "advertising" or "marketing" when purchasing the products. *See generally* Plaintiff's Compl. Thus, Plaintiff has no standing to challenge Defendants' "advertising" and "marketing" of Wet Ones® Antibacterial Hand Wipes.

2. Plaintiff lacks standing regarding any alleged misrepresentation of Wet Ones® Antibacterial Hand Wipes' directions for "children 2 years and over."

Similarly, Plaintiff fails to allege that she relied on Wet Ones® Antibacterial Hand Wipes directions for "children 2 years and over" when purchasing the product.[9] Without any allegation of reliance on the alleged misrepresentation of Wet Ones® Antibacterial Hand Wipes' directions for "children 2 years and over," Plaintiff fails to allege facts

[9] Wet Ones® Antibacterial Hand Wipes directions "for children 2 years and older" is not included in Plaintiff's general definition of "Representations" used throughout the Complaint. *See* Plaintiff's Compl. ¶¶ 23, 62.

sufficient to establish standing under the UCL, FAL, and CLRA, and any claim related to this alleged misrepresentation should be dismissed.

3. Plaintiff fails to plead reliance on misrepresentations.

Plaintiff generally alleges that she "purchased the Products in reliance on the Representations made by Defendants." *See* Plaintiff's Compl. ¶¶ 82, 112, 120. Plaintiff provides photographs of the Wet Ones® Antibacterial Hand Wipes Tropical Splash container and references to labeling and advertising, but fails to allege she viewed or read the labels with alleged misrepresentations prior to purchasing the product. Plaintiff's conclusory statement that she "relied on the representations" is not sufficient here to allege standing required for her CLRA, UCL, and FAL claims. Accordingly, Plaintiff's claims should be dismissed.

III. PLAINTIFF FAILS TO STATE A CLAIM.

Plaintiff's claims face further dismissal because they fail to state a claim upon which relief may be granted. Fed. R. Civ. P. 12(b)(6). To survive a motion to dismiss, Plaintiff must plead "sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 663 (2009) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007); *see also* Fed. R. Civ. P. 8; *Twombly*, 550 U.S. at 555 (Under Rule 8, a plaintiff's "obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do. . . . Factual allegations must be enough to raise a right to relief above the speculative level.") (internal quotations and alteration omitted). "A claim has facial plausibility when the pleaded factual content allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 129 (citing *Twombly*, 550 U.S. at 556).

A. PLAINTIFF FAILS TO MEET RULE 9(B)'S HEIGHTENED PLEADING STANDARD.

Plaintiff's CLRA, FAL, and UCL causes of action are all grounded in fraud and subject to the heightened pleading requirements of Rule 9(b). *See* Kearns v. Ford Motor Co., 567 F.3d 1120, 1125-26 (9th Cir. 2009). To meet the requirements of Rule 9(b), "a party must state with particularity the circumstances constituting fraud...." Fed.R.Civ.P. 9(b). The Plaintiff must "identify the who, what, when, where, and how of the misconduct charged." *Kearns*, 567 F.3d at 1124 (quoting *Vess v. Ciba–Geigy Corp. USA*, 317 F.3d 1097, 1106 (9th Cir.2003)).

Rule 9(b) requires that the circumstances constituting the alleged fraud "be 'specific enough to give defendants notice of the particular misconduct ... so that they can defend against the charge and not just deny that they have done anything wrong.'" *Kearns*, 567 F.3d at 1124 (quoting *Bly-Magee v. California*, 236 F.3d 1014, 1019 (9th Cir. 2001)). In *Kearns*, the plaintiff alleged defendant made misrepresentations through its national marketing campaign, sales materials, and sales personnel. *Id*. at 1125-26. Those allegations were insufficient to require Rule 9(b) dismissal. *Id*. Plaintiff "failed to articulate the who, what, when, where, and how . . .". *Id*. at 1126. He failed to specify the "particular circumstances surrounding such representations . . . when he was exposed . . . which material he relied upon in making his decision to buy. . .". *Id*. Likewise, Plaintiff alleges issues with Defendants' label, but not that she read or relied on any of them in advance of her purchase.

Rule (9)(b) also serves to deter plaintiffs from filing complaints as a pretext for discovering unknown wrongs, to protect defendants' reputations from allegations of fraud, and to prohibit plaintiffs from unilaterally imposing enormous social and economic costs on the court, parties, and society without some factual basis. *Kearns*, 567 F.3d at 1125; *see also Haskins v. Symantec Corp*., 654 Fed. Appx. 338, 339 (9th Cir. 2016) (affirming dismissal of plaintiff's UCL and CLRA claims because plaintiff "did not allege that she read and relied on a specific misrepresentation"); *Hall v. Sea World Entm't, Inc*., 3:15-CV-

660-CAB-RBB, 2016 WL 4595948, at *4 (S.D. Cal. May 13, 2016), *aff'd sub nom. Hall v. SeaWorld Entm't, Inc.*, 747 Fed. Appx. 449 (9th Cir. 2018) (dismissing plaintiffs' complaint that "fails to identify whether Plaintiffs actually saw such statements, when Plaintiffs saw them, where Plaintiffs saw them, and why such statements are measurably false").

1. Plaintiff fails to plead with particularity the circumstances of her purchase.

Plaintiff failed to plead with particularity the what, when, and where circumstances of her purchase. Plaintiff fails to plead with particularity what Wet Ones® Antibacterial Hand Wipes she purchased. *See* Plaintiff's Compl., ¶ 81 (alleging that she "purchased the Products…in various scents, sizes and configurations, including but not limited to Wet Ones travel packs, singles and canisters"). Plaintiff fails to plead with particularity when she purchased Wet Ones® Antibacterial Hand Wipes. *See* Plaintiff's Compl., ¶ 81 ("Plaintiff purchased the Products multiple times during the class period…and including in or about March of 2020"). Plaintiff also fails to plead with particularity where she purchased Wet Ones® Antibacterial Hand Wipes. *See* Venue Declaration of Plaintiff Lauren Souter ¶ 5 ("I purchased the Products at issue in San Diego, California."). Plaintiff's failure to plead with particularity the what, when, and where circumstances leaves Defendants without specific enough information to defend. *See Kearns*, 567 F.3d at 1124, 1126. The Court should not force Defendants to defend against Plaintiff's claims that lack factual basis and fail to comply with the heightened pleading standard.

2. Plaintiff fails to plead with particularity that she relied on any of the alleged misrepresentations.

Plaintiff also fails to plead with particularity how, when, and why she relied on any of the alleged misrepresentations. *See generally*, Plaintiff's Compl. Conclusory allegations that a plaintiff relied on a list of representations is insufficient. *Haskins v. Symantec Corp.*, 13-CV-01834-JST, 2014 WL 2450996, at *1 (N.D. Cal. June 2, 2014), *aff'd*, 654 Fed. Appx. 338 (9th Cir. 2016) (finding that plaintiff's UCL and CLRA claims

failed to meet the heightened standard of Rule 9(b) when plaintiff failed to identify which representation she viewed and relied on).

Plaintiff makes conclusory allegations that she "purchased the Products in reliance on the Representations made by Defendants." *See* Plaintiff's Compl. ¶¶ 82, 112, 120. Plaintiff provides photographs of the Wet Ones® Antibacterial Hand Wipes Tropical Splash container and references labeling and advertising, but fails to allege that she viewed or read the labels with alleged misrepresentations prior to purchasing the product. Instead of providing Defendants with particular notice of alleged wrongdoing as required by Rule 9(b), Plaintiff leaves Defendants guessing how and when Plaintiff became aware of the alleged misrepresentations and the extent to which she relied on any of them.

Additionally, Plaintiff fails to plead generally, let alone particularly, that she relied on the alleged misrepresentations of Wet Ones® Antibacterial Hand Wipes' directions for "children 2 years and over." Plaintiff alleges that a "French medical agency cautioned consumers not to use wipes containing [an inactive ingredient in Wet Ones® Antibacterial Hand Wipes] on children under the age of three years…" Plaintiff's Compl. ¶ 9. Plaintiff points out that the label provides directions for "children 2 years and over" to use Wet Ones® Antibacterial Hand Wipes. Plaintiff's Compl. ¶ 24; *see also* Tobias Decl. ¶ 6(g). Later, Plaintiff alleges that she purchased Wet Ones® Antibacterial Hand Wipes "for use on her son." Plaintiff's Compl. ¶ 81. Plaintiff fails to allege who her son is, how old her son is, and how or when she became aware of Wet Ones® Antibacterial Hand Wipes' directions for "children 2 years and over." *See generally* Plaintiff's Compl. Defendants are left without sufficient information to know if Plaintiff even brings a claim for such alleged misrepresentation.

Further, Plaintiff fails to plead with particularity any misrepresentation related to Defendants' marketing and advertising of Wet Ones® Antibacterial Hand Wipes. Plaintiff seeks to enjoin Defendants from marketing and advertising Wet Ones® Antibacterial Hand Wipes without identifying any specific representation contained in such marketing and

advertising. Plaintiff's Compl. ¶ 28. Plaintiff must allege the particular circumstances surrounding any marketing and advertising representations. *See Kearns*, 567 F.3d at 1128.

Plaintiff only vaguely mentions "advertising" and "marketing" throughout the complaint. *See* Plaintiff's Compl. ¶¶ 15, 19, 107. Plaintiff does not allege what advertising or marketing she viewed, read, or heard. *Id*. Nor does she allege what representations the advertising and marketing contained, when she was exposed to such representations, and where she was exposed to such representations. *Id*. Plaintiff also fails to allege that she relied on marketing and advertising, let alone how or why she relied on such marketing and advertising. *Id*. Plaintiff's claims related to marketing and advertising should be dismissed.

Accordingly, Plaintiff fails to meet the heightened pleading standard under Rule 9(b) to state a claim on this basis under the UCL, FAL, CLRA, and common law claims of Breach of Express Warranty and Quasi Contract.

B. PLAINTIFF'S CLAIMS FAIL TO MEET THE REASONABLE CONSUMER STANDARD.

Plaintiff's claims under the CLRA, UCL, and FAL are governed by the reasonable consumer standard. *Williams v. Gerber Products Co*., 552 F.3d 934, 938 (9th Cir. 2008). The "reasonable consumer" standard requires more than a mere possibility that a label "might conceivably be misunderstood by some consumers viewing it in an unreasonable manner." *Ebner v. Fresh, Inc*., 838 F.3d 958, 965 (9th Cir. 2016) (quoting *Lavie v. Procter & Gamble Co*., 105 Cal. App.4th 496, 508 (2003)). Rather, it requires a probability "that a significant portion of the general consuming public or of targeted consumers, acting reasonably in the circumstances, could be misled." *Id*. Dismissal is appropriate where a Court can conclude as a matter of law that members of the public are not likely to be deceived by an advertisement. *Ebner*, 838 F.3d at 965-66 (affirming dismissal of label-based claims with no plausible claim of deception); *Forouzesh v. Starbucks Corp*., 714 Fed. Appx. 776, 777 (9th Cir. 2018) (holding no reasonable consumer would think a 12-ounce iced drink would contain 12 ounces of liquid and no ice). Further, as this Court has

noted, "[c]ommon sense dictates [claims of deception], and [p]laintiffs cannot claim deception on label statements modeled on FDA guidance." *Andrade-Heymsfield v. Danone US, Inc.*, 19-CV-589-CAB-WVG, 2019 WL 3817948, at *8 (S.D. Cal. Aug. 14, 2019), *appeal dismissed*, 19-56082, 2020 WL 5513552 (9th Cir. Aug. 13, 2020) (granting defendant's motion to dismiss and finding that a reasonable consumer is not likely to be deceived by plaintiff's theory that claims that the product is healthy are misleading because the product makes it harder to reduce the risk of osteoporosis when the product makes no claim to treat or prevent osteoporosis and complies with FDA guidance.).

1. A reasonable consumer could not be misled by Wet Ones® Antibacterial Hand Wipes' label that states "Kills 99.9% of Germs."

Even if Wet Ones® Antibacterial Hand Wipes were ineffective against the myriad of microbes listed in Plaintiff's Complaint, Plaintiff fails to allege that a reasonable consumer would be deceived. Plaintiff fails to allege why a reasonable consumer would expect a hand wipe to be effective against sexually-transmitted diseases, such as human papillomavirus, or food borne illnesses, such as norovirus, polyomavirus, and hepatitis A. *See* Plaintiff's Compl. ¶ 35. Further, Plaintiff fails to allege why a reasonable consumer would use a hand wipe labeled "keep hands fresh and clean when soap and water are not available" after handling cat litter or undercooked food and then expect the hand wipe to kill cryptosporidium found in the cat litter or undercooked food. *See* Plaintiff's Compl. ¶ 52. Plaintiff's claims should be dismissed for lack of a plausible theory of deception under the reasonable consumer standard.

2. A reasonable consumer could not be misled by Wet Ones® Antibacterial Hand Wipes' label that states "hypoallergenic" and "gentle."

Plaintiff alleges that numerous ingredients are "known allergens or skin irritants" and therefore the products are not hypoallergenic and gentle. ¶ 63. A reasonable consumer could not believe that hypoallergenic means that the product contains absolutely no irritants

or sensitizers, but instead that the product has a decreased tendency to provoke an allergic reaction.

Plaintiff further attempts to argue that hypoallergenic and gentle means that the product does not include ingredients that could possibly contain any "adverse health effects" such as triggering asthma symptoms, depressing the central nervous system, causing reproductive and development toxicity, and causing organ damage and toxicity. *See* Plaintiff's Compl. ¶¶ 68, 20-72. No reasonable consumer could interpret hypoallergenic to encompass such alleged "adverse health effects" that have nothing to do with allergies.

Further, Plaintiff does not allege that Wet Ones® Antibacterial Hand Wipes contains amounts or concentrations likely to cause such "adverse health effects" when the product is used as directed. Even if Wet Ones® Antibacterial Hand Wipes did, a reasonable consumer could not plausibly interpret "gentle" and "hypoallergenic" to mean that they would have no possibility of such "adverse health effects" if they ingested, inhaled, or used wipes in their eyes because the Wet Ones® Antibacterial Hand Wipes label clearly states that the wipes are for "external use only," and that the wipes should be "appl[ied] to hands." Tobias Decl. at ¶¶ 6(b), 6(g). The name of the product itself, Wet Ones® Antibacterial Hand Wipes, emphasizes that the product is a hand wipe. The label also specifically states that "[w]hen using this product do not get into eyes" and "[i]f contact occurs, rinse thoroughly with water." Tobias Decl. at ¶6(e). Further, the label states to "[k]eep out of reach of children," and [i]f swallowed, get medical help or contact Poison Control Center right away." Tobias Decl. at ¶ 6(f).

It is not plausible that a reasonable consumer could be misled in the manner alleged by Plaintiff and therefore Plaintiff's claims based on Defendant's representation that Wet Ones® Antibacterial Hand Wipes are "gentle" and "hypoallergenic" should be dismissed.

IV. PLAINTIFF IS NOT ENTITLED TO EQUITABLE RELIEF.

The Court should dismiss Plaintiff's equitable claims because she failed to allege she lacked an adequate remedy at law, failed to allege she will be deceived in the future, and failed to allege facts to establish a basis for restitution. The Court lacks subject matter jurisdiction over Plaintiff's equitable claims because Plaintiff does not have standing to assert equitable claims. *See* Fed. R. Civ. P. 12(b)(1); *see also Bowker v. Morton*, 541 F.2d 1347, 1349 (9th Cir. 1976) (Standing requires proof of a particularized injury, as a result of defendants' actions, "which injury will be redressed by the remedy sought."). The Court should further dismiss Plaintiff's equitable claims for failure to state a claim. *See* Fed. R. Civ. P. 12(b)(6); *see also Conservation Force v. Salazar*, 646 F.3d 1240, 1242 (9th Cir. 2011) (Rule 12(b)(6) dismissal "is proper if there is a 'lack of a cognizable legal theory or the absence of sufficient facts alleged under a cognizable legal theory.'") (citations omitted).

A. PLAINTFF FAILS TO ESTABLISH THAT SHE LACKED AN ADEQUATE REMEDY AT LAW.

Plaintiff "must establish that she lacks an adequate remedy at law before securing equitable restitution for past harm under the UCL and CLRA." *Sonner v. Premier Nutrition Corp.*, 971 F.3d, at 844. "It is a basic doctrine of equity jurisprudence that courts of equity should not act ... when the moving party has an adequate remedy at law." *Id.* (citations omitted). In *Sonner*, the Ninth Circuit affirmed the dismissal of plaintiff's UCL and CLRA claims for equitable restitution because plaintiff failed: (i) to allege she lacked an adequate remedy at law, and (ii) to show she lacked an adequate remedy at law for damages under CLRA. *Id.* at 844-45. Here, Plaintiff "seeks compensatory, monetary and punitive damages, in addition to equitable and injunctive relief . . . [and] restitution." Plaintiff's Compl. ¶ 142, Prayer. Plaintiff's claims for equitable relief should be dismissed for failure to state an adequate remedy at law.

B. PLAINTIFF FAILED TO ALLEGE THAT SHE WILL NOT BE DECEIVED IN THE FUTURE.

To maintain standing for injunctive relief, Plaintiff must show a sufficient likelihood that she will be injured by Defendants again in a similar way and that the future injury can be redressed by injunctive relief. Plaintiff must allege that she will "suffer an actual and imminent, not conjectural or hypothetical threat of future harm." *Davidson v. Kimberly-Clark Corp*., 889 F.3d at 969. "In other words, the 'threatened injury must be certainly impending to constitute injury in fact' and 'allegations of possible future injury are not sufficient.'" *Id*. at 967 (quoting *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013)).

In *Davidson v. Kimberly-Clark*, the Court found that the threat of future harm may be satisfied by "consumer's plausible allegations that she will be unable to rely on the product's advertising or labeling in the future, and so will not purchase the product although she would like to" or "that she might purchase the product in the future, despite the fact it was once marred by false advertising or labeling, as she may reasonably, but incorrectly, assume the product was improved." 889 F.3d at 969–70.

Here, Plaintiff fails to make any such plausible allegations. Plaintiff does not allege that she will be unable to rely on the products advertising or labeling in the future or that she will not purchase the product in the future although she would like to. *See* Plaintiff's Compl. Plaintiff also does not allege that she might purchase the product in the future and may assume the product was improved. *Id*. Plaintiff merely alleges "it is possible, however, that Plaintiff would purchase the Products in the future if the Representations were truthful." Plaintiff's Compl. ¶ 85.

Plaintiff's broad and conclusory allegation of possible future injury is insufficient to establish standing. *See Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 133 (2013) ("allegations of possible future injury are not sufficient" to establish standing); *Sciacca v. Apple, Inc*., 362 F. Supp. 3d 787, 803 (N.D. Cal. 2019) (granting defendant's motion to dismiss because "[p]laintiff's allegation that he may have the watch repaired, which might result in the alleged defect manifesting again, is far from a future injury that is certainly

impending. Rather, Plaintiff only alleges possible future injury."); Lu*man v. Theismann*, 647 Fed. Appx. 804, 807 (9th Cir. 2016) (affirming dismissal of plaintiffs' claims for injunctive relief because plaintiffs failed to allege they intended to purchase the product in the future). Accordingly, Plaintiff's claims for injunctive relief should be dismissed.

C. PLAINTIFF FAILED TO ALLEGE FACTS SUFFICIENT TO ESTABLISH SHE IS ENTITLED TO RESTITUTION.

When a plaintiff receives some value from a product, the proper measure of restitution is the difference between what the plaintiff paid and the value of what the plaintiff received. *In re Tobacco Cases II*, 240 Cal. App. 4th 779, 802 (2015) (finding it "implausible to show a smoker received no value from a particular type of cigarette" and therefore holding the trial court lacked discretion to award restitution when plaintiffs "did not establish any price/value differential"). *See also Brazil v. Dole Packaged Foods, LLC*, 660 Fed. Appx. 531, 534 (9th Cir. 2016) (affirming district court's limitation of restitution under the UCL, FAL, and CLRA "to the difference between the prices customers paid and the value of the fruit they bought"); *Chowning v. Kohl's Dep't Stores, Inc*., 735 Fed. Appx. 924, 925 (9th Cir.), *amended on denial of reh'g*, 733 Fed. Appx. 404 (9th Cir. 2018) ("Under California law, where a plaintiff obtains value from the product, the proper measure of restitution is the difference between what the plaintiff paid and the value of what the plaintiff received.") Dismissal is appropriate when a plaintiff fails to allege facts sufficient to establish restitution. *See Warner v. Tinder Inc*., 105 F. Supp. 3d 1083, 1095 (C.D. Cal. 2015) (granting defendant's motion to dismiss in part because plaintiff failed to allege that the product "was worth less than what he paid for" and had "therefore not pled that he suffered a loss capable of restitution under the FAL or UCL.").

Here, Plaintiff fails to allege that the Wet Ones® Antibacterial Hand Wipes she allegedly purchased were worth any less than what she paid for or that she paid a premium for any alleged misrepresentations. *See* Plaintiff's Compl. Plaintiff fails to even allege the price she paid for Wet Ones® Antibacterial Hand Wipes. *Id*. Accordingly, Plaintiff's

claims for restitution should be dismissed for a failure to plead that she suffered a loss capable of restitution.

CONCLUSION

The Court should dismiss this action. Plaintiff's claims are subject to the primary jurisdiction of the FDA. Plaintiff's claims are expressly preempted by the FDCA, which further prohibits private enforcement actions. Plaintiff lacks Article III standing for failing to allege an injury-in-fact and statutory standing under the CLRA, UCL, and FAL because, *inter alia*, she failed to allege reliance. Plaintiff failed to meet Rule 9(b)'s heightened pleading standard which required her to plead with particularity, the circumstances of her purchase, reliance, and how plaintiff intends to meet the reasonable consumer standard. Equity relief is also barred because Plaintiff failed to allege she lacked an adequate remedy at law. Any one of the foregoing arguments represents sufficient grounds to dismiss Plaintiff's Complaint. Accordingly, the Court should dismiss this action.

DATED: October 6, 2020

By: /s/ Daniel E. Eaton
SELTZER CAPLAN MCMAHON VITEK
Daniel Eaton CASB 144663

STINSON LLP
John W. Moticka (pro hac vice pending)
Megan McCurdy (pro hac vice pending)
Ashley Crisafulli (pro hac vice pending)
Attorneys for Defendants

EDGEWELL PERSONAL CARE COMPANY, EDGEWELL PERSONAL CARE BRANDS, LLC and EDGEWELL PERSONAL CARE, LLC