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| UNITED STATES DISTRICT COURT |
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| NORTHERN DISTRICT OF CALIFORNIA |

CRYSTAL KAO, ET AL.,

Plaintiffs,

v.

ABBOTT LABORATORIES INC.,

Defendant.

Case No. 17-cv-02790-JST

ORDER GRANTING IN PART AND DENYING IN PART MOTION TO DISMISS AND STAYING CASE UNDER PRIMARY JURISDICTION DOCTRINE

Re: ECF No. 21

Before the Court is Defendant Abbott Laboratories Inc.'s ("Abbott Laboratories" or "Abbott") Motion to Dismiss. ECF No. 21. For the reasons discussed below, the Court will grant the motion in part and deny it in part, but will stay this case pending the issuance of final rules by the United States Department of Agriculture ("USDA").

I. BACKGROUND

In this putative consumer class action, Plaintiffs Crystal Kao and Nina Barwick assert claims under the Magnuson-Moss Warranty Act, claims under California and Tennessee state law, and various common law claims against Abbott Laboratories, alleging "deceptive and unfair business practices . . . in the advertisement and sale of . . . Similac Advance Non-GMO baby formula ('Similac Non-GMO')." ECF No. 1 ("Compl.") ¶ 1.

Abbott manufactures and sells several lines of baby formula, including Similac Advance, "the top commercial baby formula brand in the United States" <u>Id.</u> ¶ 27. In May 2015, Abbott began marketing and selling Similac Advance Non-GMO ("Similac Non-GMO"), a version of its Similac baby formula intended to be free of "GMOs," or genetically modified organisms. <u>Id.</u> ¶ 28. A genetically modified organism "is an organism whose genetic material has been altered in a way that does not occur in nature, typically by scientists introducing new features to the organism that

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would not naturally occur without scientific, genetic manipulation." Id. ¶ 29. Plaintiffs allege that products without GMOs are popular among consumers because of the "perceived benefits to health and well-being" and the belief that non-GMO products "help[] the environment, assist[] local and family owned farms, and assist[] factory workers who would otherwise be exposed to synthetic and hazardous substances." Id. ¶ 30. In introducing the Similac Non-GMO product, Abbott "listen[ed] to moms and dads . . . [who] told [Abbott] they want a non-GMO option." Id. ¶ 28. Similar Non-GMO features labeling prominently displaying "Non-GMO," which it defines as containing "[i]ngredients not genetically engineered." Id. ¶ 31. On its website, Abbott touts its Similar Non-GMO product as the "first leading infant formula brand labeled non-GMO " Id. ¶ 33. According to Plaintiffs, Abbott's other versions of Similac Advance "retail for less than Similac Non-GMO," meaning that customers who purchase Similac Non-GMO choose to pay more than they otherwise would for Similac Advance based on Abbott's representations that the product contains no GMOs. See id. ¶ 32.

Plaintiffs allege that "Abbott's conduct in marketing Similac Non-GMO as containing ingredients that are not genetically engineered deceived and/or was likely to deceive the public, and Plaintiff Kao and Plaintiff Barwick." Id. ¶ 36. Plaintiffs commissioned tests of Similac Non-GMO "in different lots purchased in different locations, including in California and Tennessee, at different times." Id. ¶ 37. Those tests allegedly showed "the presence of TS-40-3-2 Soy," "a genetically engineered version of soy developed by Monsanto that has been altered to be glyphosate herbicide tolerant "Id.; see also id. Ex. 1, at 24-47 (test results). According to Plaintiffs, this modified soybean line was "developed to allow for the use of Monsanto's Roundup® herbicide." Id. Plaintiffs allege "[o]n information and belief [that] no significant process changes, vendor changes, or supply-chain changes occurred in the production of Similac [Non-]GMO from the inception of the product to the market through the present," and "[t]herefore, it can be assumed that all formulations of Similac Non-GMO contain this same

¹ Plaintiffs allege that the testing showed "GMO material at 4.52%, 4.65%, 1.98%, 3.76% and 3.11% by individual ingredient weight." ECF No. 29 at 8. Abbott argues that the test results at most "show trace amounts of GMOs." ECF No. 21 at 12.

presence of GTS-40-3-2 Soy." <u>Id.</u> ¶ 38.

Plaintiff Crystal Kao resides in San Francisco, California. <u>Id.</u> ¶ 6. Plaintiff Nina Barwick resides in Nashville, Tennessee. <u>Id.</u> ¶ 7. Both Ms. Kao and Ms. Barwick allegedly "purchased Similac Non-GMO and saw and noticed the marketing indicating that Similac Non-GMO was marketed as containing no GMOs." <u>Id.</u> ¶¶ 6-7. They allegedly purchased Similac Non-GMO because they "did not want to feed [their] bab[ies] baby formula containing GMOs." <u>Id.</u>

Plaintiffs filed their complaint on May 15, 2017. Both Ms. Kao and Ms. Barwick assert claims for violations of the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301, et seq., for breach of written warranty based on allegedly misleading labeling, id. ¶¶ 42-49, and claims for unjust enrichment, id. ¶110-113. Ms. Kao also asserts claims for (i) violations of California's Unfair Competition Law ("UCL"), California Business & Professions Code §§ 17200 et seq.; (ii) false advertising under California Business & Professions Code §§ 17500 et seq.; (iii) violations of the California Consumer Legal Remedies Act ("CLRA"), California Civil Code § 1750 et seq.; (iv) breach of express warranty; (v) violation of the California Song-Beverly Consumer Warranty Act, California Civil Code §§ 1792 et seq.; (vi) negligence; and (vii) negligent misrepresentation. Id. ¶¶ 50-109. Ms. Barwick asserts a claim for deceptive business practices under Tennessee Code § 47-18-104. Id. ¶¶ 114-118.

Plaintiffs Kao and Barwick purport to sue on behalf themselves and a national class including "[a]ll persons who purchased Similac Non-GMO from any retail outlet in the United States or who resided in the United States at the time they made online purchases of Similac Non-GMO." <u>Id.</u> ¶ 14. Plaintiffs Kao and Barwick also assert claims on behalf of subclasses of purchasers from California and Tennessee, respectively." <u>Id.</u> ¶¶ 15-16.²

II. JURISDICTION

This Court has jurisdiction over this matter pursuant to 28 U.S.C. §§ 1331 and 1332. The Court has jurisdiction over this case because the amount in controversy exceeds \$75,000 and the

² Plaintiffs sue on behalf of purchasers of Similac Non-GMO over the "Period of Contamination," defined as the time period "from the inception of the product to the market through the present." Compl. ¶ 38.

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parties are citizens of different states. 28 U.S.C. § 1331. It is uncontested that Plaintiff Kao is a resident of California, Plaintiff Barwick is a resident of Tennessee, and Abbott is a resident of Delaware and Illinois. See Compl. ¶¶ 6-8, 10. The Court has federal question jurisdiction over Plaintiffs' claims under the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301. 28 U.S.C. § 1331. The Court may exercise supplemental jurisdiction over Plaintiffs' claims under California and Tennessee state law pursuant to 28 U.S.C. § 1367.

III. REQUESTS FOR JUDICIAL NOTICE

Pursuant to Federal Rule of Evidence 201(b), "[t]he court may judicially notice a fact that is not subject to reasonable dispute because it: (1) is generally known within the trial court's territorial jurisdiction; or (2) can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." The Court may also "consider materials incorporated into the complaint," where "the complaint necessarily relies upon a document or the contents of the document are alleged in a complaint, the document's authenticity is not in question and there are no disputed issues as to the document's relevance." Coto Settlement v. Eisenberg, 593 F.3d 1031, 1038 (9th Cir. 2010). The Court "must take judicial notice if a party requests it and the court is supplied with the necessary information." Fed. R. Evid. 201(c)(2).

Plaintiffs do not oppose the requests, with the exception of Exhibit A, which they argue is not relevant. ECF No. 29 at 8 n. 1.

Exhibit A to Abbott's Request for Judicial Notice is a response to a demand letter, which is explicitly referenced in the complaint. ECF No. 22-1; Compl. ¶ 48. As Plaintiffs do not challenge its authenticity and it is referenced in the complaint, the Court will take judicial notice of this letter. Coto, 583 F.3d at 1038.

Exhibit B comprises a pair of docket entries from a district court case pending in the District for Vermont, Grocery Mfrs. Ass'n v. Sorrell, No. 14-cv-00117-CR. ECF No. 22-2. Under Ninth Circuit law, courts may properly take notice of court orders and other filings of public record. Reyn's Pasta Bella, LLC v. Visa USA, Inc., 442 F.3d 741, 746 n. 6 (9th Cir. 2006). Thus, the Court will take notice of these filings, but will not take notice of any disputed facts in them. Lee v. City of Los Angeles, 250 F.3d 668, 689-90 (9th Cir. 2001).

Exhibits C-H consist of policy guidances, letters, and other documents issued by the USDA, the European Union, and the Non-GMO Project. ECF Nos. 22-3-9. The Court will take notice of these documents. See Interstate Nat. Gas Co. v. S. California Gas Co., 209 F.2d 380, 385 (9th Cir. 1953) ("We may take judicial notice of records and reports of administrative bodies."); Gustavson v. Wrigley Sales Co., No. 12-CV-01861-LHK, 2014 WL 60197, at *3 (N.D. Cal. Jan. 7, 2014) (taking judicial notice of FDA's guidance document because the document was available on the agency's website).

IV. LEGAL STANDARD

Federal Rule of Civil Procedure 8(a)(2) requires that a complaint contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). While a complaint need not contain detailed factual allegations, facts pleaded by a plaintiff must be "enough to raise a right to relief above the speculative level." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007). To survive a Rule 12(b)(6) motion to dismiss, a complaint must contain sufficient factual matter that, when accepted as true, states a claim that is plausible on its face.

Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id. While this standard is not a probability requirement, "where a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief." Id. (internal quotation marks omitted). In determining whether a plaintiff has met this plausibility standard, the Court must accept all factual allegations in the complaint as true and construe the pleadings in the light most favorable to the plaintiff. Knievel v. ESPN, 393 F.3d 1068, 1072 (9th Cir. 2005).

V. DISCUSSION

Abbott moves to dismiss Plaintiffs' complaint for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6), on the grounds that: (1) Plaintiffs' state law claims are preempted by federal law giving the USDA sole responsibility for regulating GMO labeling; and (2) Plaintiffs' lone federal claim under the Magnuson-Moss Warranty Act ("MMWA") fails as a matter of law because product labeling is not a warranty that can give rise to liability under the

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United States District Court

statute. Assuming any of these claims survive, Abbott alternatively requests that the Court exercise its discretion stay this case under the doctrine of primary jurisdiction to allow the USDA to complete its rulemaking regarding GMO labeling. The court addresses these issues in turn.

Preemption of State-Law Labeling Claims Α.

Abbott first argues that Plaintiffs' state-law claims for false and misleading labeling are preempted by the National Bioengineered Food Disclosure Standard ("NBFDS"), which President Obama signed into law on July 29, 2016. ECF No. 21 at 6. According to Abbott, the NBFDS "was adopted to bring about a single national standard that food companies could follow for GMO labeling in the United States and eliminate dueling standards developing among the states." Id. Abbott argues that actions such as this one, that purportedly seek to impose GMO labeling requirements, are expressly preempted by the NBFDS.

The Court first summarizes the relevant legal framework then applies these principles as it relates to Abbott's preemption argument.

1. **National Bioengineered Food Disclosure Act**

The NBFDS requires the Secretary of the USDA to, within two years of the statute's effective date (i.e. by July 29, 2018), "establish a national mandatory bioengineered food disclosure standard with respect to any bioengineered food and any food that may be bioengineered; and . . . establish such requirements and procedures as the Secretary deems necessary to carry out the standard." 7 U.S.C. § 1639b(a). Among other things, the statute tasks the Secretary with "determin[ing] the amounts of a bioengineered substance that may be present in food, as appropriate, in order for the food to be a bioengineered food." 7 U.S.C. § 1639(b)(2)(B). The statute precludes states from establishing "[s]tate food labeling standards" different than the GMO labeling provisions to be set by the USDA:

> Notwithstanding section 1639i of this title, no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce any requirement relating to the labeling or disclosure of whether a food is bioengineered or was developed or produced using

³ The NBFDS is an amendment to the Agricultural Marketing Act of 1946, 7 U.S.C. § 1621 et seq.

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bioengineering for a food that is the subject of the national bioengineered food disclosure standard under this section that is not identical to the mandatory disclosure requirement under that standard.

7 U.S.C. § 1639b(e) (emphasis added). Section 1639i expressly provides for "Federal preemption" of state GMO labeling regulations:

> No State or a political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food or seed in interstate commerce any requirement relating to the labeling of whether a food (including food served in a restaurant or similar establishment) or seed is genetically engineered (which shall include such other similar terms as determined by the Secretary of Agriculture) or was developed or produced using genetic engineering, including any requirement for claims that a food or seed is or contains an ingredient that was developed or produced using genetic engineering.

7 U.S.C. § 1639i(b) (emphasis added).

Notwithstanding the express preemption provision, the statute also provides that "[n]othing in this subchapter . . . shall be construed to preempt any remedy created by State or Federal statutory common law right." 7 U.S.C. § 1639j.

Shortly after the law was enacted, the USDA sent a letters to the governors of all 50 states informing them about the law and its preemption provisions, noting that "Congress . . . included these provisions as an integral part of bringing uniformity, consistency, and clarity to biotechnology disclosures across the nation." ECF No. 21-3 at 2. The USDA noted in the letter that "[o]nce the [USDA] promulgates the national bioengineered food disclosure standard, the Act allows [] state[s] to adopt standards identical to the national bioengineered food disclosure standard." Id.

2. **Legal Principles of Preemption**

"The Supremacy Clause of the United States Constitution empowers Congress to enact legislation that preempts state law." Briseno v. Conagra Foods, Inc., No. 11-05379 MMM, 2011 WL 13128869, *2 (C.D. Cal. Nov. 23, 2011) (citing Gibbons v. Ogden, 22 U.S. 1, 82 (1824)). Federal law preempts state law when: (1) Congress enacts a statute that explicitly preempts state law; (2) federal law occupies a legislative field to such an extent that it is reasonable to conclude that Congress left no room for state regulation in that field; or (3) state law actually conflicts with

federal law. Chae v. SLM Corp., 593 F.3d 936, 941 (9th Cir. 2010). "Where Congress enacts an express preemption provision, [the] task [of courts] is to interpret the provision and 'identify the domain expressly pre-empted by that language." Id. at 941-42 (quoting Medtronic, Inc. v. Lohr, 518 U.S. 470, 484 (1996)).

"When analyzing the scope of a preemption statute, a court's analysis must 'start with the

"When analyzing the scope of a preemption statute, a court's analysis must 'start with the assumption that the historic police powers of the States [are] not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." Gustavson v. Wrigley Sales Company, 961 F. Supp. 2d 1100, 1117 (N.D. Cal. 2013) (quoting Medtronic, 518 U.S. at 485). "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) (en banc) (quoting De Buono v. NYSA-ILA Med. & Clinical Servs. Fund, 520 U.S. 806, 814, (1997)).

The regulation of health and safety, including laws regulating the proper marketing of food, are traditionally within states' historic police powers. See Florida Lime & Avocado

Growers v. Paul, 373 U.S. 132, 144 (1963) ("States have always possessed a legitimate interest in 'the protection of (their) people against fraud and deception in the sale of food products' at retail markets within their borders.") (citing Plumley v. Massachusetts, 155. U.S. 461, 472 (1894)).

Thus, in such matters, "the presumption against preemption . . . is a strong one." Gustavson, 961

F. Supp. 2d at 1117; see also Medtronic, 518 U.S. at 485 ("Th[e] approach [of applying a strong presumption against preemption of state law] is consistent with both federalism concerns and the historic primacy of state regulation of matters of health and safety.").

3. Analysis

Abbott contends that Plaintiffs' state-law claims "run headlong into recent federal legislation" by attempting to "regulate Abbott's Non-GMO labeling with state consumer protection laws." ECF No. 21 at 10. According to Abbott, in enacting the NBFDS, "a national GMO law designed to impose national rules governing labels related to GMOs in food products," Congress chose to put in place "a uniform national standard for labeling related to GMOs" instead of forcing manufacturers to navigate "a patchwork of varying (and inconsistent requirements

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controlled by state law)." Id. at 10-11. Abbott notes that the NBFDS includes a "broad express

Plaintiffs dispute Abbott's contention that they seek to regulate GMO labeling under state law. ECF No. 29 at 7. Plaintiffs note that "the Complaint does not allege that Abbott is required to make any labeling disclosures" or that "Abbott must disclose the presence of GMOs on the Similar Non-GMO labeling." Id. (emphasis in original). Indeed, according to Plaintiffs "Abbott is free to disclose whatever it wants about the GMO content of its products, but both federal and state law simply require that, when it does so, the representations must be truthful and accurate." Id. at 8. Plaintiffs note that their state law claims are not preempted because (1) there are currently no NBFDS standards regarding GMO labeling, and thus no preemptive regulation; (2) the state laws on which Plaintiffs' claims are based do not purport to regulate GMO labeling, and instead "impose a generally applicable obligation to ensure that whatever appears on a label is truthful and accurate"; and (3) the savings clause of Section 1639j "carves . . . [Plaintiffs' claims] out from the scope of the preemption." See id. at 10-16. Plaintiffs also dispute Abbott's characterization of the complaint as seeking to impose a "zero-tolerance" policy, as, according to Plaintiffs' testing, Similac Non-GMO contained more than "trace" amounts of GMOs. Id.; see also id. at 8 n. 1 ("the amount of GMO material in Similac Non-GMO ranged from two to five times the allowable limit under the European Union and Non-GMO Project standard.") (emphasis in original).

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Abbott replies that "[t]he Court need not wait until the USDA promulgates regulations to hold that Kao and Barwick's claims are preempted, because they are already preempted by Congress' enactment [of] a federal statute that expressly preempts state law claims related to GMO and Non-GMO labeling, without regard to any USDA regulations." ECF No. 30 at 9. According to Abbott, it is irrelevant that Plaintiffs do not seek to impose affirmative labeling obligations, as "if Plaintiffs succeed in this lawsuit, they will have forced Abbott . . . to change or abandon its Non-GMO label as a result of the substantive requirements of state consumer protection and warranty laws." Id. at 11. Abbott notes that "federal courts . . . have routinely found that obligations imposed pursuant to state consumer protection and warranty laws . . . do constitute 'requirements' that trigger express or implied preemption." Id. at 12 (emphasis in original). Finally, Abbott argues that the savings clause of Section 1639 carves out state law <u>remedies</u> – <u>e.g.</u>, state-law actions seeking damages for violation of federal law – but not <u>claims</u> based on state law. Id. at 14. It asserts that any other reading of that provision would render the preemption clause "a nullity." Id.

As an initial matter, the Court concludes that, contrary to Plaintiffs' assertion, Abbott's preemption argument is not premature. Whether or not the USDA has enacted regulations regarding GMO labeling, the federal preemption provision of Section 1639i explicitly precludes states from imposing their own labeling requirements. Thus, the preemption issue turns not on whether the USDA has promulgated GMO labeling rules, but whether Plaintiffs' claims fall within the express preemption provision.

There is no dispute that Section 1639i is "a statute that explicitly preempts state law." Chae, 593 F.3d at 941; 7 U.S.C. § 1639i (providing for "Federal preemption"). Thus, the Court must "interpret the provision and 'identify the domain expressly pre-empted by that language."" Chae, 593 F.3d at 942 (quoting Medtronic, 518 U.S. at 484). This requires the Court to examine "the text of the [preemption] provision, the surrounding statutory framework, and Congress's stated purposes in enacting the statute " <u>Id.</u> Here, the preemption statute precludes states from "directly or indirectly establish[ing] . . . any requirement relating to the labeling of whether a food . . . is genetically engineered . . . or contains an ingredient that was developed or produced

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using genetic engineering." 7 U.S.C. § 1639i(b). Thus, the relevant question is whether, in asserting claims under state unfair competition, false advertising, and breach of warranty laws, Plaintiffs seek to "directly or indirectly establish . . . any requirement relating to the labeling of" food as it relates to GMOs.

This appears to be an issue of first impression. ⁴ The parties do not cite, and the Court is not aware of, any cases applying the express preemption provision of the NBFDS to state-law consumer protection claims. Instead, the parties each analogize to preemption cases involving different statutes.

Plaintiffs rely on Medtronic v. Lohr, 518 U.S. 470 (1996) for the notion that "the state-law duties underlying Plaintiffs' claims (i.e., truth and accuracy in product labeling) escape preemption because their generality leaves them outside the category of requirements that §§ 1639b(e) and 1639i(b)" preclude. ECF No. 29 at 13. In Lohr, the plaintiff brought a state common-law negligence claim against a manufacturer of medical devices. Lohr, 518 U.S. at 475. The manufacturer argued that such a lawsuit was precluded under the relevant preemption law, which provided states could not "establish or continue in effect with respect to a [medical] device . . . any requirement . . . which is different from, or in addition to, any requirement applicable under this chapter to the device, and . . . which relates to the safety or effectiveness of the device " See id. at 481-82 (quoting 21 U.S.C. § 360k(a)). Noting Congress's stated goal of ensuring effective federal regulation of medical devices and avoiding contradictory state requirements, the Court held that common-law negligence and other similar claims were general and did not impose "requirements" with respect to specific devices. Id. at 502. According to the Supreme Court, the general duties imposed by the plaintiffs' claims – such as the duty to warn consumers of potentially dangerous risks associated with their use of a product – were "no more a threat to federal requirements than would be a state-law duty to comply with local fire prevention regulations and zoning codes, or to use due care in the training and supervision of a work force."

⁴ A similar motion is pending before Judge Pauley of the Southern District of New York, but has not yet been resolved. Motion to Dismiss, In re Kind LLC "Healthy and All Natural" Litigation, No. 15-MD-2645 (WHP) (Lead Case) (S.D.N.Y. June 30, 2017), ECF Nos. 72 & 73.

<u>Id.</u> at 501-02. Similarly here, California does not impose specific labelling requirements with regard to the presence of GMOs in food products. And since there is no conflict between California law and existing federal law, there is no "threat to federal requirements," particularly since the FDA has not yet issued mandatory national standards for labeling foods containing genetically modified ingredients.

The Court finds two district court cases cited by Plaintiffs to be even more persuasive.

Parker v. J.M. Smucker Co., No. C 13-0690 SC, 2013 WL 451656 (N.D. Cal. Aug. 23, 2013);

Fagan v. Neutrogena Corporation, No. 13-cv-01316-SVW, 2014 WL 92255 (Jan. 8, 2014). In those cases, courts found state-law false advertising and unfair competition claims did not impose labeling requirements in addition to or different from federal law, and were therefore not preempted. ECF No. 29 at 14-15. The claims in both cases related to allegedly misleading labeling of products as "All Natural" or "100% natural." Parker, 2013 WL 451656 at * 1; Fagan, 2014 WL 92255 at *1. The defendants in both cases argued that such claims were preempted by the Food Drug and Cosmetic Act's preemption provision, which precludes states from "directly or indirectly establish[ing] . . . any requirement for the labeling of food that is not identical to the [FDCA]." 21 U.S.C § 343-1. In Parker, the court rejected the same preemption argument made by Abbott here, holding that the plaintiff's state-law unfair competition and false advertising claims were not preempted because they did not impose a "requirement" on the manufacturer:

Defendant . . . argu[es] that whatever the basis of Plaintiff's claim, her goal is ultimately to require that bioengineered foods be labeled differently from non-bioengineered foods in a way preempted by federal law. This is not an accurate statement of Plaintiff's argument. Under Plaintiff's theory, Defendant could have simply left "All Natural" off the labels. But because they included the phrase, Plaintiff claims that the labels are misleading. This is not a preempted theory. Defendant may not affirmatively be required to disclose its use of bioengineered ingredients (if any exist at all), but Plaintiff is only alleging that the "All Natural" claim might be untrue and misleading if Defendant in fact does use bioengineered ingredients or processing techniques that render a natural ingredient non-natural. Plaintiff's claim is therefore not preempted on these grounds.

<u>Id.</u> at * 4 (internal citation omitted). The court in <u>Fagan</u>, considering the same preemption statute, rejected a similar argument, noting that state-law consumer claims provide a parallel remedy to

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federal regulations by requiring manufacturers to have labels that are not misleading, and do not impose a requirement different from or in addition to those imposed by FDA regulations. Fagan, 2014 WL 92255 at *1.

The Court concludes, just as the courts in <u>Parker</u> and <u>Fagan</u> did, that Plaintiffs' state law claims do not establish a "requirement" as contemplated by the express preemption provision of the NBFDS. As Plaintiffs correctly note, they do not allege that Abbott was required to identify the precise amount of GMO ingredients in its baby formula. Indeed, under Plaintiffs' theory Abbott may choose to say nothing at all regarding the GMO content of its products. But Abbott cannot say its products are GMO free if, as Plaintiffs allege, the representation is not true.

Abbott argues that Parker and Fagan do not apply because "those cases involve a different express preemption provision with a different scope." ECF No. 30 at 13. According to Abbott, the preemption provision of the NBFDS is broader than the preemption provision of the FDCA, as it bars "any requirement" related to GMO labeling, not just those that are different or inconsistent with federal labeling requirements. <u>Id.</u> at 13 (quoting 7 U.S.C. § 1639i(b), emphasis in original). However, the courts in Parker and Fagan did not hold that the state-law claims escaped preemption because they did not impose different requirements – instead, the courts held that state-law claims such as those asserted here do not impose affirmative requirements at all. See Parker, 2013 WL 451656 at *4 ("Defendant may not affirmatively be required to disclose its use of bioengineered ingredients . . . but Plaintiff is only alleging that the 'All Natural' claim might be untrue and misleading . . . Plaintiff's claim is therefore not preempted on these grounds.").

Abbott contends that "in every case where a plaintiff's state consumer protection law claim has been dismissed as preempted, the defendant 'could have left off' the offending language—yet that argument has not served to avoid preemption." ECF No. 30 at 13. But the cases it cites in support of this contention involve labeling that had been pre-approved by a regulatory agency, or that explicitly complied with federal law. See, e.g., Brower v. Campbell Soup Co., No. 16-cv-01005-BEN-JLB, 2017 WL 1063470, at *3 (S.D. Cal. Mar. 21, 2017) (finding labeling claims under state consumer protection laws were preempted, where labels had been pre-approved by the Food Safety and Inspection Service); Barnes v. Campbell Soup Co., No. C 12-05185 JSW, 2013

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WL 5530017, at *5 (N.D. Cal. July 25, 2013) ("Because the USDA and FSIS previously approved of Defendant's Natural Chicken Tortilla soup label, however, the Defendant's Natural Chicken Tortilla soup label cannot be construed, as a matter of law, as false or misleading."); Gorenstein v. Ocean Spray Cranberries, Inc., No. CV 09-5925 GAF CWX, 2010 WL 10838229, at *1 (C.D. Cal. Jan. 29, 2010) ("Plaintiff concedes that Ocean Spray's label complies with all requirements of federal law"); see also Carrea v. Dreyer's Grand Ice Cream, Inc., 475 F. App'x 113, 115 (9th Cir. 2012) ("Carrea seeks to enjoin and declare unlawful the very statement that federal law permits and defines. Such relief would impose a burden through state law that is not identical to the requirements under section 343(r)."); Backus v. Nestlé USA, Inc., 167 F. Supp. 3d 1068, 1075 (N.D. Cal. 2016) (similar). In such cases, permitting a plaintiff to assert a claim under a state law consumer protection law would effectively impose a labeling requirement – and undermine federal agency authority – because a manufacturer would have to go through additional hoops to comply with state law even while fully complying with applicable federal law.

Here, in contrast, Plaintiffs do not seek to impose a requirement above and beyond what is required by a federal agency. Indeed, Plaintiffs' claims are consistent with the only guidance the USDA has provided to date regarding its anticipated implementation of the NBFDS. That guidance provides that "[f]ood manufacturers may voluntarily label their foods with information about whether the foods were not produced using bioengineering, as long as such information is truthful and not misleading." 5 U.S. Food & Drug Administration: Guidance for Industry: Voluntarily Labeling Indicating Whether Foods Have Or Have Not Been Derived From Genetically Engineered Plants (July 1, 2016) ("USDA Guidance") at Section II.B, available at https://www.fda.gov/RegulatoryInformation/Guidances/ucm059098.htm (emphasis added). The fact that Plaintiffs' claims are consistent with the current USDA guidance supports the Court's

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⁵ Plaintiffs cited this document in their opposition brief, but did not formally request judicial 26 notice. The Court will nevertheless take judicial notice of the document, as it is a formal and publicly available guidance provided by a government agency, and its authenticity is not reasonably in dispute. See Interstate Nat. Gas Co., 209 F.2d at 385; Gustavson, 2014 WL 60197 27 at *3; Callan v. New York Cmty. Bank, 643 F. App'x 666 (9th Cir. 2016) ("district court did not 28 abuse its discretion in sua sponte taking judicial notice").

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conclusion that allowing Plaintiffs to pursue their state-law claims would not frustrate Congressional intent in enacting the express preemption provision. See H.R. Rep. No. 114-896, 114th Cong., 2016 WL 7471589 (2d Sess. 2016) (describing goal of "ensur[ing] national uniformity regarding labeling of foods derived from genetically engineered plants by preventing a patchwork of conflicting state or local labeling laws which inherently interfere with interstate and foreign commerce."); Chae, 593 F.3d at 942 (court must interpret preemption clause keeping in mind "Congress's stated purposes in enacting the statute . . . ").

The Vermont GMO labeling statute that both parties agree is preempted by the NBFDS provides a useful contrast. See ECF No. 21 at 13 ("the Vermont statute is now preempted under § 1639i(b)"); ECF No. 29 at 11 ("state law directed solely at GMO labeling disclosure . . . is preempted under the NFBDS"). That law purported to "[e]stablish a system by which persons may make informed decisions . . . [and] avoid potential health risks of food produced from genetic engineering," and which aimed to "promot[e] the disclosure of factual information on food labels." Vt. Stat. Ann. tit. 9, § 3041. It expressly required "food offered for sale by a retailer after July 1, 2016 [to] be labeled as produced entirely or in part from genetic engineering if it is a product: (1) offered for retail sale in Vermont; and (2) entirely or partially produced with genetic engineering." Vt. Stat. Ann. tit. 9, § 3043. Unlike Vermont's preempted labeling statute, Plaintiffs' claims do not seek to impose a new regulatory system or require a manufacturer to provide specific additional information to consumers. Rather, they seek to ensure that products do not contain affirmative misrepresentations and that, consistent with the USDA Guidance, any labels manufacturers like Abbott choose to place on their products are truthful.

Given the strong presumption against federal impression in matters of health and safety, Gustavson, 961 F. Supp. 2d at 1117, the Court concludes that Plaintiffs' state-law claims are not

⁶ Citing regulations imposed by the State of Vermont and the European Union, Abbott suggests that the "trace" amount of GMOs in its baby formula may well qualify as "GMO free" under the regulations ultimately adopted by the USDA. See ECF No. 30 at 11 ("the USDA may set its own threshold standard higher than the absolute zero standard that Plaintiffs espouse"). While this may be, the USDA Guidance states that "[t]he term 'free' conveys zero or total absence unless a regulatory definition has been put in place in a specific situation." USDA Guidance at Section II.B.

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preempted by the NBFDS, and will deny Abbott's motion to dismiss on this basis.

В. **Magnuson-Moss Warranty Act Claims**

Both Plaintiffs assert claims under the MMWA, which provides a cause of action for breach of a written warranty. Plaintiffs allege that Abbott violates the MMWA because (1) Abbott "is a supplier and warrantor as defined in 15 U.S.C. § 2301(4)(5)"; (2) "Similar Non-GMO is a consumer product as defined in 15 U.S.C. § 2301(6)"; (3) Abbott's "claims that Similac Non-GMO contains 'ingredients not genetically engineered' is a Written warranty as that term is used in 15 U.S.C. § 2301(6)"; and (4) "by selling . . . Similar Non-GMO [which] contains GMOs, [Abbott] breached this written warranty." Compl. ¶¶ 44-46. For purposes of this motion, Abbott challenges Plaintiffs' allegation that the label for Similac Non-GMO constitutes a written warranty that gives rise to liability under the MMWA.

The MMWA defines an express written warranty as:

any written affirmation of fact or written promise made in connection with the sale of a consumer product by a supplier to a buyer which relates to the nature of the material or workmanship and affirms or promises that such material or workmanship is defect free or will meet a specified level of performance over a specified period of time.

15 U.S.C. § 2301(6)(A).

Abbott contends that "[t]he Non-GMO language on Abbott's Similac packaging does none of those things—it does not promise a defect-free product; it does not promise a specified level of performance; and it does not specify a period of time." ECF No. 21 at 14. Abbott argues the Non-GMO label is simply a description of the product, not an affirmation that the product actually contains no GMOs or an assurance of a certain level of performance. Id. at 15. It further contends that the "ingredients not genetically engineered" language on the label "does not include any promise involving 'a specified period of time." Id. Finally, it argues that the MMWA does not apply because the statute does not apply to a written warranty governed by federal law. Id. at 16

⁷ Because the Court concludes that Plaintiffs' claims are not preempted under the express preemption provision of the NBFDS, it does not reach the parties' arguments regarding whether Plaintiffs' claims survive the general preemption provision based on the savings clause in Section 1639j.

(citing 15 U.S.C. § 2311(d)).

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Plaintiffs counter that, under Daniel v. Ford Motor Co., 806 F.3d 1217, 1227 (9th Cir. 2015), it can maintain a claim under the MMWA so long as it has a viable claim for breach of express or implied warranty under state law. ECF No. 29 at 18. Since Abbott does not challenge the adequacy of those claims under Rule 12(b)(6), Plaintiffs contend their MMWA claims must survive as well. Id. at 19. Plaintiffs further argue that under California and Tennessee law, "product labels are in fact actionable warranties." Id. Abbott replies that the standards for a breach of warranty claim under California or Tennessee law do not apply to Plaintiffs' claim under the MMWA. ECF No. 30 at 18. Moreover, Abbott notes that the complaint clearly cites to relevant provisions of the MMWA based on the text of that statute, and not based on a breach of warranty under state law. Id. at 19.

The Court concludes that Plaintiffs' claims under the MMWA fail as a matter of law. As one court described it, "[t]he MMWA's disjunctive language ('or') identifies two kinds of written warranties, the first warranting a 'defect free' product and the second warranting a product that will 'meet a specified level of performance over a specified period of time.'" Colucci v. ZonePerfect Nutrition Co., No. 12-2907-SC, 2012 WL 6737800, at *6 (N.D. Cal. Dec. 28, 2012). Plaintiffs do not, and cannot, allege that the Non-GMO labeling is a warranty that the product is "defect-free," nor do they allege that the label is a promise of performance over a specified period of time. Thus, the product label for Similac Non-GMO cannot give rise to liability under the MMWA. The Court's conclusion is supported by the opinions of several other courts in this district, which have consistently rejected the argument made here by Plaintiffs – namely, that a product label constitutes an "express warranty" under the MMWA. Wilson v. Frito-Lay N. Am., <u>Inc.</u>, No. 12-1586 SC, 2013 WL 1320468, at *15 (N.D. Cal. Apr. 1, 2013) ("This Court has held repeatedly that such arguments are meritless, since product descriptions like 'All Natural' labels 'do not constitute warranties against a product defect."") (quoting Astiana v. Dreyer's Grand Ice Cream, Inc., No. C 11-2910 EMC, 2012 WL 2990766, at *3 (N.D. Cal. July 20, 2012)); Astiana, 2012 WL 2990766 at *3 ("Numerous courts have also held that product descriptions do not constitute warranties against a product defect.").

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The Court rejects Plaintiffs' argument that its claims under the MMWA and its state-law warranty claims rise and fall together. First, as Abbott correctly notes, Plaintiffs' claims under the MMWA make specific reference to the definitions and requirements under the text of the MMWA itself. See Compl. ¶¶ 44-46. They do not allege a breach of written warranty under the MMWA based on state law. Second, the Court does not read the Ninth Circuit's decision in Daniel, as Plaintiffs do, to completely eviscerate the plain language of the statute, which defines an express warranty in unambiguous terms. In Daniel, the plaintiffs brought a class action based on an alleged latent defect in a model of Ford automobiles. Daniel, 806 F.3d at 1220-21. The district court granted summary judgment on the plaintiffs' claims various state-law warranty claims "because the court concluded that [plaintiffs] failed to present evidence that their vehicles became unmerchantable within the duration of the implied warranty" and because the warranty "did not cover the alleged design defect." Id. at 1221. Based on these conclusions, the district granted summary judgment on the plaintiffs' claims under the MMWA. Id. The Ninth Circuit reversed the district court's grant of summary judgment on the state-law warranty claims, holding that the district court erroneously applied a time limit to the breach of implied warranty claims and concluding that the express warranty was ambiguous. See id. 1222-25. Because the district court's disposition of the MMWA claim was based on its erroneous conclusions with respect to the state-law warranty claims, the Ninth Circuit reversed the district court's grant of summary judgment on the MMWA claim as well. Id. at 1227. The Ninth Circuit remarked that, in that situation, the state-law warranty claims and the MMWA claims rose and fell together, but did not hold that a plaintiff could assert an MMWA claim even where it does not meet the statutory requirements of the claim. See id.

Plaintiffs' MMWA claims are inconsistent with the plain language of the statute and therefore must be dismissed. Moreover, based on the alleged contents of the label, Plaintiffs' MMWA claims cannot be remedied through amendment and fail as a matter of law. Thus, the Court will grant Abbott's motion to dismiss these claims with prejudice. See Wilson, 2013 WL 1320468 at *15 ("Plaintiffs' MMWA claims are DISMISSED WITH PREJUDICE. Amendment United States District Court Northern District of California could not save these claims and would be prejudicial to Defendants.").8

C. Stay Under Primary Jurisdiction Doctrine

Abbott alternatively asks the Court to "defer to the USDA under the doctrine of primary jurisdiction and . . . stay any claims that are not dismissed." ECF No. 21 at 17.

As described by the Ninth Circuit:

The primary jurisdiction doctrine allows courts to stay proceedings or to dismiss a complaint without prejudice pending the resolution of an issue within the special competence of an administrative agency. . . . [T]he doctrine is 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.

<u>Clark</u>, 523 F.3d at 1114. The doctrine should be invoked "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." <u>Id.</u> (internal citation and quotations omitted).

Abbott argues that resolution of Plaintiffs' claims requires the Court and parties to "litigate the propriety of a non-GMO label," which Abbott contends was explicitly delegated by Congress to the USDA. ECF No. 21 at 17. Abbott argues that the specific issue raised by Plaintiffs' complaint – whether to impose a "zero-tolerance" standard for Non-GMO labeling – is one that the USDA "has been actively considering" and "there is no need for this Court to wade through th[is] complex question" <u>Id.</u> at 18.

Plaintiffs respond that the doctrine of primary jurisdiction does not apply, because, contrary to Abbott's assertion, Plaintiffs are not trying to litigate the meaning of GMO, and "[t]here is nothing novel or 'particularly complicated' about Plaintiffs' claims." ECF No. 29 at 17 (quoting <u>Clark v. Time Warner Cable</u>, 532 F.3d 1110, 1114 (9th Cir. 2008)).

A court traditionally weighs four factors in deciding whether to apply the primary

⁸ The Court therefore does not reach Abbott's argument that the MMWA claims must be dismissed because they, purportedly, relate to a warranty governed by federal law under 15 U.S.C. § 2311(d).

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jurisdiction doctrine: "(1) the need to resolve an issue that (2) has been placed by Congress within the jurisdiction of an administrative body having regulatory authority (3) pursuant to a statute that subjects an industry or activity that (4) requires expertise or uniformity in administration." Syntek Semiconductor Co., Ltd. v. Microchip Tech., Inc., 307 F.3d 775, 781 (9th Cir. 2002).

These factors support a stay under the doctrine of primary jurisdiction. Even though Plaintiffs' claims are not preempted, to prevail on their claims they must generally establish that the labels on Similac Non-GMO were misleading. The USDA, to whom Congress has exclusively provided authority to regulate GMO labeling in the interest of uniformity in administration, will be issuing rules that bear directly on this inquiry. By law, the USDA is required to implement regulations for the NBFDS by July 2018. 7 U.S.C. § 1639b(a). These regulations will address the level of genetically modified ingredients that a product can contain while still being marketed as "GMO-free" or "Non-GMO." See ECF No. 22-7 (Ex. G to RJN) at Section 4.3 (indicating that the USDA will propose regulations for notice and comment regarding "established tolerance levels or thresholds for the presence of a bioengineered substance in food, both for mandatory disclosure requirements or for absence claims, such as non-GMO."); see also ECF No. 22-8 (Ex. H to RJN) at 4 (requesting comment on question "What is the amount of a bioengineered substance present in a food that should make it be considered bioengineered? (Sec. 293(b)(2)(B))"). If the USDA issues a zero-tolerance rule, Plaintiffs need only prove that Similac Non-GMO contained even a trace amount of genetically modified ingredients to prevail on their claim. If the rule allows for some threshold amount of genetically modified ingredients, all that will be required is to compare the test results with the threshold amount set by rule. If Abbott's labeling complies with USDA rules, Plaintiffs would have great difficulty in proving their claims for unfair competition, false advertising, or breach of warranty. In any event, the agency action will dramatically streamline this case. Astiana v. Hain Celestial Grp., Inc., 783 F.3d 753, 760 (9th Cir. 2015) ("Under our precedent, 'efficiency' is the 'deciding factor' in whether to invoke primary jurisdiction.").

The Court's conclusion is consistent with recent Ninth Circuit cases affirming district court orders staying proceedings under the primary jurisdiction doctrine in labeling cases. For example, in Astiana, the Ninth Circuit found a stay appropriate where, "[i]n response to a flurry of litigation

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over food labeling, three other district courts invoked the agency's primary jurisdiction to see if 2 the FDA intended to offer further regulations regarding the use of the term 'natural," and the 3 FDA issued a guidance outlining the complexities of the issue, suggesting it would resolve the dispute. Astiana, 783 F.3d at 761. In Kane v. Chobani, LLC, 645 F. App'x 593, 594 (9th Cir. 4 2016), which concerned the permissible use of the terms "natural" and "evaporated cane juice," 5 the Ninth Circuit affirmed a district court's stay order where the FDA issued a request for 6 7 comment on the issue and sent a letter to the district court providing an expected date for its final 8 guidance. Just as in these cases, the USDA will be providing rules and guidance that may well be 9 dispositive of the claims in the litigation. 10

Plaintiffs cites two cases in which courts in this district declined to stay mislabeling claims under the doctrine of primary jurisdiction, but neither is applicable. In Brazil v. Dole Food Company, Inc., 935 F. Supp. 2d 947, 957 (N.D. Cal. 2013), the court declined to stay the plaintiff's claims – and distinguished Astiana – because "the FDA ha[d] [already] established requirements applicable to all of the alleged violations Brazil assert[ed]," so the court would not gain the benefit of the agency's expertise through a stay. In Jones v. ConAgra Foods, Inc., 912 F. Supp. 2d 889, 899 (N.D. Cal. 2012), the court declined to stay labeling claims where it was clear through the FDA's "inaction with respect to the term 'natural" that the FDA did not intend to provide any guidance or adopt any rules that would inform the district court litigation. Neither of these situations applies here. The USDA has not yet adopted GMO labeling rules, but is statutorily obligated to do so.

The Court will therefore stay this action in its entirety pending the USDA's issuance of rules related to GMO labeling.

CONCLUSION

The Court denies Abbott's motion to dismiss Plaintiffs' state-law claims based on preemption. The Court grants Abbott's motion to dismiss Plaintiffs' claims under the MMWA, and dismisses these claims with prejudice.

The Court stays this case in its entirety pending the USDA's issuance of rules regarding GMO labeling. The USDA is statutorily required to issue its rules for implementing the NBFDS

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by July 29, 2018. The parties are ordered to file a joint status report within 14 days of the issuance of these rules. The Court will then lift the stay and set a case management conference.

If the USDA does not issue its rules by July 29, 2018, the parties are ordered to file a joint status report providing an update as to when these rules will issue and their respective positions on the lifting of the stay. ⁹

IT IS SO ORDERED.

Dated: November 13, 2017

JON S. TIGAR United States District Judge

⁹ Should the FDA fail to enact mandatory national GMO disclosure standards by the statutory deadline, considerations of efficiency – "the 'deciding factor' in whether to invoke primary jurisdiction," <u>Astiana</u>, 783 F.3d at 760 – will no longer weigh as heavily.