

1 THE HONORABLE JOHN C. COUGHENOUR
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7 UNITED STATES DISTRICT COURT
8 WESTERN DISTRICT OF WASHINGTON
9 AT SEATTLE

10 SHANNON MACK, and LINDSEY
11 FARROW, *individually and on behalf of all*
12 *others similarly situated,*

13 Plaintiffs,

14 v.

15 AMAZON.COM, INC.,

16 Defendant.

17 CASE NO. C22-1310-JCC

18 ORDER

19 This matter comes before the Court on Defendant’s motion to dismiss Plaintiffs’ first
20 amended class action complaint (“FAC”) (Dkt. No. 29). Having thoroughly considered the
21 briefing and the relevant record, and finding oral argument unnecessary the Court DENIES the
22 motion for the reasons explained herein.

23 **I. BACKGROUND**

24 Plaintiffs allege they purchased and used Solimo, a melatonin supplement manufactured
25 and sold by Defendant on Amazon.com. (Dkt. No. 29 at 4, 6.) Solimo comes in two forms—
26 tablet and gummy—with the label for each purporting to provide a specific dose of melatonin per
serving (e.g., 3mg or 5mg). (*Id.* at 4.) Melatonin is believed to manage the body’s circadian
rhythm (24-hour internal clock). (*Id.* at 1.) As such, it is commonly used as a sleep-aid. (*Id.*) Like
any supplement, melatonin is regulated by the Food and Drug Administration (“FDA”), the

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1 Federal Trade Commission (“FTC”), and state agencies. *See generally* FDCA, 21 U.S.C. § 301 *et*
 2 *seq.*, 21 C.F.R. Part 100 *et seq.*, 21 U.S.C.S. § 343-1. The FAC asserts that Defendant, through
 3 its false labeling, substantially understates Solimo’s true melatonin dosage in each serving. (Dkt.
 4 No. 26 at 5.) This, in turn, deceptively enticed Plaintiffs to purchase the product and has the
 5 capacity to do the same for others. (*Id.*)

6 According to Plaintiffs, the actual dosage of melatonin per serving, relative to the labeled
 7 amount, exceeds what would be a “reasonable excess” allowed by the FDA. (*Id.* at 7.) As
 8 Plaintiffs define it, a “reasonable excess” is any amount greater than that needed for a
 9 supplement to meet “the amount specified on the label throughout the product’s shelf life.” (*Id.*
 10 at 9 (quoting 21 C.F.R. § 101.36(f)(1)).) Plaintiffs assert that, as a result of this excess melatonin,
 11 they suffered injury. (*Id.* at 13–14.) Had they known Solimo’s true melatonin dosage, they would
 12 not have purchased it *at any price*. (*Id.*)

13 Plaintiffs bring causes of action for (1) violations of Washington’s Consumer Protection
 14 Act (“CPA”), (2) breach of contract, (3) breach of express warranty, and (4) breach of implied
 15 warranty. (*Id.* at 16–20.) Defendant moves to dismiss pursuant to Rules 12(b)(1) and 12(b)(6).
 16 (*See generally* Dkt. No. 29). It argues that (1) Plaintiffs lack standing; (2) the Federal Food,
 17 Drug, and Cosmetic Act (“FDCA”) preempts Plaintiffs’ claims; (3) Plaintiffs fail to plausibly
 18 allege any of their causes of action; and, finally, that (4) Plaintiffs’ breach of warranty claims are
 19 legally deficient. (*See* Dkt. No. 29 at 13–30.)

20 II. DISCUSSION

21 A. Legal Standards

22 Pursuant to Rule 12(b)(1), a complaint must be dismissed if the Court determines at any
 23 point that it lacks subject matter jurisdiction over the claims asserted. *Intl. Union of Operating*
 24 *Eng’rs. v. Cnty. of Plumas*, 559 F.3d 1041, 1043–44 (9th Cir. 2009). And if a plaintiff lacks
 25 standing, the Court lacks subject matter jurisdiction. *See Steel Co. v. Citizens for a Better Env’t*,
 26 523 U.S. 83, 101–02 (1998). A Rule 12(b)(1) challenge may be facial or factual. Fed. R. Civ. P.

1 12(b)(1), *see Safe Air for Everyone v. Meyer*, 373 F.3d 1035, 1039 (9th Cir. 2004). In a facial
 2 attack, such as this one, the defendant asserts a complaint's allegations are insufficient to confer
 3 federal jurisdiction. In reviewing such an attack, the Court assumes all material allegations in the
 4 complaint are true. *Thornhill Publ'g Co. v. General Tel. Elec.*, 594 F.2d 730, 733 (9th Cir. 1979).
 5 Whereas, upon a Rule 12(b)(6) motion, a complaint must be dismissed if it lacks a "cognizable
 6 legal theory" or "sufficient factual matter, accepted as true, to state a claim to relief that is
 7 plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citation omitted); *Balistreri v.*
 8 *Pacifica Police Dep't*, 901 F.2d 696, 699 (9th Cir. 1988). A claim is plausible when the "plaintiff
 9 pleads factual content that allows the court to draw the reasonable inference that the defendant is
 10 liable for the misconduct alleged." *Id.* at 678.

11 **B. Standing**

12 In general, to establish standing, "a plaintiff must show (i) that [s]he suffered an injury in
 13 fact that is concrete, particularized, and actual or imminent; (ii) that the injury was likely caused
 14 by the defendant; and (iii) that the injury would likely be redressed by judicial relief."

15 *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2203 (2021). This must be shown "for each claim
 16 that they press and for each form of relief that they seek." *Id.* at 2208. At the pleading stage,
 17 "general factual allegations of injury resulting from the defendant's conduct may suffice." *Lujan*
 18 *v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992) (internal citations omitted). This is not an
 19 onerous burden, though, "for on a motion to dismiss we presum[e] that general allegations
 20 embrace those specific facts that are necessary to support the claim." *Id.* Defendant contends that
 21 Plaintiffs lack standing to pursue (a) monetary relief because they have not alleged an injury-in-
 22 fact traceable to the products purchased and (b) injunctive relief because they have not alleged a
 23 certainly impending or substantial risk of future harm. (Dkt. No. 29 at 7.) Neither argument is
 24 persuasive.

25 As to the issue of an injury-in-fact, Plaintiffs allege that they "relied on the claimed
 26 melatonin content on Amazon's labels," that the bottles were "inaccurately labelled and

1 unreasonably overdosed,” and had they known the true dosage, they “would not have purchased
 2 the product at the price [they] paid . . . [i]n fact, knowing the truth, [it] was worthless to [them].”
 3 (Dkt. No. 26 at 13, 15.) This is sufficient to allege a price injury. *See Reid v. Johnson & Johnson*,
 4 780 F.3d 952, 958 (9th Cir. 2015) (price injury can be pleaded by alleging that one relies on a
 5 misrepresentation, had they known the truth, they would have paid less or, perhaps, nothing at
 6 all).¹ No more is required. Regarding future harm, Plaintiffs allege that, if not for the fact that
 7 they cannot confidently rely on Solimo’s labeling, they would purchase the product again. (Dkt.
 8 No. 29 at 16.) Again, this is all that is required to establish injury. *See Davidson v. Kimberly-*
 9 *Clark Corporation*, 889 F.3d 956, 968–70 (2018) (injury can be actual and imminent if the
 10 plaintiff alleges that they would purchase the product again if they were able to confidently rely
 11 on the label).

12 Accordingly, the Court FINDS that Plaintiffs have sufficiently pleaded injury to support
 13 standing for the relief sought.

14 **C. Preemption**

15 To the extent a claim is preempted by federal law, it is legally deficient and subject to
 16 dismissal pursuant to Rule 12(b)(6). *See SmileCare Dental Group v. Delta Dental Plan of Calif.*,
 17 *Inc.*, 88 F.3d 780, 783–84 (9th Cir. 1996). However, “FDA preemption, like all federal
 18 preemption, is an affirmative defense;” therefore, Defendant bears the burden. *Durnford v.*
 19 *MusclePharm Corp.*, 907 F.3d 595, 603 n.8 (9th Cir. 2018). “Federal law imposes a
 20 comprehensive regulatory scheme for dietary supplements.” *Lopez v. Zarbee’s, Inc.*, 2023 WL
 21 210878, slip op. at 1 (N.D. Cal. 2023). And “FDA regulations require that the quantity of

22
 23 ¹ Moreover, even if Plaintiffs received “the benefit of the bargain,” as Defendant
 24 contends, (see Dkt. No. 29 at 15), they can still allege economic loss if they overpaid based on a
 25 misrepresentation. *See Guido v. L’Oréal*, 2011 WL 13152488, slip op. at 4–5 (C.D. Cal. 2011).
 26 Nor need Plaintiffs test the actual product purchased, *see Lorentzen v. Kroger Co.*, 532 F. Supp.
 3d 901, 908 (C.D. Cal. 2021), as Defendant asserts. (See Dkt. No. 29 at 13–14.) An allegation
 that Defendant “is consistently selling the product purchased with false information” suffices.
Lorentzen, 532 F. Supp. 3d at 908 (cleaned up).

1 melatonin ‘be at least equal to the value . . . declared on the label’ for the product’s full shelf
 2 life.” *Id.* (citing 21 C.F.R. § 101.9(g)(4)(i)). On this basis, Defendant asserts that Plaintiffs’
 3 claims are preempted because (1) the FDA permits melatonin overages and (2) Plaintiffs’
 4 allegations are supported by a test that deviates from the FDA’s 12-sample testing protocol. (Dkt.
 5 No. 29 at 17–21.) Neither contention has merit.

6 1. Permissible Overages

7 Because supplements like melatonin degrade over time, the FDA allows manufacturers to
 8 formulate the supplement with some overages to ensure “that the finished product can meet the
 9 label declaration for that dietary ingredient through the product’s shelf life.” *Lopez*, 2023 WL
 10 210878 at 1 (citing 68 Fed. Reg. 12158, 12203 (Mar. 13, 2002)). This “safe harbor” allows a
 11 reasonable excess over labeled amounts, so long as it is within “good manufacturing practice.”
 12 21 C.F.R. § 101.36(f)(1). But while the FDA allows for some overages, it does not intend to
 13 “allow the manufacturer to add excess dietary ingredients in unspecified amounts that would be
 14 in excess of the amount actually needed to meet the label declaration.” *Lopez*, 2023 WL 210878
 15 at 1 (citing 68 Fed. Reg. 12158, 12203 (Mar. 13, 2002)). Said another way, if a product’s label
 16 falsely states the dosage, relative to this permissible excess, the product is mislabeled. *See*
 17 *Durnford*, 907 F.3d 595 at 601.

18 Relying on the fact that the FDA allows some overages, Defendant contends that
 19 Plaintiffs’ claims are preempted. (Dkt. No. 29 at 11–12.) Specifically, Defendant asserts that, by
 20 alleging they wanted “a 5mg dose and no more,” Plaintiffs ostensibly contend that *any* amount of
 21 melatonin over this amount is “unreasonable, misleading, and deceptive.” (*Id.* at 12.) And based
 22 on the FDA’s requirement that a supplement contain a minimum dose at the end of its shelf life,
 23 thereby requiring additional melatonin at the beginning, Plaintiffs’ claims are preempted. (*Id.* at
 24 10–11.) This misconstrues Plaintiffs’ allegations.² They state that “by selling inaccurately

26 2 Also, the Court notes that Defendant’s cited cases here are not helpful. They involve
 27 false advertising claims based on structure/function and “unreasonable consumer” claims—not
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1 labeled and *unreasonably* overdosed Solimo Melatonin, Amazon engaged in unfair and
 2 deceptive practice.” (Dkt. No. 26 at 18 (emphasis added).) Plaintiffs recognize that *some* overage
 3 is allowed, but contend that the amount in Solimo “increases the risk of adverse side effects” and
 4 puts at issue its “long-term safety” and, for these reasons, it is an “unreasonable excess . . .
 5 prohibited (not permitted) by FDA regulations” and results in “false and misleading labeling.”
 6 (*Id.* at 12.)

7 Defendant next contends Plaintiffs are trying to impose a “made-up standard, under
 8 which any overage greater than 10–15% of the labeled amount is *per se* unreasonable.” (Dkt. No.
 9 29 at 19.) Again, this mischaracterizes the FAC. It articulates such a range to compare Solimo’s
 10 melatonin overage to others. (Dkt. No. 26 at 10). The only limit that Plaintiffs ask be enforced is
 11 that set by the FDA, (*see* Dkt. No. 26 at 9), *i.e.*, the “amount actually needed to meet the label
 12 declaration.” *Ochoa v. Church & Dwight Co., Inc.*, 2018 WL 4998293, slip op. at 4 (C.D. Cal.
 13 2018).

14 2. Testing

15 The FDA requires that compliance with food labeling requirements be determined
 16 through a 12-sample testing protocol. *See* 21 C.F.R. § 101.9(g)(2). Defendant argues that,
 17 because the FAC does not allege that Plaintiffs actually used this protocol when testing Solimo,
 18 their claims are preempted. (Dkt. No. 29 at 21.)

19 But *Durnford* clarified the scope of the testing requirement, at least for pleading
 20 purposes. *See* 907 F.3d at 603 n.8. It indicated that “plaintiffs are generally not expected to
 21 provide evidence in support of their claims at the pleading stage . . . nor are they required to
 22 plead the ‘probability’ of their entitlement to relief.” *Id.* While this was not central to the
 23 *Durnford* holding, many courts have since adopted its reasoning, holding that a plaintiff need not
 24 comply with the FDA’s 12-sample protocol at the pleading stage. *See e.g.*, *Murphy v. Olly Public*

25
 26 ingredient overages. (*See, e.g.*, Dkt. No. 29 at 17–19 (citing *Greenberg v. Target Corp.*, 985 F.3d
 650 (9th Cir. 2021); *Dachauer v. NBTY, Inc.*, 913 F.3d 844, 848 (9th Cir. 2019)).)

1 *Benefit Corporation*, 2023 WL 210838, slip op. at 6 (N.D. Cal. 2023). While Defendant contends
 2 otherwise, the cases it cites in support are primarily pre-*Durnford* and, regardless, in the
 3 minority. (See Dkt. No. 29 at 21.) The Court sees no reason to depart from the majority of cases.
 4 Applying this standard, Plaintiffs' allegations are sufficient to avoid preemption on the issue of
 5 testing, at least at the pleading stage.³ Nor has Defendant shown that Plaintiffs have "pledged
 6 themselves out of court by pleading facts that establish [Defendant's] compliance with FDA
 7 regulations." *Murphy*, 2023 WL 210838, at 7.

8 As such, the Court FINDS that Plaintiffs claims are not preempted.

9 **D. Plausibility of Claims**

10 Defendant next makes a series of plausibility arguments supporting Rule 12(b)(6)
 11 dismissal. The first, though, is a regurgitation of its standing argument. (See Dkt. No. 29 at 22
 12 (contending that the FAC fails to plausibly state the injury required for any of Plaintiffs'
 13 claims).) The Court rejects it for the same reasons it did above. *See supra* Part II.B. The
 14 remaining two, (see Dkt. No. 29 at 22–27), while also without merit, require some discussion.

15 As federal courts frequently repeat, a cause of action must be supported by more than
 16 labels and conclusions. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 545 (2007). While "Rule 8
 17 does not require detailed factual allegations, it demands more than an unadorned, the-defendant-
 18 unlawfully-harmed-me accusation." *Iqbal*, 556 U.S. at 678 (cleaned up). It requires plausible
 19 allegations supporting each cause of action. *See id.* And to the extent a claim sounds in fraud or
 20 mistake, the complaint "must state with particularity the circumstances." Fed. R. Civ. P. 9(b).
 21 This is often referred to as the "who, what, when, where, and how" enhanced pleading standard.

22

23 ³ According to the FAC, Plaintiffs tested bottles of Solimo comparable to what they
 24 consumed, which resulted in the discovery of significant melatonin excesses over the amount(s)
 25 indicated on each label. (See Dkt. No. 26 at 8–9.) The FAC further alleges that third-party testing
 26 confirms such overages are common and widespread in the industry. (*Id.*) In addition, they
 contend that Defendant possesses unique knowledge to confirm these excesses throughout
 Defendant's Solimo product line. (*Id.*) This is because Defendant has testing data unavailable to
 Plaintiffs, at least without discovery (*Id.*)

1 *Cafasso, United States ex rel. v. Gen. Dynamics C4 Sys., Inc.*, 637 F.3d 1047, 1055 (9th Cir.
 2 2011).

3 According to Defendant, the “logical leap” here between the FAC’s allegations and that
 4 required by Rule 9 is simply too great. (Dkt. No. 32 at 15.) The Court disagrees. The FAC’s
 5 allegations are sufficiently particular to support a CPA claim, irrespective of whether Rule 9
 6 applies. (See Dkt. No. 26 at 8–9, 15–16.) This is particularly true in light of the FAC’s contention
 7 that Defendant possesses non-public FDA compliance testing data regarding the actual melatonin
 8 dosage within Solimo sold. (See *id.* at 26 at 9.) As such, it would be unfair to dismiss the FAC
 9 before Plaintiffs have the opportunity to see this data. *See Nayab v. Capital One Bank (USA),*
 10 *N.A.*, 942 F.3d 480, 495 (9th Cir. 2019).

11 Defendant also asserts that, because the FAC does not affirmatively identify *which*
 12 contract Defendant breached and *when* the breach occurred, it fails to plausibly allege a breach of
 13 contract claim. (Dkt. No. 29 at 27.) But this relies on an obtuse interpretation of the FAC. It is
 14 black letter law that the Court must accept Plaintiffs’ allegations as true and draw reasonable
 15 inferences in their favor. *See Vasquez v. Los Angeles Cnty.*, 487 F.3d 1246, 1249 (9th Cir. 2007).
 16 Defendant would ask the Court to do otherwise.

17 According to the FAC, when Defendant advertises Solimo as for sale on its website, the
 18 listing contains a copy of the nutritional label. (See Dkt. No. 26 at 6–7, 14–16.) And it is
 19 reasonable to infer that consumers can glean other key terms from this listing, such as the
 20 product’s price and quantity. When Defendant shipped the product to Plaintiffs, Defendant was
 21 bound by those terms. (See *id.* at 19–20.) This is all that is required to establish a contract, *see, e.g., Becker v. Washington State U.*, 266 P.3d 893, 899 (Wash. App. 2011), even in the internet
 22 age, *see, e.g., Nguyen v. Barnes & Noble, Inc.*, 2015 WL 12766130, slip op. at 6 (C.D. Cal. June
 23 16, 2015).

25 Accordingly, the Court FINDS that the FAC plausibly alleges all claims against
 26 Defendant, including breach of contract.

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1 **E. Breach of Warranty Claims**

2 Finally, Defendant moves to dismiss the FAC's breach of express and implied warranty
3 claims, arguing they are legally deficient in light of (a) the disclaimer contained in Defendant's
4 standard Conditions of Use ("COU") and (b) Plaintiffs' failure to adequately plead notice. (Dkt.
5 No. 29 at 27–30.) In support, Defendant introduces facts and evidence outside of the FAC,
6 namely the COU. (See Dkt. No. 30-1 at 29–34.) This is not appropriate in a Rule 12(b)(6)
7 motion.⁴ *See Lee v. City of Los Angeles*, 250 F.3d 668, 688 (9th Cir. 2001). And the Court
8 DECLINES to consider this issue.

9 **III. CONCLUSION**

10 For the foregoing reasons, the Court DENIES Defendant's motion to dismiss.

11 DATED this 16th day of March 2023.

12 
13 John C. Coughenour
14 UNITED STATES DISTRICT JUDGE

23

24 ⁴ Perhaps the Court could take judicial notice of the COU and its terms. *See Fed. R. Evid.*
25 201(b). But Defendant makes no affirmative request or argument supporting such a request. (*See generally* Dkt. Nos. 29, 32.) Therefore, the Court will not consider the import of the COU and its
26 terms in deciding Defendant's Rule 12(b)(6) motion. *See Indep. Towers of Washington v.*
 Washington, 350 F.3d 925, 929 (9th Cir. 2003) ("Judges are not like pigs, hunting for truffles
 buried in briefs.").