UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

INGRID ANGLIN, COLLEEN GORMAN, PAUL LAMBRAKIS, ELIJAH NATAL, MATTHEW NELSON, COURTNEY PARKER, and SHAYAN TARI, Individually and on Behalf of All Others Similarly Situated,	)	
Plaintiffs,	)	
v.	)	**Case No. 4:18-CV-00639-NCC**
EDGEWELL PERSONAL CARE COMPANY; EDGEWELL PERSONAL CARE BRANDS, LLC; EDGEWELL PERSONAL CARE LLC; PLAYTEX PRODUCTS, LLC; and SUN PHARMACEUTICALS, LLC,	)	
Defendants.	)	

MEMORANDUM AND ORDER

This matter is before the Court on Defendants' Motion to Dismiss or Stay Plaintiffs' Complaint, or, in the Alternative, Strike the Nationwide Class Allegations. (Doc. 21.) The seven named Plaintiffs in this putative class action and Defendants have consented to the jurisdiction of the undersigned United States Magistrate Judge pursuant to 28 U.S.C. 636(c)(1). (Doc. 13.) The Motion is fully briefed and ready for disposition. For the following reasons, Defendants' Motion will be **GRANTED, in part,** and **DENIED, in part.**

I. BACKGROUND

Plaintiffs Ingrid Anglin, Colleen Gorman, Paul Lambrakis, Elijah Natal, Matthew Nelson, Courtney Parker, and Shayan Tari ("Plaintiffs") bring this putative class action mislabeling lawsuit against Defendants Edgewell Personal Care Company; Edgewell Personal Care Brands,

LLC; Edgewell Personal Care LLC; Playtex Products, LLC; and Sun Pharmaceuticals, LLC ("Defendants"), on behalf of themselves and all other similarly situated persons who purchased Banana Boat Kids Tear-Free Sting-Free Continuous Spray Sunscreen ("Banana Boat Kids Spray"), Banana Boat Baby Tear-Free Sting-Free Continuous Spray Sunscreen ("Banana Boat Baby Spray"), and Banana Boat Baby Tear-Free Sting-Free Lotion Sunscreen ("Banana Boat Baby Lotion"), labeled as "SPF 50" or "SPF 50+" ("Products").[1] (Doc. 1 ¶ 3.)

The individual Plaintiffs allege they each purchased one or more of these Products and allege that the Products were labeled as having an "SPF 50" or "SPF 50+" but, in fact, had a lower SPF. (*Id.* ¶¶ 8, 17–23, 36.) Plaintiffs allege that "[i]n actuality, rigorous scientific testing has revealed that the Products do not provide an SPF of 50, much less '50+'." (*Id.* ¶ 36.) Specifically, Plaintiffs allege that *Consumer Reports* magazine reported in May 2016 that "its own testing had revealed that Banana Boat Kids SPF 50 sunscreen lotion had an SPF of only 8." (*Id.* ¶ 37.) In addition, Plaintiffs allege that they conducted their own independent testing utilizing FDA methods and that such tests demonstrated the Products had SPFs lower than listed on the label. (*See id*. ¶¶ 38–41.) Plaintiffs allege that Defendants knew or should have known, based on testing, that these Products have a lower SPF than stated on the label. (*Id.* ¶ 7.) Had they known the Products contained less UV protection than advertised, Plaintiffs and the putative class members would not have purchased the sunscreen, relied on it to protect them, or paid as much for the product. (*Id.* ¶ 11, 54.) As a result of Defendants' false, misleading, deceptive, and reckless labeling and marketing of the Products, Plaintiffs claim they and putative class members have suffered economic injury by paying for a falsely advertised product and being deprived of the full intended use of their purchased sunscreen. (*Id.* ¶¶ 5, 9, 12, 55, 57–58.)

[1] In their Class Action Complaint, Plaintiffs seek certification of a nationwide class and five state-specific subclasses (New York, New Jersey, Florida, Illinois, and California) each pertaining to individuals who purchased the Products from March 2, 2014, to the present. (Doc. 1 ¶¶ 64–66.)

Based on these allegations, Plaintiffs seek damages and equitable remedies as set out in the following eleven counts: Breach of Warranty (Count I), Breach of Implied Contract (Count II), Unjust Enrichment (Count III), Illinois Consumer Fraud & Deceptive Business Practices Act, 815 ILCS 505/1, *et seq.* (Count IV), New York General Business Law § 349 (Count V), New York General Business Law § 350 (Count VI), New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1, *et seq.* (Count VII), New Jersey Truth in Consumer Contract, Warranty, and Notice Act, N.J.S.A. 56:12-14 et seq. (Count VIII), Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. §§ 501.201, *et seq.* (Count IX), California Unfair Competition Law, Cal. Bus. & Prof. Code §§ 17200, *et seq.* (Count X), and California Consumers Legal Remedies Act, Cal. Civil Code §§ 1750, *et seq.* (Count XI).[2]

Defendants moved to dismiss or stay the case or, in the alternative, strike the nationwide class allegations. (Doc. 21.) They argue that Plaintiffs' claims fall under the primary jurisdiction of the U.S. Food & Drug Administration ("FDA"), and, as a result, the primary jurisdiction doctrine compels dismissal or a stay of the case. (*Id.* ¶ 1.) Defendants argue the Complaint should also be dismissed because Plaintiffs' claims are preempted in their entirety by federal law. (*Id.* ¶ 2) In the alternative, Defendants argue several of the state law claims should be dismissed because Plaintiffs have not pleaded essential elements of their state law claims, and thus fail to state a claim for relief. (*Id.*¶ 3.) Finally, and also in the alternative, Defendants move this Court to enter an order striking Plaintiffs' nationwide class allegations, arguing that individual issues predominate. (Docs. 21, 22.)

[2] Plaintiffs bring Counts I, II and III on behalf of the putative nationwide class and each subclass. They bring Count IV by Plaintiff Gorman on behalf of the Illinois Subclass; Counts V and VI by Plaintiffs Lambrakis and Nelson on behalf of the New York Subclass; Counts VII and VIII by Plaintiffs Natal and Parker on behalf of the New Jersey Subclass; Count IX by Plaintiff Anglin on behalf of the Florida Subclass; and Counts X and XI by Plaintiff Tari on behalf of the California Subclass.

II. LEGAL STANDARD

Federal Rule of Civil Procedure 8(a)(2) requires "a short and plain statement of the claim showing that the pleader is entitled to relief." Federal Rule of Civil Procedure 12(b)(6) provides for a motion to dismiss based on the "failure to state a claim upon which relief can be granted." To survive a motion to dismiss a complaint must show "'that the pleader is entitled to relief,' in order to 'give the defendant fair notice of what the . . . claim is and the grounds upon which it rests.'" *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957)). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice" to defeat a motion to dismiss. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Twombly*, 550 U.S. at 555). "[O]nly a complaint that states a plausible claim for relief survives a motion to dismiss." *Iqbal*, 556 U.S. at 679 (citing *Twombly*, 550 U.S. at 556). "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." *Iqbal*, 556 U.S. at 678 (citation omitted). The pleading standard of Rule 8 "does not require 'detailed factual allegations,' but it demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 555). "When ruling on a defendant's motion to dismiss, a judge must accept as true all of the factual allegations contained in the complaint." *Erickson v. Pardus*, 551 U.S. 89, 94 (2007). The Court must "draw all reasonable inferences in favor of the nonmoving party." *Coons v. Mineta*, 410 F.3d 1036, 1039 (8th Cir. 2005). However, "[w]here the allegations show on the face of the complaint there is some insuperable bar to relief, dismissal under Rule 12(b)(6) is appropriate." *Benton v. Merrill Lynch & Co.*, 524 F.3d 866, 870 (8th Cir. 2008).

III. ANALYSIS

A. Primary Jurisdiction Doctrine

Defendants first argue that the FDA has primary jurisdiction over Plaintiffs' claims and, as a result, the primary jurisdiction doctrine compels dismissal or a stay of the case. Defendants argue that sunscreen is one of the most highly regulated consumer products, particularly for SPF, and is statutorily regulated by the FDA under the Food, Drug, and Cosmetic Act ("FDCA") as an over-the counter drug. Because it falls within the FDA's statutory mandate, the FDA has primary jurisdiction over the at-issue Products. In fact, Defendants argue, the FDA published a "sunscreen Final Rule," codified in 21 C.F.R. § 201.327, mandating a whole host of highly specialized, highly scientific, and precise technical and scientific protocols that manufacturers must follow relating to testing and labeling. Defendants further contend a stay or dismissal is warranted particularly since the FDA is actively engaged in regulating issues central to the case. For these reasons, Defendants argue the Court should defer to the FDA and dismiss, or, at a minimum, issue a stay pending resolution of the FDA's ongoing agency action and investigation. (Doc. 22.)

Primary jurisdiction is a common law doctrine used to coordinate judicial and administrative decision making. *George v. Blue Diamond Growers*, No. 4:15-CV-962-CEJ, 2016 WL 1464644, at *1 (E.D. Mo. Apr. 14, 2016) (citing *City of Osceola, Ark. v. Entergy Arkansas, Inc.*, 791 F.3d 904, 908–09 (8th Cir. 2015) (quotation and citation omitted). Even when jurisdiction is proper in a given case, a court must consider whether an executive agency has primary jurisdiction. *Entergy Arkansas*, 791 F.3d at 908. The primary jurisdiction 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.'" *Alpharma, Inc. v. Pennfield Oil Co.*, 411 F.3d 934, 938 (8th Cir. 2005) (quoting *United States v. W. Pac. R. R. Co.*, 352 U.S. 59, 63-64 (1956)). The

doctrine allows a court with jurisdiction to refer a case to the appropriate administrative agency for initial decision. *Thornton v. Pinnacle Foods Grp., LLC*, No. 4:16-CV-00158-JAR, 2016 WL 5793193, at *1 (E.D. Mo. Sept. 30, 2016).

There is no "fixed formula" for deciding whether an agency has primary jurisdiction over a case. *Entergy Arkansas*, 791 F.3d at 909. Instead, the applicability of the doctrine depends on whether the reasons for the doctrine are present and whether applying the doctrine will aid the purposes for which the doctrine was created. *Access Telecomms. v. Sw. Bell Tel. Co.*, 137 F.3d 605, 608 (8th Cir. 1998). The Eighth Circuit has stated that courts apply the doctrine for two main reasons. *Id.* First, the doctrine may be applied "to obtain the benefit of an agency's expertise and experience," as "the principle is firmly established 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.'" *Id.* (quoting *Far East Conference v. United States*, 342 U.S. 570, 547 (1954)). "In fact, agency expertise is the most common reason for applying the doctrine." *Id.* Second, courts apply the doctrine is "to promote uniformity and consistency with the particular field of regulation." *Id.*; *see also Entergy Arkansas*, 791 F.3d at 909 ("courts consider whether 'desirable uniformity' would result from an agency determination and whether 'the expert and specialized knowledge' of the agency is needed") (citations omitted) (quoting *W. Pac. R. R. Co.*, 352 U.S. at 64); *Alpharma*, 411 F.3d at 938 ("Among the reasons and purposes served are the promotion of consistency and uniformity within the areas of regulation and the use of agency expertise 'in cases raising issues of fact not within the conventional experience of judges or cases requiring the exercise of administrative discretion.'")

"When it is determined that primary jurisdiction to resolve an issue lies with an agency, a court otherwise having jurisdiction over the case may stay or dismiss the action pending the agency's

resolution of the question." *George*, 2016 WL 1464644, at * 1 (citing *Alpharma*, 411 F.3d at 938). However, the doctrine is to be "invoked sparingly, as it often results in added expense and delay." *Thornton*, 2016 WL 5793193, at *1 (quoting *Alpharma*, 411 F.3d at 938).

Considering the reasons for applying the doctrine, and in light of the Eighth Circuit's caution that this doctrine should be invoked sparingly, the Court declines to apply the primary jurisdiction doctrine in this case.

1. Agency Expertise versus Conventional Experience of Judges

While this Circuit has not addressed the primary jurisdiction doctrine in the context of sunscreen labeling cases, cases in several other circuits have. In each instance, the courts have declined to apply the primary jurisdiction doctrine. The Court is persuaded by those cases. Consistent with those cases, the Court finds that Plaintiff's claims falls within the conventional wisdom of judges. Plaintiffs clearly note they are not claiming that the FDA's sunscreen Final Rule is improper, that the FDA should change its testing procedures, or that the FDA should adopt new testing procedures for SPF. (Doc. 26 at 14.) Instead, Plaintiffs claim that, based on the long-established SPF testing procedures and standards, Defendants overstated the SPF content of the Products in violation of various state consumer laws. (*Id.*) In other words, "[t]he gravamen of Plaintiffs' claims is that Defendants violated [state] consumer protection statutes by marketing their sunscreen products in a false and/or misleading manner so as to induce consumers to purchase those products. Whether Defendants did so is the type of factual question that is routinely committed to the courts." *Corra v. Energizer Holdings, Inc.*, 962 F. Supp. 2d 1207, 1216 (E.D. Cal. 2013) (declining to apply primary jurisdiction doctrine); *Dapeer v. Neutrogena Corp.*, 95 F. Supp. 3d 1366, 1376 (S.D. Fla. 2015) (declining to apply the doctrine because "determining whether a [sunscreen] manufacturer has misled consumers," including determining whether the sunscreen manufacturer's "marketing of its high SPF products is false and misleading" because it did not

provide the marketed SPF protection, "is squarely within the judicial function"); *Langan v. Johnson & Johnson Consumer Cos.*, 95 F. Supp. 3d 284, 292 (D. Conn. 2015) (declining to apply primary jurisdiction doctrine and holding claims relating to whether a manufacturer misled consumers and violated state consumer laws in using the phrase "all natural" on a sunscreen label are "one[s] to which courts are eminently well suited, even well versed") (citations omitted). In fact, in two pending Banana Boat SPF mislabeling cases, judges have found the courts are well equipped to address such claims. *See, e.g.*, *In re Edgewell Personal Care Co. Litig.*, Case No. 1:16-CV-3371-KAM-RLM, slip. op. at 13 (E.D.N.Y. Sept. 4, 2018) (collecting cases from various circuits and concluding "[c]ourts are well-equipped to assess whether a [sunscreen] label is misleading."); *Keskinen v. Edgewell Personal Care Co.*, Case No. 2:17-CV-07721-AB (PJWx), slip. op. at 6 (C.D. Cal. Apr. 17, 2018) (citation omitted) (declining to apply doctrine in Banana Boat sunscreen case, noting "[c]ourts are generally well-equipped to handle state-law challenges to labeling of FDA-regulated products" and, "[t]hus, courts 'routinely retain jurisdiction over false advertising cases involving such products, even when some scientific examination might be necessary").

Citing to the codified sunscreen Final Rule, Defendants assert this Court will undoubtedly be called upon to determine whether Plaintiffs' or Defendants' tests followed the technical and scientific requirements of that Rule. (Doc. 22 at 10.) Defendants argue the FDA possesses the experience and discretion to interpret these scientific and technical protocols for determining a sunscreen's SPF. (*Id.*) Defendants rely on non-binding, non-sunscreen cases in support of their argument. (*Id.* at 9–10.) However, multiple courts have declined to apply the primary jurisdiction doctrine in sunscreen cases even when the label relates to a scientific or technical claim, as is the case with SPF labeling. *See, e.g.*, *In re Edgewell*, at 14; *Dapeer*, 95 F. Supp. 3d at 1376; *Keskinen*, at 7 (reasoning, "Plaintiff alleges Defendants affirmatively and intentionally misrepresented the results of their SPF tests on the Sunscreen Products' labels. If that allegation is true, then discovery

is likely to resolve Plaintiff's claims without the need to resort to a technical examination of Defendants' SPF testing procedures"). And even assuming this Court will be called upon to assess whether Plaintiffs' or Defendants' tests complied with the FDA regulations, this Court is equipped to address such technical and scientific questions, as this and other courts routinely do on a regular basis. Finally, the argument that the FDA is in the "best" position to interpret the sunscreen Final Rule does not mean this Court cannot do the same or that this Court is compelled to apply the primary jurisdiction doctrine. *See, e.g.*, *In re Edgewell*, at 18 ("To the extent defendants argue that SPF testing [of Banana Boat sunscreen products] itself is so technical, complicated, and/or scientific that only the FDA can resolve plaintiff's claims of inaccuracy, the court is unconvinced"); *Keskinen*, at 7 (finding that whether SPF tests complied with FDA regulations "can be proved or disproved scientifically," that courts "frequently deal with such determinations," and that the court "is capable of doing the same in this case").[3]

2. Uniformity and Consistency

Defendants also argue that failure to dismiss or stay the case presents an "issue of consistent or uniform regulation," as the FDA is engaged in regulating issues central to this case. Defendants primarily rely on three FDA actions in support of their argument. First, Defendants note that the FDA solicited bids in a July 2016 "Request for Quote" ("RFQ") for determining the SPF of twenty U.S. marketed sunscreen products using the procedure in the sunscreen Final Rule. Second,

[3] As noted previously, Defendants cite to non-binding, non-sunscreen cases in arguing this Court must abstain from determining whether a regulated product meets technical or scientific agency requirements. However, as pointed out in both *In re Edgewell* and *Keskinen*, what differentiates the sunscreen cases from some other cases cited by Defendants is the fact that while the FDA regulations provide mandatory SPF testing procedures, "the FDA's involvement in this case's central question ends there." *Keskinen*, at 6. Manufacturers, not the FDA, perform those SPF tests. *See* 21 C.F.R. § 201.327(i–j). Moreover, the manufacturers are not required to obtain pre-marketing review or approval of their labels from the FDA. *Keskinen*, at 6. Therefore, "while the FDA provides rules for SPF testing, it is up to Defendants to follow those rules and properly label their Sunscreen Products." *Id.* Like in those cases, here, Plaintiffs "allege[] that Defendants have failed to do so." *Id.* Therefore, like in those cases, Plaintiffs' claims do not require resolution of an issue within the unique province of a regulatory agency. *See id.*; *In re Edgewell*, at 19.

Defendants note that in May 2018, the FDA issued a public statement entitled "Statement from FDA Commissioner Scott Gottlieb, M.D., on new FDA action to keep consumers safe from the harmful effects of sun exposure, and ensure the long-term safety and benefits of sunscreens" ("FDA Statement"). Third, and related to the FDA Statement, the FDA also issued a "Guidance for Industry" in May 2018, reaffirming that SPF testing must be conducted according to the specific method specified in the sunscreen Final Rule. (Doc. 22 at 11–12.)[4]

In the RFQ, the FDA has solicited bids for testing to be performed on twenty U.S. marketed sunscreen products, including eight SPF 50 products. (Doc. 22-2 at 2.) That testing will be performed off-site by a contractor and must be consistent with the testing procedures outlined in the sunscreen Final Rule. (*Id.*) Defendants argue that the test results from the RFQ "will provide guidance that will promote a uniform interpretation of the Final Rule." (Doc. 22 at 11.) However, the Court finds this argument to be speculative at this point.

First, it is unknown if or when these test results will be completed, and even if the testing is completed, it is not certain that the FDA will issue any relevant formal ruling based on those possible results. *In re Edgewell*, at 21–22. Thus, contrary to Defendants' contention, it not certain at this point when the FDA "will provide guidance" or that any such guidance "will promote" uniformity. (*See* Doc. 22 at 11.) Defendants argue that the Guidance for Industry states that

[4] When ruling on a motion to dismiss under Rule 12(b)(6), the Court generally may not consider materials outside the pleadings. *Noble Sys. Corp. v. Alorica Cent., LLC,* 543 F.3d 978, 982 (8th Cir. 2008). It may, however, consider public records or materials that are necessarily embraced by the pleadings. *Id.*; *Stahl v. U.S. Dep't of Agric.,* 327 F.3d 697, 700 (8th Cir. 2003). The Court takes judicial notice of these three sources as they are publicly available documents from the FDA, a source "whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201; *see also Thompson v. Allergan USA, Inc.*, 993 F. Supp. 2d 1007, 1011 (E.D. Mo. 2014) (concluding court could consider publicly-available FDA documents). Plaintiffs do not object to or contest the substance of these documents. In their Reply brief, Defendants point to an additional source, an FDA request for comments on SPF labeling and testing for over-the-counter sunscreen drug products, published on August 22, 2018, in the Federal Register. (Doc. 34 at 14 n.6.) For similar reasons discussed in this section of the Court's Order, this source does not alter the Court's analysis on primary jurisdiction.

"'[s]everal other ongoing and planned rulemaking proceedings will also address [over the counter sunscreens].'" (Doc. 34 at 14.) However, even if the FDA issues future formal rulings, there is no indication that such rulings will have any retroactivity. Thus, it is speculative whether those rulings would have impact on actions or testing that occurred relating to this pending litigation. Defendants also argue that the FDA has consistently made known its "continued undertakings" in the field of SPF testing. Thus, Defendants contend this case is distinguishable from *Alpharma*, "where the Eighth Circuit noted 'substantial delay would result[] from staying or dismissing the cases, particularly since the FDA ha[d] taken no action . . . [for] nearly two years' on the regulated product at issue." (Doc. 22 at 11) (citing *Alpharma*, 411 F.3d at 939). Yet that seems to be the situation here. As noted in *In re Edgewell*, as of September 2018 and confirmed by the parties in that case, "it appears that no action has been taken pursuant to the FDA RFQ." *In re Edgewell*, at 21 n.11.[5] Therefore, it has been over two years since that RFQ, with no concrete action resulting, which seems to implicate at least some of the same concerns as in *Alpharma*.

Second, the Court finds that Defendants' arguments based on the RFQ are speculative because only eight SPF 50 products will be tested, and the RFQ does not specify which products will be tested. (*See generally* Doc. 22-2.) Nowhere does the RFQ mention any particular sunscreen, including the Banana Boat Products at issue in this case. (*Id.*) The Court takes judicial notice of the fact that there are many SPF 50 products marketed in the United States. There is no guarantee the Products at issue in this case will be part of the RFQ testing. *In re Edgewell*, at 23. Moreover, as Plaintiffs note—and Defendants do not contest—there is no indication that the FDA is testing Defendants' Products or investigating the accuracy of Defendants' SPF label on the at-issue

[5] There is overlap between the plaintiffs and defendants in the Banana Boat SPF mislabeling cases pending in the United States District Court for the Eastern District of New York and this matter.

Products, and Defendants have not applied, as they are entitled to do so, to have the FDA complete such testing or investigation.[6] (Doc. 26 at 17.)

Next, Defendants argue that the May 2018 FDA statement and Guidance for Industry require a dismissal or stay. Defendants maintain that the FDA statement "left no doubt about [the FDA's] place in the field of [SPF efficacy]," as it states the FDA is committed to "making sure the products consumers use deliver their advertised benefits." (Doc. 22 at 11.) Defendants also argue that the Guidance for Industry, which reiterated that SPF testing must be conducted according to the method proscribed in the sunscreen Final Rule, warrants deference to the FDA. (*Id.* at 12.) However, "[n]othing in the FDA Statement or the Guidance for Industry indicates that the FDA will, or is even contemplating, issuing a ruling on the issue at hand in this action — namely whether defendants improperly labeled the Products with an SPF 50 rating." *In re Edgewell*, at 25.

Therefore, the Court finds that these sources, considered either singularly or in combination, do not warrant the application of the primary jurisdiction doctrine.[7]

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[6] Importantly, as Plaintiffs note and Defendants do not contest, the FDA Statement indicates that the FDA is not investigating Defendants, as the FDA has identified just three companies who were subject to FDA investigation and who received warning letters due to deceptive warning practices. (Doc. 26 at 16.) Defendants were not included on that list and did not receive a warning letter. (*Id.*) Defendants concede it is unclear whether the testing will include the Products at issue here. (Doc. 34 at 14.) This further suggests that abstention based on primary jurisdiction is unwarranted. *See Keskinen*, at 7 (finding that "Defendants present no reason for the Court to believe that the FDA will resolve the issue of whether the SPF ratings on their Sunscreen Products are accurate" because "it does not appear [from the RFQ] that the Sunscreen Products will be among those tested.") Should it become clear at some point that one or more of the Products at issue in this case will be tested pursuant to the RFQ or otherwise investigated by the FDA, Defendants may make a motion for this Court to revisit this issue.

[7] The Court is mindful that there are multiple sunscreen cases pending involving the same manufacturers (and, in some instances, the same products). Defendants argue that the more these matters are litigated and resolved in varying judicial settings, uniformity and consistency will be further threatened. (Doc. 22 at 15.) However, that does not warrant the application of primary jurisdiction, as there are separate mechanisms in place for addressing such concerns should they persist, including potential transfer or other consolidation of the actions. *See, e.g.*, 28 U.S.C. §§ 1404, 1407.

B. Preemption

Defendants also argue for dismissal asserting that, as pleaded, Plaintiffs' claims are preempted by federal law. (Doc. 22 at 12–16.) Defendants argue that Plaintiffs must rely on FDA-compliant testing, but the *Consumer Reports* and independent testing they reference in the Complaint did not comply with FDA regulations. (*Id.* at 13–16.) Since Plaintiffs have failed to plead sufficient facts to plausibly assert that their claims are founded on the sunscreen Final Rule, they fail to state a claim for relief. (*Id.* at 13.)

The Supremacy Clause of the Constitution provides that "the Laws of the United States . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. Therefore, any state law conflicting with an existing federal law is considered to be "without effect" and preempted by the federal law. *Baker v. NNW, LLC*, No. 15-00222-CV-W-GAF, 2015 WL 12843827, at *2 (W.D. Mo. July 8, 2015) (citing *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981).

Relevant to this matter, the FDCA contains an express preemption clause. Section 379r, "National uniformity for nonprescription drugs," of the FDCA states in relevant part:

> (a) In general
>
> > Except as provided in subsection (b), (c)(1), (d), (e), or (f), no State or political subdivision of a State may establish or continue in effect any requirement—
> > . . .
> >
> > (2) that is different from or in addition to, or that is otherwise not identical with, a requirement under this chapter . . . .

21 U.S.C. § 379r(a)(2);[8] *see also Carrol v. S.C. Johnsons & Son, Inc.*, No. 17-CV-05828, 2018 WL 1695421, at *2 (N.D. Ill. Mar. 29, 2018) (in sunscreen SPF mislabeling case, noting section 379r

[8] Common law causes of action "constitute [state] 'requirements' within the meaning of FDCA preemption" and, thus, also are preempted. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 323–25 (2008).

"expressly preempts claims seeking to enforce state requirements that differ from those established by the FDA"); *Dayan v. Swiss-Am. Prod., Inc.*, No. 15CIV6895DLIVMS, 2017 WL 9485702, at *2 (E.D.N.Y. Jan. 3, 2017), *report and recommendation adopted*, No. 15CV6895DLIVMS, 2017 WL 1214485 (E.D.N.Y. Mar. 31, 2017) (noting 379r(a) is an express preemption clause). The FDCA regulates over-the-counter drugs, including non-prescription sunscreen. *See, e.g.*, 21 U.S.C. § 360fff–6.

In addition, and as both parties agree, the FDA has enacted regulations relating SPF testing procedures and labeling requirements for the Products. The federal requirements for sunscreen labeling and testing are codified in a "sunscreen Final Rule," 21 C.F.R. § 201.327 ("Over-the-counter sunscreen drug products; required labeling based on effectiveness testing"). Among other things, that regulation sets out the SPF labeling requirements and lengthy, detailed scientific and technical procedures and parameters for testing a sunscreen's SPF. *See id.* § 201.327(i). The methodology in § 201.327 is used to determine whether SPF claims comply with the regulation. In the preemption analysis, "federal regulations carry the same preemptive effect as federal statutes." *Baker*, 2015 WL 12843827, at *2 (citing *Fid. Fed. Savings & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 153 (1982)).

The Eighth Circuit Court of Appeals has affirmed the dismissal of actions on federal preemption grounds at the pleading stage. *See, e.g.*, *Brinkley v. Pfizer, Inc.*, 772 F.3d 1133, 1139 (8th Cir. 2014) (finding design defect and implied warranty claims were preempted by the FDCA and affirming the lower court's dismissal pursuant to a motion for judgment on the pleadings); *Moretti v. Mut. Pharm. Co.*, 518 Fed. App'x 486, 487 (8th Cir. 2013) (affirming district court's grant of judgment on the pleadings on the basis of FDA preemption); *see also Ideus v. Teva Pharm. USA, Inc.*, No. 4:16-CV-3086, 2017 WL 6389630, at *2 (D. Neb. Dec. 12, 2017) (internal quotations and citation omitted) (dismissal is nonetheless appropriate under Rule 12(b)(6) if the facts

alleged in the complaint do not plausibly give rise to a claim that is not preempted."); *Dougherty v. Source Nats., Inc.*, 148 F. Supp. 3d 831, 835–36 (E.D. Mo. 2015) (granting motion to dismiss in labeling case based on FDCA preemption). To avoid preemption under the FDCA, Plaintiffs' state law claim must fit in a narrow gap. *Dougherty*, 148 F. Supp. 3d at 834. "'[I]n order for a state law claim to survive, plaintiff's claim "must be premised on conduct that both (1) violates the FDCA and (2) would give rise to a recovery under state law even in the absence of the FDCA.'" *Id.* (quoting *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009)).

The Court agrees that to the extent Plaintiffs' state law claims do not seek to impose any requirements on Defendants beyond those which federal law already requires (Docs. 1 ¶ 60–61; 26 at 3), those claims are not preempted. *See* 21 U.S.C. § 379r(f); *see also, e.g.*, *Baker*, 2015 WL 12843827, at *2 ("a state law is not preempted when the state law seeks to impose liability [for mislabeling] consistent with the FDCA."); *Curran v. Bayer Healthcare LLC*, No. 17 C 7930, 2018 WL 2431981, at *3 (N.D. Ill. May 30, 2018) (in SPF mislabeling case, holding "to the extent plaintiff is merely seeking to use state-law causes of action to enforce the labeling requirements set out in 21 C.F.R. § 201.327, his claims are not preempted."). To the extent Plaintiffs seek to add or change the requirements for sunscreen labeling or testing, however, those claims would be preempted. *See, e.g.*, *Curran*, 2018 WL 2431981, at *3. Further, if Plaintiffs rely on FDA-compliant testing of the Products in "an attempt to enforce the identical requirements of the FDCA as it applies to SPF labeling . . . [such] claims are not preempted." *Curran*, 2018 WL 2431981, at *3. If, however, Plaintiffs' testing is not in compliance with the sunscreen Final Rule, and if Plaintiffs seek to use that testing in support of their Complaint, as they have so alleged, they would in essence be asking this Court to find Defendants liable based on a change or deviation from the testing requirements as set out in the Final Rule. *Cf. Corra v. Energizer Holdings, Inc.*, 962 F. Supp. 2d 1207, 1215 (E.D. Cal. 2013) (finding sunscreen claims not preempted when a plaintiff's claims

"are not based on (and do not require interpretation of) the Final Rule");[9] *Lombardo v. Johnson & Johnson Consumer Companies, Inc.*, No. 13-60536-CIV, 2014 WL 10044838, at *4 (S.D. Fla. Sept. 10, 2014) (finding sunscreen claims not preempted when plaintiff did not allege that the SPF values on labels were inaccurate).

The parties agree that 21 C.F.R. § 201.327 applies to this case. They disagree about what suffices to avoid preemption and whether testing must comply with the FDA methodology in order to avoid preemption. *See, e.g.*, *Mee v. I A Nutrition, Inc.*, No. C-14-5006 MMC, 2015 WL 2251303, at *4 (N.D. Cal. May 13, 2015) ("As each district court to have considered the matter has found, where, as here, an FDA regulation provides that the question of compliance must be determined using the method specified therein, a state law claim that seeks to establish a violation of such regulation by a different methodology is preempted.") (collecting cases); *see also Dougherty*, 148. F. Supp. 3d at 835, 836 (quoting *Mee* with approval for this proposition and stating "state law claims that rely on a different methodology to demonstrate such labeling violations are inconsistent with the FDCA and are thus preempted").

Plaintiffs allege that *Consumer Reports* article sets forth "in May 2016 that its own testing had revealed 'that Banana Boat Kids SPF 50 sunscreen lotion had an SPF of only 8 and stated "the most problematic products were Banana Boat Kids Tear-Free, Sting-Free Lotion . . . which [was] labeled as SPF 50 but [was] found to have only SPF 8.'" (Doc. 1 ¶ 37.) The Court agrees with Defendants that Plaintiffs include no allegations about the methodology of the *Consumer Reports*

[9] In *Corra*, the plaintiffs brought suit against sunscreen manufacturers regarding their labeling of some products with an SPF of 85 to 110. *Corra*, 962 F. Supp. 2d at 1214. As the Court noted, and unlike the matter before this Court, the plaintiffs did not argue that the "SPF 85–110 ratings on Defendants' products are themselves per se false or misleading." *Id.* Instead, the plaintiffs argued that the products were marketed in such a way that led customers to buy them even though there was evidence tending to show products with an SPF above fifty did not provide proportionally greater protection than lower-rated SPF products. *Id.* at 1214–15. Therefore, because the plaintiffs' claims were not based on and did not require an interpretation of the Final Rule, the court found those claims were not preempted. *Id.*

testing or any facts demonstrating that such testing complied with FDA-prescribed methodology. (*See* Doc. 22 at 14.) In fact, Plaintiffs clarify and concede in their response to Defendants' Motion to Dismiss that "Plaintiffs' claims are not actually based on the *Consumer Reports* testing." (emphasis in original) (Doc. 26 at 7.)[10] Nor could they be, as Plaintiffs have not included any allegations in support of the notion that the *Consumer Reports* testing complies with the regulations for testing sunscreen as codified in the Final Rule. (*See*, *e.g.*, Doc. 1 ¶ 37.) Indeed, in their strong statements of non-reliance on the *Consumer Reports* testing, Plaintiffs seem to at least implicitly concede that the testing does not, in fact, comply with those regulations. (*See* Doc. 26 at 7.) Therefore, to the extent Plaintiffs seek to rely on or otherwise invoke the *Consumer Reports* testing in support of their claims, those claims are preempted. *See*, *e.g.*, *Curran*, 2018 WL 2431981, at *3 ("To the extent plaintiff is claiming that the sunscreen's label needed to reflect the [SPF] testing conducted by *Consumer Reports*, those claims are preempted, because such labeling is not identical to the requirements set out in federal law."); *Baker*, 2015 WL 12843827, at *2 (dismissing complaint as preempted because plaintiff failed to allege testing of the subject product used relevant FDA-mandated methodology).

[10] Plaintiffs assert that the "Complaint makes clear" that "while the *Consumer Reports* article first alerted Plaintiffs to the potential inaccuracy in Defendants' labels," Plaintiffs' claims are actually based on their independent testing, not the *Consumer Reports* testing. (Doc. 26 at 7.) The Court disagrees that the Complaint made this clear. Instead, Plaintiffs' allegations, on their face, place reliance on the *Consumer Reports* testing. (*See* Doc. 1 ¶¶ 36–37) ("[R]igorous scientific testing has revealed that the Products do not provide an SPF of 50, much less '50+' . . . . Such testing includes, but is not limited to, testing conducted by the noted consumer protected periodical Consumer Reports . . . .") The Court declines to decide at this time the general admissibility of such testing as background information said to have "first alerted Plaintiffs to the potential inaccuracy in Defendants' SPF labels." (Doc. 26 at 7.)

The Court will now address Plaintiffs' independent SPF testing. Defendants argue that if Plaintiffs rely on testing that "does not employ the *precise* methodology found in the Final Rule, [Plaintiffs'] claims are preempted." (Doc. 22 at 13.) In part, the relevant allegations are as follows:

> 38. In addition, Plaintiffs conducted their own independent testing of the Products, utilizing the methodology for SPF testing mandated by the FDA.
>
> 39. Specifically, the independent testing conducted by Plaintiffs was conducted in compliance with all FDA testing methods embodied in FDA Final Rule, 21 CFR Parts 201 and 310, (Federal Register/Vol 76, No 117/Friday, June 17, 2011/Rules and Regulations, including 21 CFR 201.327).
>
> 40. The results of the independent testing conducted by Plaintiffs were consistent with the results suggested by Consumer Reports' test results and confirmed that the Products had actual SPFs substantially lower than the claimed SPF 50 or "50+".
>
> 41. Plaintiffs' investigation concluded that all three products, clearly labeled as containing SPF 50 or "50+", contained an SPF of less than 37.8 and no more than a 30.1.

(Doc. 1.) Defendants argue Plaintiffs have "failed to plead facts sufficient to make plausible their assertion that their claims are founded on the Final Rule Method." (Doc. 22 at 13.) More specifically, Defendants argue that Plaintiffs' "naked assertions" regarding their independent testing, which are "undetailed" and void of facts, amount to a "legal conclusion" and are insufficient to state a plausible claim for relief. (*See* Doc. 22 at 15–16; Doc. 34 at 1, 3–12.) Defendants argue Plaintiffs' bare allegations are particularly insufficient given that the some claims sounds in fraud and misrepresentation, and such claims must be pleaded with particularity in accordance with Eighth Circuit and Supreme Court precedent. (*See*, *e.g.*, Doc. 22 at 16–17.) Plaintiffs do not contest the notion that their independent testing must comply with the methodology as codified in the FDA Final Rule. Plaintiffs instead maintain that their description of testing methods in the Complaint is sufficient to avoid dismissal under federal pleading standards. (Doc 26 at 9.) However, Plaintiffs are prepared to file an amended pleading providing additional details regarding their independent testing if the Court orders otherwise. (*Id.*)

The relevant allegations demonstrate that Plaintiffs' claims are premised on and dependent upon the independent product testing results. (*See* Doc. 1 ¶¶ 36, 38–41.) But if Plaintiffs are relying on testing that does not comply with FDA methodology in support of their claims, Plaintiffs cannot show that Defendants' statements on the product labels violated the FDCA labeling requirements. Thus, they cannot establish a violation of the FDCA. And as a result, they face preemption. *See, e.g.*, *Salazar v. Honest Tea, Inc.*, 74 F. Supp. 3d 1304, 1313 (E.D. Cal. 2014). As an initial matter, Plaintiffs' claims must be premised on conduct that violates the FDCA in order to survive. *See Dougherty*, 148 F. Supp. 3d at 834. Therefore, the Court finds that compliance with FDA-mandated testing is a threshold issue in this case.[11]

The Court further finds that even under a liberal reading of the Complaint, Plaintiffs' allegations regarding their independent testing are insufficient to avoid dismissal under preemption at this stage of the litigation. The crux or centerpiece of Plaintiffs' Complaint is that all three Products do not in fact meet the stated SPF on their respective labels. All claims flow from and are premised on that presumption. Yet in their thirty-four page, one-hundred-and-sixty paragraph, Complaint, Plaintiffs devote just four paragraphs to their testing. (*See* Doc. 1 at ¶¶ 38–42.) And only one of those paragraphs, just over three lines, mentions anything about the specific methodology employed. (*See id.* ¶ 39.) In that sole paragraph, Plaintiffs offer nothing more than a conclusory statement that the testing complied with the FDA Final Rule, an ultimate question this Court may be called upon to decide in the future. *See, e.g.*, *Wiles v. Capitol Indemnity Corp.*, 280 F.3d 868, 870 (8th Cir. 2002) ("While the court must accept allegations of fact as true when considering a motion to dismiss, the court is free to ignore . . . legal conclusions cast in the form of factual allegations."); *Baker*, 2015 WL 12843827, at *1 (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) ("courts are 'not bound to accept as true a legal conclusion couched as a factual

[11] Defendants recognize that if Plaintiffs' testing complies with FDA requirements, Plaintiffs' claims may not be preempted. (Doc. 22 at 16.)

allegation' and such 'labels and conclusions' or "'formulaic recitation[s] of the elements of a cause of action will not do.'"); *Ladd v. St. Louis Bd. of Police Comm'rs*, No. 405CV916UNA RHK/AJB, 2006 WL 2862165, at *2 (E.D. Mo. Oct. 4, 2006) (quoting *Kaylor v. Fields*, 661 F.2d 1177, 1182 (8th Cir. 1981)) ("Courts need not consider conclusory allegations, however, or 'blindly accept legal conclusions drawn by the pleader of the facts'"). Moreover, even under a liberal reading of the Complaint, it is uncertain whether Plaintiffs have FDA-compliant test results relating to all three Products even though the Products have differences. (*See id.* ¶¶ 38–42 and Figures 1–3; *see also* Doc. 34 at 10–11.) Another district court interpreting near-identical independent SPF sunscreen testing allegations recently found that a sunscreen SPF labeling claim "is preempted if it seeks to enforce a labeling requirement that is not identical; and, in order to make his claim plausible, plaintiff must do more than insert a conclusory allegation that the testing was identical." *Curran*, 2018 WL 2431981, at *4. That reasoning applies with equal force here.

Therefore, the Court finds that Plaintiffs have not pleaded sufficient facts to avoid preemption at this stage. Plaintiffs implicitly, if not explicitly, recognize the need for FDA-compliant SPF testing in this matter, but it is ambiguous whether Plaintiffs have testing on all products that complies with the FDA-mandated methodologies. Given the threshold nature of this issue, the Court finds it prudent to grant Defendants' motion to dismiss on this basis, as the allegations do not suffice under the pleading standards for the reasons stated. *See, e.g.*, *Dougherty*, 148 F. Supp. 3d at 833 (alteration in original) (citation omitted) (quoting *Benton v. Merrill Lynch & Co.*, 524 F.3d 866, 870 (8th Cir. 2008) (finding "'[w]here the allegations show on the face of the complaint there is some insuperable bar to relief, dismissal under Rule 12(b)(6) is appropriate.'"); *Crump v. Boester*, No. 4:14 CV-01975-RWS, 2016 WL 1624017, at *3 (E.D. Mo. Apr. 25, 2016) (quoting *Iqbal*, 556 U.S. at 678–79) (noting "'[r]ule 8 . . . does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions'").

This conclusion is consistent with holdings of some other district courts in this and other circuits when analyzing independent testing-related allegations in the context of the FDCA. The *substance* of the allegations is particularly important in determining the *sufficiency* of those allegations in situations where, as here, the governing FDA regulation imposes a specific, lengthy, and very detailed methodology for testing the products, including the specific number of subjects to be tested, timelines for testing, etc. *See*, *e.g.*, *Dougherty*, 148 F. Supp. 3d at 835–36 (in mislabeling case involving the amount of vitamins and minerals in an over-the-counter vitamin, dismissing claims as preempted when the allegations regarding plaintiff's independent testing did not allege product testing complied with the twelve-sample testing method, were based on a random sample, or used bottles from the same lot, as required by the applicable FDA-mandated testing regulation); *Baker*, 2015 WL 12843827, at 3–4 (in mislabeling case involving whey protein, dismissing claims as preempted when plaintiff did not allege he tested the product "under the twelve-subsample analytical methodology mandated by [the applicable codified regulation]" and otherwise "failed to articulate any precise methodology he used"); *see also*, *e.g.*, *Curran*, 2018 WL 2431981, at *4 (in case with virtually identical allegations in sunscreen SPF case, holding that plaintiff failed to state a plausible claim to avoid preemption when "plaintiff offer[ed] nothing more than his conclusion that his testing was the same as is required by the FDA");[12] *Mee*, 2015 WL 2251303, at *4 (in dietary

[12] The relevant allegations the *Curran* court analyzed stated the following:

> 37. In addition, Plaintiff conducted his own independent testing of Coppertone Sport High Performance SPF 30 sunscreen spray, utilizing the methodology for SPF testing mandated by the FDA.
>
> 38. The independent testing performed by Plaintiff was conducted in compliance with all FDA testing methods embodied in FDA Final Rule, 21 CFR Parts 201 and 310, Federal Register/Vol 76, No 117/Friday, June 17, 2011/Rules and Regulations, including 21 CFR 201.327.

Curran, No. 1:17-CV-07930 (N.D. Ill. Nov. 2, 2017), ECF No. 1 ¶¶ 37–38.

supplement mislabeling case, holding that claims were preempted because plaintiff's independent testing attached to complaint did not comply with FDA-mandated twelve sample methodology); *Salazar v. Honest Tea, Inc.*, 74 F. Supp. 3d 1304, 1313 (E.D. Cal. 2014) (granting 12(b)(6) dismissal based on preemption in tea mislabeling case when plaintiff failed to allege he tested correct number of samples as required by the FDA-mandated regulation, reasoning "Consequently, the Complaint does not show that defendant's statements on the product labels violates the FDCA's labeling requirements. Because plaintiff's allegations do not show a violation of the FDCA, plaintiff's state law claims are preempted; if allowed to proceed, the state law claims would impose liability inconsistent with the FDCA."); *Burke v. Weight Watchers Int'l, Inc.*, 983 F. Supp. 2d 478, 483 (D.N.J. 2013) (dismissing complaint as preempted when plaintiff made conclusory allegation that testing complied with a specific FDA-mandated regulatory provision, reasoning the allegations were insufficient to establish a violation of the FDCA because plaintiff "has not pled that she tested the [product] using every one of the Five Methods [specified in the regulation] . . . has not pled that every one of the test results [failed to meet the standards set out in the regulation] and also failed to test each of the at-issue products).[13]

[13] Two of the cases Plaintiffs rely upon in their argument are distinguishable because the plaintiffs in those cases attached the independent testing to their complaints, but Plaintiffs have not chosen to do the same here. *See, e.g.*, *Muir v. NBTY, Inc.*, No. 15 C 9835, 2016 WL 5234596, at *5–6 (N.D. Ill. Sept. 22, 2016) (plaintiff attached multiple independent testing results to the complaint in dietary supplement mislabeling case); *Gubala v. CVS Pharmacy, Inc.*, No. 14 C 9039, 2016 WL 1019794, at *8 (N.D. Ill. Mar. 15, 2016) (citation omitted) (in protein powder mislabeling case, holding "Plaintiff may rely on the [independent] testing results attached to the amended complaint to nudge his claims based on an overstated declaration of protein content 'across the line from conceivable to plausible.'"). While the *Carrol* court allowed the plaintiffs to avoid dismissal when the allegations did not state independent testing was in compliance with FDA methodology, the court specifically relied upon district court case law within that circuit allowing mislabeling claims based on preliminary testing that was not completed in compliance with FDA standards. *See Carrol v. S.C. Johnsons & Son, Inc.*, No. 17-CV-05828, 2018 WL 1695421, at *3 (N.D. Ill. Mar. 29, 2018). The district courts in this circuit (*e.g.*, *Dougherty* and *Baker*) have taken a different approach, consistent with multiple district courts from other circuits.

However, in the interests of justice and given the early stage of this litigation, the Court also finds it prudent to allow Plaintiffs to amend their Complaint to address Defendants' concerns about their independent testing, consistent with other courts interpreting FDA testing requirements at the pleading stage. *See, e.g.*, *Curran*, 2018 WL 2431981, at *4 (allowing plaintiff to amend, stating plaintiff "needs to include at least some facts" about his testing procedure "in order to make it plausible that defendant's [sunscreen SPF] label was not in compliance with the requirements of 21 C.F.R. § 201.327."); *Dougherty*, 148 F. Supp. 3d at 837 (allowing plaintiff to amend when, as here, plaintiff requested she be allowed to amend in event court granted motion to dismiss); *Mee*, 2015 WL 2251303, at *4 (allowing leave to amend); *Salazar*, 74 F. Supp. 3d at 1318 (E.D. Cal. 2014) (same); *Burke*, 983 F. Supp. 2d at 484 (same). In fact, in another Banana Boat sunscreen SPF mislabeling case involving almost identical allegations and parallel preemption arguments, the court in the Eastern District of New York ordered plaintiffs to file an amended complaint addressing concerns regarding plaintiffs' compliance with FDA testing results. *In re Edgewell*, Case No. 1:16-CV-3371-KAM-RLM (E.D.N.Y. Oct. 23, 2018), ECF Minute Entry.[14]

For these reasons, the Court will grant Defendants' motion to dismiss based on preemption in part, allowing Plaintiffs leave to amend their Complaint.

[14] Defendants argue in their Memorandum in Support and Reply some specific ways in which they assert Plaintiffs' allegations are deficient and could be remedied. (See Doc. 22 at 15–16; Doc. 34 at 6–8, 10–12). It would be improper for the Court to order with specificity how Plaintiffs should amend their Complaint. However, like in *Curran* and *In re Edgewell*, the Court would expect that Plaintiffs will address the issues raised here and include facts about the testing procedure of each of the three products in order to make it plausible that each individual product was not in compliance with the FDA regulation. Plaintiffs must decide whether to attach such testing. *See Curran*, 2018 WL 2431981, at *4; *Curran*, No. 1:17-CV-07930 (N.D. Ill. June 25, 2018), ECF No. 87.

C. Class Action Certification

Plaintiffs seek to bring this case as a class action pursuant to Federal Rule of Civil Procedure 23(b)(2) or 23(b)(3). (Doc. 1 ¶ 64.) Plaintiffs seek certification of a nationwide class. (*Id.* ¶ 65.) Additionally, or alternatively, Plaintiffs seek certification of defined state sub-classes for New York, New Jersey, Florida, Illinois, and California. (*Id.* ¶ 66.) Defendants move to strike the nationwide class allegations, arguing that individual issues predominate. (Doc. 21.) More specifically, Defendants argue that individual issues predominate on Plaintiffs' claims for unjust enrichment, implied contract, and breach of warranty asserted on behalf of a purported nationwide class. (Doc. 22 at 22.) Because the elements of such claims are variable among the laws of the states, and because there are significant outcome-determinative conflicts across the laws of the fifty states and the District of Columbia, Defendants argue the Court should strike those nationwide class allegations now. (*Id.*) Though the Court need not decide the issue at this juncture given the ruling on preemption, the Court deems it helpful to address it now to provide guidance to the parties in light of the upcoming Scheduling Conference pursuant to Federal Rule of Civil Procedure 16. A class action may be maintained if Federal Rule of Civil Procedure Rule 23(a) is satisfied and if "the court finds that the questions of law or fact common to class members predominate over any questions affecting only individual members, and that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy."[15] Because the dispositive inquiry here is whether Plaintiffs' class allegations can plausibly meet Rule 23(b)(3)'s predominance requirement, the Court need not address the Rule 23(a) factors or Rule 23(b)(3)'s superiority

[15] Rule 23(a) contains the prerequisites for class actions, namely that a class member can sue on behalf of a class only if (1) the class is so numerous that joinder of all members is impracticable; (2) there are questions of law or fact common to the class; (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class; and (4) the representative parties will fairly and adequately protect the interests of the class. *See* Fed. R. Civ. P. 23(a). The Court need not determine today whether the prerequisites are met in ruling on this Motion.

requirement at this time. *See, e.g., Kraetsch v. United Service Auto. Ass'n*, 2015 WL 1457015, at *4 (E.D. Mo. Mar. 30, 2015).

In the Eighth Circuit, "class claims that fail to meet the requirements of Rule 23 may be properly dismissed by granting a Rule 12(b)(6) motion." *McCrary v. Stifel, Nicolaus & Co.*, 687 F.3d 1052, 1059 (8th Cir. 2012); *see also In re Zurn Pex Plumbing Products Liab. Litig.*, 644 F.3d 604, 611 (8th Cir. 2011) (same); *Blades v. Monsanto Co.*, 400 F.3d 562, 566 (8th Cir. 2005) ("If, to make a prima facie showing on a given question, the members of a proposed class will need to present evidence that varies from member to member, then it is an individual question"); *Kraetsch*, 2015 WL 1457015, at *5 (internal quotations and citation omitted) (striking class claims and stating "[a]t the core of Rule 23(b)(3)'s predominance requirement is the issue of whether the defendant's liability to all plaintiffs may be established with common evidence."). Indeed, Federal Rule of Civil Procedure Rule 23(c)(1)(A) provides "[a]t an early practicable time after a person sues or is sued as a class representative, the court must determine by order whether to certify the action as a class action." However, while judges enjoy liberal discretion to strike pleadings, the Eighth Circuit has also recognized that striking a party's pleading "is an extreme and disfavored measure." *BJC Health Sys. v. Columbia Cas. Co.*, 478 F.3d 908, 917 (8th Cir. 2007); *see also Doyel v. McDonald's Corp.*, No. 4:08-CV-1198-CAS, 2009 WL 350627, at *5 (E.D. Mo. Feb. 10, 2009) (noting that "[s]triking plaintiffs' class action allegations prior to discovery and the class certification stage is a rare remedy"); *Knowles v. Standard Fire Ins. Co.*, No. 4:11-CV-04044, 2013 WL 6497097, at *2 (W.D. Ark. Dec. 11, 2013) (noting that "in many cases, a motion to strike or dismiss a plaintiff's class allegations prior to discovery on class-related issues and prior to the submission of a motion for class certification would be premature."); *Nobles v. State Farm Mut. Auto. Ins. Co.*, No. 10-04175-CV-C-NKL, 2012 WL 4090347, at *2 (W.D. Mo. Sept. 17, 2012) ("[t]he weight of authority indicates that

courts should meet motions to dismiss class allegations at the 12(b)(6) stage with a great deal of skepticism.")

Defendants contend that nationwide class certification of Plaintiffs' breach of warranty, unjust enrichment, and implied contract claims is not appropriate. *See, e.g.*, *In re Bridgestone/Firestone Tires Prods. Liab. Litig.*, 288 F.3d 1012, 1015 (7th Cir. 2002) (holding that "warranty . . . suits may not proceed as nationwide classes"); *True v. Conagra Foods, Inc.*, No. 07-00770-CV-W-DW, 2011 WL 176037, at *9 (W.D. Mo. Jan. 4, 2011) (citation omitted) (declining to certify nationwide class on unjust enrichment, finding that "[p]erhaps the greatest discrepancy in state law is found in Plaintiffs' claim for unjust enrichment" and "[c]ourts have repeatedly recognized that 'the law of unjust enrichment varies materially from state to state"); *Tyler v. Alltel Corp.*, 265 F.R.D. 415, 422 (E.D. Ark. Feb. 23, 2010) (declining to certify a nationwide class on unjust enrichment); *Thompson v. Jiffy Lube Int'l, Inc.*, 250 F.R.D. 607, 626 (D. Kan. 2008) (finding "there are differences nationwide in the very definition of unjust enrichment and its availability as a remedy . . . [and] [b]ecause of such variations, federal courts have generally refused to certify a nationwide class based upon a theory of unjust enrichment.");[16] *Avritt v. Reliastar Life Ins. Co.*, 615 F.3d 1023, 1030–31 (8th Cir. 2010) (declining to certify a nationwide class on breach of contract claims where "liability to the entire class for breach of contract [could not] be established with common evidence" and further declining to certify the class because establishing a duty of good faith and fair dealing would require evidence of the understanding each purchaser attached to the

[16] In fact, one district court in this circuit recently dismissed plaintiffs' claims for a nationwide unjust enrichment class based on federal common law, finding that "Plaintiffs fail to identify any source of law that would serve as a basis for a national unjust enrichment class," and "[a]s a threshold matter, 'there is no federal general common law.'" *In re: Dollar Gen. Corp. Motor Oil Mktg. & Sales Practices Litig.*, No. 16-02709-MD-W-GAF, 2017 WL 3863866, at *5 (W.D. Mo. Aug. 3, 2017).

contract and "would be essential to establishing liability").[17] As a result, the Court expresses some preliminary concerns over whether Plaintiffs will ultimately be able to satisfy the predominance requirement for these claims.

Plaintiffs do not challenge this case law. Instead, Plaintiffs merely assert that striking the pleadings is an extreme remedy and that subsequent discovery and briefing is necessary. However, while the Court has doubts regarding whether Plaintiffs can ultimately meet the standards set forth in Rule 23, at this stage in the proceedings these doubts must be resolved in favor of Plaintiffs. In fact, in all of the cases cited by Defendants in support of their arguments on these nationwide class allegations, the courts reached their decisions at the class certification stage after motion by the plaintiffs, not at the pleadings stage.

Going forward, Plaintiffs may likely have difficulty satisfying the predominance requirements on these nationwide claims based on the case law cited by Defendants. At this point in the proceeding, however, the Court finds it proper to allow plaintiffs to conduct discovery or to motion the Court and provide additional briefing to determine whether the prerequisites of Rule 23 can be satisfied. *See, e.g., In re: Dollar Gen. Corp. Motor Oil Mktg. & Sales Practices Litig.*, No. 16-02709-MD-W-GAF, 2017 WL 3863866, at *5 (W.D. Mo. Aug. 3, 2017) ("Plaintiffs propose that the Court should delay ruling on whether the proposed class should be stricken or certified until Plaintiffs are allowed to fully brief a case-management strategy and provide an analysis of varying state laws . . . [and] such a course follows the majority of guidance from the various circuit courts of

[17] The Court also notes that in the consolidated Banana Boat cases pending in the Eastern District of New York, the judge dismissed in its entirety Plaintiffs' claim for breach of implied contact on behalf of the nationwide class and each subclass. *In re Edgewell Personal Care Co. Litig.*, Case No. 1:16-CV-3371-KAM-RLM, slip. op. at 25–27 (E.D.N.Y. Sept. 4, 2018). Plaintiffs alleged an implied-in-law contract between plaintiffs and defendants regarding plaintiffs' purchases of Banana Boat SPF 50 sunscreen lotion. (*Id.* at 25–26.) Defendants argued there is no implied covenant without a contract, and an implied-in-law contract is not a contract. (*Id.* at 26.) The court agreed, reasoning contracts implied-in-law are not true contracts, and in the absence of a contact, there is no implied covenant of good faith and fair dealing. (*Id.* at 26–27.) As a result, the court dismissed the breach of implied contract claims with prejudice. (*Id.* at 27.)

appeal, which caution that plaintiffs seeking to certify a nationwide class "must credibly demonstrate, through an '*extensive analysis*' of state law variances, 'that class certification does not present insuperable obstacles.'") (emphasis in original) (citations omitted)*; Knowles*, 2013 WL 6497097, at *3 ("in an abundance of caution" and "construing the class claims liberally," denying motion to strike when "it appears unlikely that Plaintiff will prevail on a motion for class certification, even after class discovery is completed . . . [but] [o]n the other hand, the Court recognizes that Plaintiff has not had the opportunity to take any meaningful discovery on class certification issues, and the Court is therefore hesitant to issue an order foreclosing the possibility of any class-wide remedy at this stage of litigation"); *Doyel*, 2009 WL 350627, at *5–6 (declining to strike class allegations at pleading stage and instead allowing class certification discovery).

Therefore, the Court will exercise its discretion and decline to strike the nationwide class allegations at this time.

IV. CONCLUSION

Accordingly,

IT IS HEREBY ORDERED that Defendants' Motion to Dismiss or Stay Plaintiff's Complaint, or, in the Alternative, Strike the Nationwide Class Allegations (Doc. 21) is **GRANTED, in part,** and **DENIED, in part**.

IT IS FURTHER ORDERED that Defendants' motion to dismiss or stay the proceedings based on the primary jurisdiction doctrine (Doc. 21 ¶ 1) is **DENIED, without prejudice**.

IT IS FURTHER ORDERED that Defendants' motion to dismiss based on federal preemption (Doc. 21 ¶ 2) is **GRANTED, in part.**

IT IS FURTHER ORDERED that Defendants' motion to dismiss the New York General Business Law § 349 (Count V), New York General Business Law § 350 (Count VI), New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1, *et seq.* (Count VII), New Jersey Truth in Consumer Contract,

Warranty, and Notice Act, N.J.S.A. 56:12-14 et seq. (Count VIII), California Unfair Competition Law, Cal. Bus. & Prof. Code §§ 17200, *et seq.* (Count X), and California Consumers Legal Remedies Act, Cal. Civil Code §§ 1750, *et seq.* (Count XI) (Doc. 21 ¶ 3) is **DENIED, as moot.**

IT IS FURTHER ORDERED that Defendants' motion to strike Plaintiffs' nationwide class allegations (Doc. 21) is **DENIED, without prejudice.**

IT IS FINALLY ORDERED that Plaintiffs shall file a first amended complaint no later than thirty (30) days from the date of this Order.

Dated this 7th day of December, 2018.

/s/ Noelle C. Collins
NOELLE C. COLLINS
UNITED STATES MAGISTRATE JUDGE