UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

KRISTEN BRINKERHOFF, On Behalf of Herself and All Others Similarly Situated,

Plaintiff,

v.

L'ORÉAL USA, INC.,

Defendant.

Case No.: 3:18-cv-2034-BTM-WVG

ORDER GRANTING IN PART, DENYING IN PART DEFENDANT'S MOTION TO DISMISS AND STAYING ACTION PENDING ADMINISTRATIVE ACTION

[ECF No. 10]

Defendant L'Oréal USA, Inc. manufactures, markets, distributes, and sells various skin care products, including CeraVe Eye Repair Cream (the "Cream"). (ECF No. 7, ¶ 1.) The Cream's packaging prominently displays various representations regarding the Cream, including that it "help[s] repair and restore the . . . skin barrier around [users'] eyes" (hereinafter, the "Repair Representations"). (Id. ¶¶ 2, 12 & Ex. A.) In Fall 2017, Plaintiff Kristen Brinkerhoff purchased the Cream from an independent retailer for approximately fifteen dollars. (Id. ¶ 10.) Plaintiff alleges she relied upon the Repair Representations when she purchased the Cream, forgoing "less expensive competitor cosmetic eye

products" based thereon. (Id.) Plaintiff subsequently learned, however, that Defendant had not presented the United States Food & Drug Administration (the "FDA") with evidence of the Cream's safety and effectiveness before its marketing and sale. (Id.) Plaintiff alleges she "would not have purchased the [Cream] and certainly would not have paid a premium price for it" had she known that the Repair Representations had not been approved by the FDA.[1] (Id.)

Plaintiff's sole claim in her First Amended Complaint is that Defendant's marketing and sale of the Cream was "unlawful" under California's Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code § 17200, et seq., because Defendant did not receive approval from the FDA prior to marketing and selling the Cream, which Plaintiff contends is a "drug" under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, et seq., and California's Sherman Food, Drug, and Cosmetic Law ("Sherman Law"), Cal. Health & Safety Code § 109875, et seq., in violation of the FDCA and Sherman Law. (Id. ¶¶ 2-4, 32-41.) Indeed, unlike purely cosmetic items, "new drugs" generally may not be marketed or sold without preapproval from the FDA through the New Drug Application ("NDA") process.[2] 21 U.S.C. §§ 331(d) & 355; Cal. Health & Safety Code § 111550.

---

[1] Notably, Plaintiff does not allege that she believed the Cream had been submitted to or otherwise been approved by the FDA at the time of her purchase. (See ECF No. 7, ¶ 10 ("Had Plaintiff known that the FDA prohibits manufacturers from selling products with repair and restore representations that the FDA had not determined are both safe and effective and that Defendant had not presented the FDA with the required evidence of safety and effectiveness, Plaintiff would not have purchased the [Cream] and certainly would not have paid a premium price for it." (emphasis added)).

[2] Under the FDCA, a "cosmetic" includes "articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance." 21 U.S.C. § 321(i)(1); see also Cal. Health & Safety Code § 109900. Nevertheless, a cosmetic may also be a "drug" if it is "intended to affect

Plaintiff contends that that the Repair Representations rendered the Cream a drug for which FDA preapproval via the NDA process was necessary. (ECF No. 7, ¶¶ 2, 16-19, 35.) Further, Plaintiff alleges that, "[b]y making the unlawful [Repair Representations,] Defendant is . . . able to charge a substantial premium for [the Cream] over what competitors charge for similar cosmetic eye products which . . . claim only to moisturize and visibly improve the skin's appearance or look and do not make . . . unlawful drug claims." (Id. ¶ 21.) Plaintiff alleges that "but for Defendant's illegal conduct" of marketing the Cream with the Repair Representations without obtaining approval from the FDA, "the [Cream] would not have been on the market" and therefore she would have been unable to purchase it. (Id. ¶¶ 35-36.) In addition to seeking declaratory relief and an injunction preventing sale of the Cream with the Repair Representations until the NDA process is completed, Plaintiff seeks restitution of all money she paid for the Cream "or, at a minimum, the premium paid for the [Cream]." (Id. ¶ 39-41.) Defendant subsequently moved to dismiss Plaintiff's claims for lack of standing, federal preemption, or, in the alternative, to stay this action or dismiss Plaintiff's claim without prejudice and refer Plaintiff's claim to the FDA pursuant to the "primary jurisdiction" doctrine. (ECF No. 10.)

Because standing under Article III of the U.S. Constitution is an essential element of the Court's subject matter jurisdiction, see Lujan v. Defs. of Wildlife, 504 U.S. 555, 560 (1992), the Court addresses it first. "[T]o satisfy Article III's

---

the structure or any function of the body of man or other animals." 21 U.S.C. § 321(g)(1)(C); 21 U.S.C. § 359; see also Cal. Health & Safety Code § 109925(c)(3). Notably, the FDCA differentiates between "drugs" and "new drugs." Compare 21 U.S. § 321(g)(1) & (p). Only "new drugs" need to undergo the NDA process. 21 U.S.C. § 355(a) ("No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug." (emphasis added)).

standing requirements, a plaintiff must show[:] (1) it has suffered an 'injury in fact' that is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical; (2) the injury is fairly traceable to the challenged action of the defendant; and (3) it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc., 528 U.S. 167, 180–81 (2000) (citing Lujan, 504 U.S. at 560-61) see also Lujan, 504 U.S. at 561 ("The party invoking federal jurisdiction bears the burden of establishing these elements."). Where a 12(b)(1) motion to dismiss is based on lack of standing, the Court must defer to the plaintiff's factual allegations and must "presume that general allegations embrace those specific facts that are necessary to support the claim." Lujan, 504 U.S. at 561 (internal quotation marks omitted). Indeed, "[a]t the pleading stage, general factual allegations of injury resulting from the defendant's conduct may suffice." Id. at 560.

"To have standing under California's UCL, as amended by California's Proposition 64,[3] plaintiffs must establish that they (1) suffered an injury in fact and (2) lost money or property as a result of the unfair competition." Birdsong v. Apple, Inc., 590 F.3d 955, 959 (9th Cir. 2009) (citations omitted); Cal. Bus. & Prof. Code

---

[3] "In 2004, the electorate substantially revised the UCL's standing requirement; where once private suits could be brought by any person acting for the interests of itself, its members or the general public, now private standing is limited to any person who has suffered injury in fact and has lost money or property as a result of unfair competition. The intent of this change was to confine standing to those actually injured by a defendant's business practices and to curtail the prior practice of filing suits on behalf of clients who have not used the defendant's product or service, viewed the defendant's advertising, or had any other business dealing with the defendant. While the voters clearly intended to restrict UCL standing, they just as plainly preserved standing for those who had had business dealings with a defendant and had lost money or property as a result of the defendant's unfair business practices." Kwikset Corp. v. Superior Court, 51 Cal. 4th 310, 320–21, (2011) (internal quotations, citations, and alterations omitted).

§ 17204 ("Actions for relief pursuant to this chapter shall be prosecuted exclusively in a court of competent jurisdiction . . . by a person who has suffered injury in fact and has lost money or property as a result of the unfair competition."). "Thus, to plead a UCL claim, the plaintiffs must show, consistent with Article III, that they suffered a distinct and palpable injury as a result of the alleged unlawful or unfair conduct." Birdsong, 590 F.3d at 960 (citations omitted). "The requisite injury must be an invasion of a legally protected interest which is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical." Id. (internal quotations and citations omitted)). Moreover, Proposition 64's amendments to the UCL require "that a plaintiff must now demonstrate some form of economic injury," although "[t]here are innumerable ways" in which to do so. Kwikset Corp. v. Superior Court, 51 Cal. 4th 310, 323 (2011). For example, "[a] plaintiff may (1) surrender in a transaction more, or acquire in a transaction less, than he or she otherwise would have; (2) have a present or future property interest diminished; (3) be deprived of money or property to which he or she has a cognizable claim; or (4) be required to enter into a transaction, costing money or property, that would otherwise have been unnecessary." Id. "Because . . . economic injury is itself a form of injury in fact, proof of lost money or property will largely overlap with proof of injury in fact." Id. at 325 ("If a party has alleged or proven a personal, individualized loss of money or property in any nontrivial amount, he or she has also alleged or proven injury in fact.").

Defendant argues that Plaintiff lacks standing under both Article III and the UCL because she fails to allege a cognizable injury-in-fact. In support thereof, Defendant highlights that Plaintiff has not challenged the veracity of the Repair Representations or the Cream's safety or effectiveness, but only Defendant's failure to engage in the NDA process and obtain FDA approval prior to marketing and selling the Cream with the Repair Representations. (ECF No. 10-1, at 9-13 (citing ECF No. 7, ¶ 5).) Further, Defendant takes issue with Plaintiff's failure to

allege that she would have paid less for the Cream had it gone through the NDA process or that, at the time of her purchase, she believed the Cream was a drug based upon the Repair Representations or that the FDA had deemed the Cream to be safe and effective or otherwise approved it for marketing or sale. (Id. (citing ECF No. 7, ¶ 10).) Defendant argues that Plaintiff "got exactly what [she] expected and wanted" when she purchased the Cream and therefore has not suffered an economic loss simply because she bought a product for which Defendant lacked legal permission to sell. (Id. at 11; see also ECF No. 15, at 8 ("Absent an allegation that [Plaintiff] is unhappy with the Cream, she received the benefit of her bargain, lost no money or property, and there is no standing.").)

Yet, during the parties' briefing of the instant motion, the Ninth Circuit issued a memorandum holding that a plaintiff who made nigh-identical allegations as to a competing lotion had standing to pursue the same claim Plaintiff now asserts. See Franz v. Beiersdorf, Inc., 745 F. App'x 47 (9th Cir. 2018). As stated by the Ninth Circuit:

> Plaintiff alleges that Defendant sold a "drug" – Nivea CoQ10 – without FDA approval. Plaintiff contends that doing so violates the [FDCA], see 21 U.S.C. §§ 331(d), 355(a), and California's Sherman Law, see Cal. Health & Safety Code § 111550. Plaintiff alleges that, as a result, she spent money on a product that should not have been on the market. Those allegations are sufficient to establish standing under the UCL. See Medrazo v. Honda of N. Hollywood, 205 Cal. App. 4th 1, 11–13 (2012), *modified on denial of reh'*g (Apr. 16, 2012). Plaintiff need not plead reliance because neither the alleged FDCA violation nor the alleged Sherman Law violation requires allegations of fraud or deception. See id. at 12 (explaining that claims based on a theory of fraud require a plaintiff to demonstrate reliance to establish standing because "reliance is the causal mechanism of fraud." (quoting In re Tobacco II Cases, 46 Cal. 4th 298, 326 (2009))). . . . Plaintiff likewise has standing under Article III of the United States Constitution. Plaintiff alleged injury in fact – she spent money on Nivea CoQ10. Defendant's allegedly illegal conduct caused that injury, insofar as Defendant allegedly sold a product in commerce that it should not have sold. And

> the injury is redressable – in restitution – by a favorable court decision. Spokeo, Inc. v. Robins, ___ U.S. ___, 136 S. Ct. 1540, 1547 (2016).

Franz, 745 F. App'x at 48; see also Medrazo, 205 Cal. App. 4th at 13 (plaintiff established economic injury where "[s]he testified that she made the first two months payments, and owes more than $12,000 on a motorcycle that [the defendant] allegedly was not legally allowed to sell (or at least was not allowed to sell at the price for which it was sold) because it failed to disclose the dealer-added charges on a hanger tag attached to the motorcycle"). Moreover, the cases Defendant argue "better reflect California UCL standing law" are distinguishable from the instant case because, unlike those cases, Plaintiff has alleged that the Cream she purchased was overpriced compared to competing products that had not undergone the NDA process but which did not display the Repair Representations or other representations rendering them drugs that must undergo the NDA process. See Demeter v. Taxi Computer Servs., Inc., 21 Cal. App. 5th 903, 916–17 (2018) ("Demeter has not provided evidence that the service he purchased from TAXI was somehow not up to par, nor has he established a dispute of fact concerning whether the amount he paid for his TAXI membership was more than it was worth because of TAXI's (then) unbonded status."); Peterson v. Cellco P'ship, 164 Cal. App. 4th 1583, 1591 (2008) (plaintiffs failed to allege economic injury from an insurance agent's unlicensed sale of insurance policy where they did "not allege they could have bought the same insurance for a lower price either directly from the insurer or from a licensed agent"); Medina v. Safe-Guard Prod., Internat., Inc., 164 Cal. App. 4th 105, 114 (2008), as modified (July 11, 2008) ("Medina has not alleged that he didn't want wheel and tire coverage in the first place, or that he was given unsatisfactory service or has had a claim denied, or that he paid more for the coverage than what it was worth because of the unlicensed status of Safe–Guard."). Accordingly, the Court concludes that Plaintiff has demonstrated standing to assert her present claim.

Defendant argues that Plaintiff's claim under the UCL and Sherman Law are preempted by the FDCA and that Plaintiff can not assert a private cause of action under the FDCA. "Under the Supremacy Clause, U.S. Const., Art. VI, cl. 2, the enforcement of a state regulation may be pre-empted by federal law in several circumstances: first, when Congress, in enacting a federal statute, has expressed a clear intent to pre-empt state law; second, when it is clear, despite the absence of explicit preemptive language, that Congress has intended, by legislating comprehensively, to occupy an entire field of regulation and has thereby left no room for the States to supplement federal law; and, finally, when compliance with both state and federal law is impossible or when the state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." Capital Cities Cable, Inc. v. Crisp, 467 U.S. 691, 698–99 (1984) (internal quotations and citations omitted). "[T]he purpose of Congress is the ultimate touchstone in every pre-emption case[,]" which "primarily is discerned from the language of the pre-emption statute and the statutory framework surrounding it." Medtronic, Inc. v. Lohr, 518 U.S. 470, 485-86 (1996) (internal quotations, citations, and alterations omitted). "Also relevant . . . is the structure and purpose of the statute as a whole, as revealed not only in the text, but through the reviewing court's reasoned understanding of the way in which Congress intended the statute and its surrounding regulatory scheme to affect business, consumers, and the law." Id. at 486. "Where the field which Congress is said to have pre-empted includes areas that have been traditionally occupied by the States, congressional intent to supersede state laws must be clear and manifest." English v. Gen. Elec. Co., 496 U.S. 72, 79 (1990) (internal quotations, citations, and alterations omitted); Lohr, 518 U.S. at 485 ("[W]e start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." (internal quotations and citations omitted)). "Parties seeking to invalidate a state law based

on preemption bear the considerable burden of overcoming the starting presumption that Congress does not intend to supplant state law." Stengel v. Medtronic Inc., 704 F.3d 1224, 1227–28 (9th Cir. 2013) (citing 1228 De Buono v. NYSA–ILA Med. & Clinical Servs. Fund, 520 U.S. 806, 814 (1997)); but see Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 347-48 (2001) ("presumption against pre-emption" did not apply to "state-law fraud-on-the-FDA claims" where the defendant's pertinent "dealings with the FDA were prompted by the [the Medical Device Amendments of 1976 to the FDCA], and the very subject matter of [the defendant's] statements were dictated by that statute's provisions.").

Defendant argues that the provisions of the FDCA "cannot be enforced by private citizens." (ECF No. 10-1, at 14 (citing 21 U.S.C. § 337(a) ("Except as provided in subsection (b), all such proceedings for the enforcement, or to restrain violations, of this chapter [i.e., the FDCA] shall be by and in the name of the United States.")).) Defendant argues Plaintiff's attempt to circumvent this prohibition by couching her claim in state law fails because the predicate "unlawful" act she relies upon as the basis of her UCL claim is nevertheless Defendant's failure to undergo the NDA process and obtain preapproval from the FDA in violation of the FDCA. (Id. at 16-19.) Defendant further argues that Plaintiff's references to the Sherman Law are unavailing, as it "merely adopts the FDCA as California law" and "does not create a stand-alone, state-law drug approval process or standard that can be separately enforced without referring to and applying the FDCA standards and FDA premarket approval process." (Id. (citing Cal. Health & Safety Code § 110111); see also Cal. Health & Safety Code § 111550.) Thus, Defendant argues, "[a]ny claim brought to enforce premarket approval under the Sherman Law originates from, is governed by, and terminates according to federal law and is really just a violation of the FDCA." (Id. at 19 (internal quotations and citations omitted).) Defendant further argues that permitting Plaintiff and other private citizens to enforce the FDCA through the Sherman Law and UCL would conflict

with the FDCA's enforcement scheme, which grants the FDA discretion in enforcement. (ECF No. 10-1, at 16-17 (citing 21 U.S.C. § 336 ("Nothing in this chapter shall be construed as requiring the Secretary to report for prosecution, or for the institution of libel or injunction proceedings, minor violations of this chapter whenever he believes that the public interest will be adequately served by a suitable written notice or warning.")).) Moreover, Defendant argues that unlike "[o]ther state law claims that parallel federal rules" that have been held to not be preempted by the FDCA, such as common law fraud based upon misleading food labeling, Plaintiff's claims do not rely upon traditional theories of state law that predate the FDCA. (ECF No. 10-1, at 19.) In response, Plaintiff argues that her instant claim "is within states' historic police powers" and thus subject to a starting presumption of no preemption, that the Sherman Law's imposition of obligations identical to the FDCA "does not substantively transform [her] action into one seeking to enforce federal law," and that "while allowing private remedies based on violations of state laws identical to the FDCA may arguably result in actions that the FDA itself may not have pursued," such private claims pose little risk of disrupting federal enforcement of the FDCA. (ECF No. 13, at 13-17 (citing Farm Raised Salmon Cases, 42 Cal. 4th 1077 (2008).)

The Court need not decide whether Plaintiff's claim is preempted at this time because Defendant argues in the alternative that the Court should either dismiss this case without prejudice or stay its proceedings because Plaintiff's claims implicitly seek a ruling that the Cream is a "new drug" that must undergo the NDA process, which Defendant contends is a predicate issue that lays within the primary jurisdiction of the FDA. The "primary jurisdiction" doctrine is not a jurisdictional doctrine, but "[r]ather . . . a 'prudential' one, under which a court determines that an otherwise cognizable claim implicates technical and policy questions that should be addressed in the first instance by the agency with regulatory authority over the relevant industry rather than by the judicial branch." Clark v. Time Warner

Cable, 523 F.3d 1110, 1114 (9th Cir. 2008) (citations omitted). "[I]t is to be used only if a claim requires resolution of an issue of first impression, or of a particularly complicated issue that Congress has committed to a regulatory agency, and if protection of the integrity of a regulatory scheme dictates preliminary resort to the agency which administers the scheme. Id. (internal quotations and citations omitted); see also Brown v. MCI WorldCom Network Servs., Inc., 277 F.3d 1166, 1172 (9th Cir. 2002) ("[P]rimary jurisdiction is properly invoked when a case presents a far-reaching question that requires expertise or uniformity in administration." (internal quotations and citations omitted)). "Although no fixed formula exists for applying the doctrine of primary jurisdiction, . . . [the Ninth Circuit] held that the doctrine applies in cases where there is: (1) a 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." Clark, 523 F.3d at 1115 (internal quotations, citations, and alterations omitted); cf. Maronyan v. Toyota Motor Sales, U.S.A., Inc., 658 F.3d 1038, 1048–49 (9th Cir. 2011) ("The primary jurisdiction doctrine prescribes deference to an administrative agency where (1) the issue is not within the conventional experiences of judges, (2) the issue involves technical or policy considerations within the agency's particular field of expertise, (3) the issue is particularly within the agency's discretion, or (4) there exists a substantial danger of inconsistent rulings."). Notably, the Supreme Court has stated that:

> "In cases raising issues of fact not within the conventional experience of judges or cases requiring the exercise of administrative discretion, agencies created by Congress for regulating the subject matter should not be passed over. This is so even though the facts after they have been appraised by specialized competence serve as a premise for legal consequences to be judicially defined. Uniformity and consistency in the regulation of business entrusted to a particular agency are secured, and the limited functions of review by the judiciary

> are more rationally exercised, by preliminary resort for ascertaining and interpreting the circumstances underlying legal issues to agencies that are better equipped than courts by specialization, by insight gained through experience, and by more flexible procedure."

Weinberger v. Bentex Pharm., Inc., 412 U.S. 645, 654 (1973) (internal quotations, citations, and alterations omitted).

Here, the Court concludes that the primary jurisdiction doctrine is applicable to this matter and it should therefore be referred to the FDA. First, Plaintiff alleges that Defendant acted unlawfully by selling the Cream without undergoing the NDA process and obtaining FDA approval. This requires a determination that the Repair Representations were not just cosmetic marketing puffery, but rather representations of the Cream's ability to "affect the structure or any function of the body of man or other animals." See 21 U.S.C. § 321(g)(1)(C). Further, because only "new drugs" are required to go through the NDA process, see 21 U.S.C. § 355(a), the Court must also determine whether the Cream's "composition . . . is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. § 321(p)(1). Second, "[t]he Supreme Court has ruled that while the federal courts and the FDA share concurrent jurisdiction to determine whether a drug sought to be marketed constitutes a 'new drug' subject to the provisions of the [FDCA], the FDA has primary jurisdiction." Biotics Research Corp. v. Heckler, 710 F.2d 1375, 1376 (9th Cir. 1983) (citing Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609, 627 (1973)); see also Hynson, Westcott & Dunning, 412 U.S. at 624 ("It is clear to us that FDA has power to determine whether particular drugs require an approved NDA in order to be sold to the public."); 21 C.F.R. § 10.25(b) ("FDA has primary jurisdiction to make the initial determination on issues within its statutory mandate, and will request a court

to dismiss, or to hold in abeyance its determination of or refer to the agency for administrative determination, any issue which has not previously been determined by the agency or which, if it has previously been determined, the agency concluded should be reconsidered and subject to a new administrative determination."). Third, the FDCA subjects the drug and cosmetic industries to a comprehensive regulatory authority. See 21 U.S.C. § 301, et seq. Fourth, determining "[w]hether a particular drug is a 'new drug,' depends in part on the expert knowledge and experience of scientists based on controlled clinical experimentation and backed by substantial support in scientific literature." Bentex Pharm., 412 U.S. 645, 652 (1973). And while Plaintiff argues that policy memoranda and warning letters issued by the FDA provide guidance as to whether the FDA would consider the Cream a "drug" based upon the Repair Representation, she points to no guidance as to whether the FDA would consider the Cream a "new drug." [4] (See ECF No. 13, 18-21.)

Accordingly, all factors favor the application of the primary jurisdiction doctrine and the referral to the FDA. To avoid statute of limitations concerns, the Court will stay this matter to allow the parties a reasonable opportunity to seek an

---

[4] In support of her response in opposition to Defendant's motion to dismiss, Plaintiff filed a request for judicial notice ("RJN") of a "Cosmetic Labeling Guide" issued by the FDA and attached as Exhibit B to Plaintiff's response. (ECF No. 14; see also ECF No. 13-3.) Defendant did not oppose or otherwise respond to the RJN. Because the FDA's Cosmetic Labeling Guide was made publicly available by a government entity and neither party disputes its authenticity or accuracy, the Court will grant Plaintiff's RJN and take judicial notice of Cosmetic Labeling Guide. See Daniels-Hall v. Nat'l Educ. Ass'n, 629 F.3d 992, 998 (9th Cir. 2010); see also Fed. R. Evid. 201(b)(2) (courts may take judicial notice of "a fact that is not subject to reasonable dispute because it . . . can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned); Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 322 (2007) (when considering Rule 12(b)(6) motion, courts may consider "matters of which a court may take judicial notice").

administrative ruling from the FDA as to whether the Cream constitutes a "new drug" that must undergo the NDA process.[5] See Brown, 277 F.3d at 1173 (courts may stay proceedings where statute of limitations may expire in the event the court does not retain jurisdiction during referral to administrative agency). Moreover, because the administrative process may obviate the need for further proceedings in this matter, the Court denies without prejudice Defendant's preemption arguments. Defendant may renew its preemption arguments after the completion of the administrative process.

CONCLUSION

Based upon the foregoing and due consideration, Defendant's motion to dismiss (ECF No. 10) is **GRANTED IN PART, DENIED IN PART, DEFERRED IN PART**. Plaintiff's request for judicial notice (ECF No. 14) is **GRANTED**. Further, the Court **STAYS** this action pending a determination by the FDA as to whether the Cream is a "new drug" that must undergo the NDA process. The parties shall cooperate in expediting the presentation and explanation of this question to the FDA and will notify the Court promptly of any determination by the FDA. A status conference is hereby scheduled for Tuesday, May 12, 2020 at 2:00 p.m., at which counsel for the parties shall appear.

IT IS SO ORDERED.

Dated: October 8, 2019

Honorable Barry Ted Moskowitz
United States District Judge

[5] FDA regulations provide that interested persons may petition the FDA "to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action" via, inter alia, a citizen's petition. 21 C.F.R. § 10.25(a); see also 21 C.F.R. § 10.30 (citizen's petition requirements). Generally, a response to such citizen's petition must be provided within 180 days of its receipt. 21 C.F.R. § 10.30(e)(2).