1 2 3 4 5 6 UNITED STATES DISTRICT COURT 7 FOR THE EASTERN DISTRICT OF CALIFORNIA 8 9 MELANIE KELLEY, 1:17-cv-117-LJO-BAM 10 Plaintiff, MEMORANDUM DECISION AND ORDER RE DEFENDANT'S MOTION 11 TO DISMISS (Doc. 11) v. 12 WWF OPERATING COMPANY, 13 Defendant. 14 15 I. INTRODUCTION 16 17 Plaintiff Melanie Kelley brings this proposed class action on behalf of herself and others who 18 purchased certain Silk Almondmilk beverages from Defendant WWF Operating Company dba Whitewave Services, Inc., alleging that Defendant's marketing practices violated and continue to violate 19 20 (1) California's Consumer Legal Remedies Act ("CLRA"), Cal. Civil Code §§ 1770 et seq.; (2) California's unfair competition law ("the UCL"), Cal. Bus. & Prof. Code §§ 17200 et seq.; and (3) 21 California's False Advertising Law ("FAL"), Cal. Bus. & Prof. Code § 17500. Doc. 1. Defendant moves 22 to dismiss the case with prejudice under Federal Rule of Civil Procedure 12(b)(6) on a number of 23 grounds, including that the case should be dismissed under the "primary jurisdiction doctrine." See Doc. 24 25 11. 1

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The Court took the matter under submission on the papers pursuant to Local Rule 230(g). Doc. 15. For the following reasons, the Court agrees with Defendant that the primary jurisdiction doctrine applies here, but finds it appropriate to STAY this case pending appropriate administrative proceedings before the Food and Drug Administration ("FDA") instead of dismissing the case.

# II. FACTUAL AND PROCEDURAL BACKGROUND<sup>1</sup>

To resolve Defendant's motion, Plaintiff's allegations can be briefly summarized. Defendant makes, among other things, eight different kinds of Silk Almondmilk beverages, which Plaintiff alleges contain "false, misleading, and deceptive" information on their packaging. Doc. 1, Complaint ("Compl."), at ¶ 1; *id.* at 1 n.1. Plaintiff purchased Silk Unsweetened Vanilla Almondmilk, *id.* at ¶ 18, which she claims contained misleading information that, coupled with one of Defendant's television commercials for Silk Almondmilk beverages, led her to believe that Silk Amondmilk beverages are "nutritionally superior to dairy milk and contained comparable amounts of the essential vitamins and nutrients contained in dairy milk and contained higher amounts of protein and vitamin D than dairy milk." *Id.* at ¶ 20. But, according to Plaintiff, Silk Almondmilk beverages are "nutritionally inferior to dairy milk," and, had she known that, she would not have purchased any, or would have paid less for them, or would have bought an alternative product. *See id.* at ¶¶ 12, 20, 43.

Plaintiff therefore claims the Silk Almondmilk products are "misbranded" under 21 C.F.R. § 101.3(e) ("§ 101.3(e)") "because they substitute for and resemble dairy milk, are nutritionally inferior to dairy milk, and fail to state 'imitation milk' on their labels as required." Doc. 13 at 11. According to Plaintiff's opposition, her assertion that Defendant's products violate § 101.1(e) forms the basis for all of Plaintiff's claims. 2 See Doc. 13 at 7 (Plaintiff stating her "UCL, FAL and CLRA claims are

<sup>&</sup>lt;sup>1</sup> The following facts are drawn from Plaintiff's complaint and are assumed as true for purposes of Defendant's moton.

<sup>&</sup>lt;sup>2</sup> Plaintiff claims Defendant's conduct also violates 21 U.S.C. § 343(a), 21 U.S.C. § 343(c). *See* Doc. 13 at 15. But if Defendant has not violated § 101.3(e), then it has not violated §§ 343(a) or (c), as the former is an interpretive regulation promulgated pursuant to the latter statutes. For purposes of Plaintiff's claims, they are materially identical.

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principally predicated on Defendant's violation of FDA regulation, 21 C.F.R. § 101.3(e)"); see also id. at 9; id. at 12.<sup>3</sup>

Defendant moves to dismiss on a number of grounds. As a threshold matter, Defendant argues Plaintiff does not have standing. Second, Defendant contends Plaintiff's claims fail as a matter of law because no reasonable customer would be misled the use of the term "almondmilk" on its products.

As to Plaintiff's assertion that Silk Almondmilk beverages' labeling violate § 101.3(e)—the basis for Plaintiff's claims—Defendant argues that the beverages are distinct from dairy milk, their labeling complies with the applicable regulations, namely, 21 C.F.R. §§ 101.3(b)(1)-(3), and is not otherwise misleading. Defendant therefore contends Plaintiff seeks to impose labeling requirements on Silk Almondmilk beverages that go beyond what is required by the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301-399f, and, accordingly, Plaintiff's claims are expressly preempted by the FDCA.

### III. STANDARDS OF DECISION

A motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6) is a challenge to the sufficiency of the allegations set forth in the complaint. A 12(b)(6) dismissal is proper where there is either a "lack of a cognizable legal theory" or "the absence of sufficient facts alleged under a cognizable legal theory." *Balisteri v. Pacifica Police Dept.*, 901 F.2d 696, 699 (9th Cir. 1990). In considering a motion to dismiss for failure to state a claim, the court generally accepts as true the allegations in the complaint, construes the pleading in the light most favorable to the party opposing the motion, and resolves all doubts in the pleader's favor. *Lazy Y. Ranch LTD v. Behrens*, 546 F.3d 580, 588 (9th Cir. 2008).

To survive a 12(b)(6) motion to dismiss, the plaintiff must, in accordance with Rule 8, allege

<sup>&</sup>lt;sup>3</sup> The Court emphasizes that Plaintiff has repeatedly represented throughout her opposition that this is her position, despite the fact that her complaint suggests she has other theories of Defendant's liability, as Defendant correctly pointed out in its opposition. *See* Doc. 14 at 2. The Court has therefore contained its analysis to an assessment of whether Defendant's products violate § 101.3(e).

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"enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "A claim has facial plausibility when the Plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* (quoting *Twombly*, 550 U.S. at 556). "While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a Plaintiff's obligation to provide the 'grounds' of his 'entitlement to relief' requires more than labels and conclusions." *Twombly*, 550 U.S. at 555 (internal citations omitted). Thus, "bare assertions . . . amount[ing] to nothing more than a 'formulaic recitation of the elements' . . . are not entitled to be assumed true." *Iqbal*, 556 U.S. at 681. "[T]o be entitled to the presumption of truth, allegations in a complaint . . . must contain sufficient allegations of underlying facts to give fair notice and to enable the opposing party to defend itself effectively." *Starr v. Baca*, 652 F.3d 1202, 1216 (9th Cir. 2011). In practice, "a complaint . . . must contain either direct or inferential allegations respecting all the material elements necessary to sustain recovery under some viable legal theory." *Twombly*, 550 U.S. at 562.

## IV. ANALYSIS

### A. Plaintiff has standing to assert her claims

Plaintiff's claims are premised on her contentions that Defendant's Silk Almondmilk beverages are (1) mislabeled, in violation of § 101.3(e), because they should be identified as "imitation" dairy milk; and (2) the use of the term "almondmilk" is misleading. *See* Doc. 13 at 9. Among other things, Defendant contends Plaintiff lacks standing to bring any claim under the UCL, CLRA, or FAL because she has suffered no cognizable injury and, in any event, her claim fails as a matter of law.

Although Defendant mentions Article III standing principles, its argument that Plaintiff lacks standing is based on its position that Plaintiff lacks *statutory* standing under the UCL, FAL, and CLRA because she has not suffered a cognizable injury under those statutes. *See* Doc. 11 at 25; *see also* 

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*Hinojos v. Kohl's Corp.*, 718 F.3d 1098, 1104 n.3 (9th Cir. 2013) (finding Plaintiff easily satisfied Article III's injury requirement but discussing in depth whether the injury was sufficient for statutory standing under the UCL and FAL).

To determine whether a plaintiff has standing under these statutes, the Court must assess whether the plaintiff's complaint sufficiently alleges she suffered a sufficient economic injury as a result of the defendant's allegedly unfair, unlawful, or fraudulent business practice that is the basis for the complaint. See Kwikset Corp. v. Superior Court, 51 Cal. 4th 310, 323 (2011); see also Swearingen v. Santa Cruz Natural, Inc., No. 13-cv-4291-SI, 2016 WL 4382544, at \*3 (N.D. Cal. Aug. 17, 2016).

Plaintiff sufficiently alleges that she suffered an economic injury under the UCL, FAL, and CLRA. She alleges that (1) the Silk Almondmilk products were mislabeled because they failed to state that they are "imitation" dairy milk; (2) she bought at least one of the almondmilks, relying in part on their purportedly misleading labels; and (3) had she known that the almondmilk was nutritionally inferior to dairy milk, she would not have bought it, would have paid less for it, or would have bought an alternative product. This is sufficient to satisfy *Kwikset*'s requirements. *See Hinojos v. Kohl's Corp.*, 718 F.3d 1098, 1105 (9th Cir. 2013). Because Plaintiff has statutory standing under *Kwikset*, it follows that she has Article III standing as well. *See id.* at 1104, 1104 n.4.

Defendant disputes whether Plaintiff has standing to assert claims against the Silk Almondmilk beverages that she did not buy. There is no controlling authority on the issue, and district courts within the Ninth Circuit are severely split. *Khasin v. R.C. Bigelow, Inc.*, No. C 12-02204 JSW, 2013 WL 2403579, at \*4 (N.D. Cal. May 31, 2013). But "[t]he majority of the courts that have carefully analyzed the question . . . hold that a plaintiff may have standing to assert claims for unnamed class members based on products he or she did not purchase so long as the products and alleged misrepresentations are substantially similar." *Id.* The Court finds the majority position more persuasive and follows it here.

### B. Plaintiff's claims fall within the FDA's primary jurisdiction

"Primary jurisdiction is a prudential doctrine that permits courts to determine that an otherwise

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1	cognizable claim implicates technical and policy questions that should be addressed in the first instance
2	by the agency with regulatory authority over the relevant industry rather than by the judicial branch."
3	Astiana v. Hain Celestial Group, Inc., 783 F.3d 753, 760 (9th Cir. 2015) (citation and quotation marks
4	omitted). "The doctrine applies when protection of the integrity of a regulatory scheme dictates
5	preliminary resort to the agency which administers the scheme." United States v. Gen. Dynamics Corp.,
5	828 F.2d 1356, 1365 (9th Cir. 1987). Courts use the doctrine "to allocate initial decisionmaking
7	responsibility between agencies and courts where such [jurisdictional] overlaps and potential for
3	conflicts exist." Syntek Semiconductor Co., Ltd. v. Microchip Tech., Inc., 307 F.3d 775, 780 (9th Cir.
9	2002) (citation and quotation marks omitted).
10	To determine whether to invoke the doctrine, courts must consider
11	(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
12	that subjects an industry or activity to a comprehensive regulatory authority that (4) requires expertise or uniformity in administration.
13	Astiana, 783 F.3d at 760 (citation and quotation marks omitted). The doctrine thus applies only under "a
14	limited set of circumstances," including when the case "requires resolution of an issue of first
15	impression, or of a particularly complicated issue that Congress has committed to a regulatory agency."
16	Id. (citations and quotation marks omitted). Further, these circumstances must "present[] a far-reaching
17	question that requires expertise or uniformity in administration." Brown v. MCI WorldCom Network
18	Servs., Inc., 277 F.3d 1166, 1172 (9th Cir. 2002).
19	For instance, in Clark v. Time Warner Cable, 523 F.3d 1110, 1115 (9th Cir. 2008), the court
20	confronted whether a provider of a new technology that used the internet to make phone calls
21	"qualifie[d] as a 'telecommunications carrier' [under 47 U.S.C. § 258(a)] or is otherwise subject to §
22	258(a)'s requirements," an issue that "fits squarely" within the Federal Communication Commission's
23 24	delegation of authority from Congress. <i>Id.</i> Recognizing that the issue was one of first impression and
	that the FCC was developing "a uniform regulatory framework to confront" the new technology, the
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Ninth Circuit held that the district court properly invoked the doctrine of primary jurisdiction to refer the claim to the FCC. *Id.* at 1115-16; *see also id.* at 1115 ("We need not determine whether the existence of this scheme alone would warrant the referral to the FCC of a § 258(a) claim that raises no particularly novel issues, as Clark's claim raises a question of first impression.").

In doing so, the Ninth Circuit relied on its prior decision *Syntek*, in which the court "approved of the use of the primary jurisdiction doctrine where it is unclear whether a federal statute applies to a new technology." *Id.* at 1115. *Syntek* involved the issue of "whether a party may obtain a judgment declaring that a copyright registration owned by another is invalid." 307 F.3d at 778. The court recognized this was an issue that was properly addressed in the first instance by the Register of Copyrights for four reasons. *Id.* at 781-82. First, Congress intended "to have national uniformity in copyright." *Id.* at 781. Second, the issue was one of first impression, and was a complicated one "that Congress ha[d] committed to the Register of Copyrights." Third, the issue "require[d] an analysis of whether the agency acted in conformance with its own regulations when it granted the [challenged] registration." *Id.* Fourth, the plaintiff sought an administrative remedy, but it was unclear whether that remedy was available. *Id.* at 782.

Clark and Syntek counsel applying the doctrine of primary jurisdiction here for at least three reasons. First, there is no dispute that Congress has enacted a comprehensive scheme to maintain uniformity in food labeling and has delegated the authority of administering it to the FDA. See generally 21 U.S.C. §§ 343, 343-1(a); 21 C.F.R. § 101.3. Second, though neither party acknowledges it, Plaintiff's position—that Defendant's almondmilk is mislabeled in that it should be labeled as an "imitation"—is an issue of first impression. The Court has conducted extensive research and is unable to locate any authority that suggests the issue has been considered officially by the FDA or the courts.

Third, the issue of whether Defendant's products (or any other plant-based "milk") should be deemed an "imitation" under § 101.3(e) fits squarely within the FDA's authority, and will require the agency's expertise in determining how to fashion labels so they adequately inform consumers. *Cf. Am.* 

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Meat Inst. v. U.S. Dep't of Ag., 496 F. Supp. 64 (finding Department of Agriculture rule concerning the
label "Turkey Ham – Cured Turkey Thigh Meat" for all-turkey product was arbitrary because agency
found the rule misled some consumers to believe the product contained pork, but declining to order that
any "Turkey Ham" product be labeled "imitation" ham because it required more research and analysis
from agency), vacated, 646 F.2d 125 (4th Cir. 1981). This Court is not the appropriate forum to decide
in the first instance whether almondmilk "substitutes for," is "nutritionally inferior" to, and "resembles"
dairy milk such that it should be labeled "imitation" milk under § 101.3(e)—an issue which forms the
entire basis for Plaintiff's case. See Nat'l Commc'ns Ass'n, Inc. v. AT&T, 46 F.3d 220, 222-223 (2d Cir.
1995) ("The doctrine of primary jurisdiction allows a federal court to refer a matter extending beyond
the 'conventional experiences of judges' or 'falling within the realm of administrative discretion' to an
administrative agency with more specialized experience, expertise, and insight.") (citations omitted).
The doctrine is particularly appropriate here because that issue "involves technical questions of fact
uniquely within the expertise and experience of an agency." Nader v. Allegheny Airlines, Inc., 426 U.S.
290, 304 (1976) (emphasis added). <sup>4</sup>

As Defendant points out, members of Congress called for the FDA to address the issue approximately six months ago. *See* Los Angeles Times, *Stop calling almond, soy and rice milks 'milk,'* 25 members of Congress say, http://www.latimes.com/business/la-fi-almond-milk-soy-milk-20161223-story.html (Congress members "want the FDA to require plant-based products to adopt a name other than milk, which they say is deceptive"). The issue is therefore on the FDA's radar.<sup>5</sup> The FDA should, at

<sup>4</sup> The Court notes that whether a product is an "imitation" is fact-intensive. Accordingly, the few (and potentially outdated) cases to consider whether a product is an imitation of another hold that the issue is a question of fact. See Coffee-Rich, Inc. v. Kansas State Bd. of Health, 192 Kan. 431 (1964) ("Whether one product is an imitation of another is a question of fact. Cases

relied upon by appellants uniformly hold this to be the law.") (citing *United States v. 651 Cases, etc.*, 114 F. Supp. 430, 431 (N.D.N.Y. 1953); see also 38 Fed. Reg. 20702 (1973) (promulgating FDA regulation on "imitation" products and citing 651

Cases and 62 Cases, More or Less, Each Containing Six Jars of Jam v. United States, 340 U.S. 593, 599 (1951) approvingly as "fully consistent" with the regulation's definition of "imitation" and Coffee-Rich as among "the most current and definitive

judicial interpretation[s] of the term 'imitation'"). In the absence of definitive guidance from the FDA, the issue therefore

does not appear amenable to a motion to dismiss because it is contingent on factual determinations.

<sup>&</sup>lt;sup>5</sup> The Court also notes that the FDA received on March 2, 2017, a Citizen Petition requesting the FDA promulgate

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the very least, have the opportunity to decide whether it will address the issue. See Swearingen v. Santa
Cruz Natural, Inc., No. C 13-04291 SI, 2014 WL 1339775, at *3 (N.D. Cal. Apr. 2, 2014) ("[C]ourts
find it particularly appropriate to defer to an agency when, as is true here, the agency is in the process of
making a determination on a key issue in the litigation."). Further, given that the FDA appears poised to
have the opportunity to consider the issue presented in this case, the Court's consideration of the issue
could lead to inconsistent results, which weighs in favor of applying the doctrine. See Davel Commc'ns,
Inc. v. Qwest Corp., 460 F.3d 1075, 1089 (9th Cir. 2006) ("the central focus of the primary jurisdiction
doctrine [is] the desirability of uniform determination and administration of federal policy embodied in
the agency's orders"). "Applying the doctrine of primary jurisdiction allows the Court to benefit from
the FDA's expertise on food labeling and will ensure uniformity in administration of the regulations."
Swearingen, 2014 WL 1339775, at *4.

The Court acknowledges that "[c]ommon sense [dictates] that even when agency expertise would be helpful, a court should not invoke primary jurisdiction when the agency is aware of but has expressed no interest in the subject matter of the litigation." *Astiana*, 783 F.3d at 761. As the court in *Gitson v*. *Trader Joe's Co.*, noted, in 2008 the FDA issued a "warning letter" to a producer of soymilk that informed the producer that its soymilk was mislabeled under 21 U.S.C. § 343(g) and stated: "we do not consider 'soy milk' to be an appropriate common or usual name because it does not contain 'milk." 2015 WL 9121232, at \*2. The FDA issued an identical warning to a different soymilk producer in 2012. *Id.* Thus, the FDA has, at the very least, been aware that producers label soymilk as such and has, to some extent, taken a stance on whether that is appropriate. But it is questionable whether those warning letters should be entitled to any deference as a matter of law or logic. *See Gitson*, 2015 WL 9121232, at

<sup>&</sup>quot;regulations clarifying how foods may be named by reference to the names of other foods." See Citizen Petition from The Good Food Institute, available at https://www.regulations.gov/docket?D=FDA-2017-P-1298 (last visited May 25, 2017). Briefly summarized, the petition requests, among other things, that the FDA issue regulations that would permit plant-based beverages to be called "milk." See id. at 24-25, 38. Notably, the petitioner contends that, like Defendant here, soymilk and almondmilk cannot reasonably be understood to be "imitations" of dairy milk. Id. at 25. If the FDA were to act on this petition, it could potentially resolve this case definitively.

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\*2 (finding the warning letters without support and implausible); see also Hood v. Wholesoy & Co., Modesto Wholesoy Co., LLC, No. 12-cv-5550-YGR, 2013 WL 3553979, at \*6 (N.D. Cal. July 12, 2013) (finding the warning letters "do[] not provide clear guidance for food producers or the Court," and referring the case to the FDA under the doctrine of primary jurisdiction); Ang v. Whitewave Foods Co., 2013 WL 6492353, at \*3 (N.D. Cal. Dec. 10, 2013) (finding warning letters are "far from controlling" on whether using the term "soymilk" is proper, and noting that the FDA "has yet to arrive at a consistent interpretation . . . with respect to milk substitutes").

More importantly, while *Gitson*, *Hood*, and *Ang* addressed the issue of whether soy-based products' use of the term "milk" or "yogurt" rendered them mislabeled as violating the "standard of identity" for milk and yogurt, or whether they appropriately used their "common and usual name," none of the cases addressed whether those products are mislabeled because they are "imitations" under § 101.3(e), like Plaintiff alleges here with regard to Defendant's products. As noted above, the Court is confident this is an issue of first impression. The Court cannot locate, and Plaintiff does not provide, anything to indicate that the FDA is "aware of [the issue] but has expressed no interest in addressing" beyond the December 2016 request from Members of Congress and the March 2017 citizen petition discussed above, both of which explicitly ask the FDA to provide guidance on the issue. As it stands, it appears the FDA is currently considering whether to opine on a dispositive issue in this case.

The Court therefore finds the doctrine of primary jurisdiction should apply here, and the case is accordingly referred to the FDA. *See Syntek*, 307 F.3d at 782.<sup>6</sup> "[H]aving decided that referral of this matter to the administrative agency is appropriate, [the Court] must also determine whether this action should be stayed or dismissed without prejudice." *Id.* As the Ninth Circuit recently explained in *Astiana*:

Once a district court determines that primary jurisdiction is appropriate, it may either stay proceedings or dismiss the case without prejudice. When the purpose of primary

<sup>&</sup>lt;sup>6</sup> The Ninth Circuit has explained that when the primary jurisdiction doctrine applies, courts must "refer" the case to the appropriate administrative agency. *See Syntek*, 307 F.3d at 782. "Referral" is merely a "term of art" because "the parties are responsible for initiating the appropriate proceedings before the agency." *Id.* at 782 n.3.

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jurisdiction is for "parties [to] pursue their administrative remedies," a district court will "[n]ormally" dismiss the case without prejudice. However, when a court invokes primary jurisdiction "but further judicial proceedings are contemplated, then jurisdiction should be retained by a stay of proceedings, not relinquished by a dismissal." In either circumstance, the district court must be attuned to the potential prejudice arising from the dismissal of claims. Because the Ninth Circuit "has not clearly adopted the doctrine of equitable tolling in primary jurisdiction cases," prudence dictates that a court should stay proceedings rather than dismissing them when there is a "possibility" that the running of the statute of limitations during administrative proceedings could affect the parties' rights.

783 F.3d at 761-62 (citations and footnote omitted).

Plaintiff did not take any stance in her opposition as to whether the case should be stayed or dismissed if the Court were to find the primary jurisdiction doctrine applicable here. "The factor most often considered in determining whether a party will be disadvantaged by dismissal is whether there is a risk that the statute of limitations may run on the claims pending agency resolution of threshold issues." *Qwest*, 460 F.3d at 1089. The statute of limitations for Plaintiff's UCL claim is four years, *see Beaver v. Tarsadia Hotels*, 816 F.3d 1170, 1178 (9th Cir. 2016), and three years for her CLRA and FAL claims. *See* Cal. Civ. Code § 1783; Cal. Civ. Code of Proc. § 338(a). Frankly, the Court has no way of knowing how long it may take the parties to pursue appropriate proceedings before the FDA, but is cognizant that "[a]gency decisionmaking often takes a long time." *AT&T*, 46 F.3d at 225 (noting the parties estimated FCC decisionmaking would take two to five years) (citation and quotation marks omitted). Even if the FDA makes a decision on the issue of whether Defendant's claims violate § 101.3(e), future proceedings in this Court will be necessary to assess that determination and rule on Plaintiff's state-law claims. Accordingly, in an abundance of caution, the Court STAYS this case so that the statutes of limitations for Plaintiff's claims will not expire, and REFERS the matter to the FDA. The Court therefore need not address Defendant's multiple alternative arguments.

# V. CONCLUSION AND ORDER

For the foregoing reasons, the Court finds the doctrine of primary jurisdiction applicable here.

Accordingly, this case is REFERRED to the FDA and STAYED pending a determination from the FDA on whether Defendant's products must be labeled "imitation" under § 101.3(e), or when it appears the

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1	FDA does not intend to address the matter. See Astiana, 783 F.3d at 761. The parties are directed to	
2	submit joint status reports every six months updating the Court on the FDA proceedings and, if	
3	appropriate, the parties' positions on how this case should proceed in light of those proceedings.	
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5	IT IS SO ORDERED.	
6	Dated: June 5, 2017 /s/ Lawrence J. O'Neill	
7	UNITED STATES CHIEF DISTRICT JUDGE	
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