UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

STACY SCIORTINO, *et al.*,

Plaintiffs,

v.

PEPSICO, INC.,

Defendant.

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No. C-14-0478 EMC

CONSOLIDATED CASES

No. C-14-0713 EMC
No. C-14-1099 EMC
No. C-14-1105 EMC
No. C-14-1192 EMC
No. C-14-1193 EMC
No. C-14-1316 EMC
No. C-14-2023 EMC

ORDER GRANTING IN PART AND DENYING IN PART DEFENDANT'S MOTION TO DISMISS

(Docket No. 82)

Pending before the Court is Defendant Pepsico, Inc.'s ("Pepsi's") Motion to Dismiss Plaintiffs' Consolidated Amended Complaint. Docket No. 82 ("Motion"). The operative complaint is the Consolidated Amended Complaint ("CAC"). Docket No. 68. For the reasons discussed herein, the Court **GRANTS** in part and **DENIES** in part Pepsi's Motion to Dismiss.

I. FACTUAL & PROCEDURAL BACKGROUND

Nine putative class actions were filed against Defendant PepsiCo, Inc. ("Pepsi"). The Court appointed counsel for Plaintiffs Hall and Ree as interim lead counsel and consolidated the actions.[1] Docket No. 65. Pending before the Court is a motion to dismiss the CAC in the consolidated

[1] The Court severed the *Riva* case from the consolidated actions to allow Plaintiffs Riva and Ardagna an opportunity to plead a personal injury claim seeking medical monitoring.

actions, which Plaintiffs Mary Hall, Kent Ibusuki, and Kelly Ree ("Plaintiffs") have brought on behalf of themselves and a putative class of California consumers who purchased Pepsi, Diet Pepsi, or Pepsi One (the "Pepsi Beverages") at any time after January 23, 2010 ("Class").

The CAC concerns Pepsi's alleged "intentional concealment and/or failure to warn consumers in California that [the Pepsi Beverages] contain a harmful and carcinogenic chemical called 4-Methylimidazole ("4-MeI") at levels above the safety threshold set by the State of California in Proposition 65." CAC ¶ 1. The Pepsi Beverages contain caramel coloring, which makes the cola products brown. *Id.* at ¶ 16. Only the Class III and Class IV types of caramel coloring are created using a process that produces 4-MeI as a byproduct. *Id.* ¶¶ 18-19. Pepsi uses Class IV caramel coloring in the Pepsi Beverages. *Id.* ¶ 19.

In January of 2014, Consumer Reports published the results of tests it conducted in 2013 on a number of soft drinks, including the Pepsi Beverages. *Id.* ¶¶ 34-35. Consumer Reports found that the amounts of 4-MeI in the Pepsi Beverages were higher than in other soft drinks tested. *Id.* ¶ 37. The Consumer Reports testing revealed amounts of 4-MeI in a can or bottle of Pepsi Beverages that exceeded 29 micrograms – the safe harbor for daily exposure established by Proposition 65 below which the Proposition deems there is "no significant risk." *Id.* ¶¶ 2; 26, 37-38. Consumer Reports's findings as to the levels of 4-MeI in a single can or bottle were significant, because studies have concluded that soda consumers typically drink more than one twelve-ounce serving per day. *Id.*

According to the CAC, Pepsi made statements in its Annual Reports from 2010 to 2013 that suggested that it knew that it was subject to Proposition 65. *Id.* ¶ 30. Additionally, in a public statement, Pepsi said:

> [W]hen the regulatory requirements on 4-MEI changed in California, PepsiCo moved immediately to meet the new requirements and in order to maintain a harmonized supply chain globally committed to rolling out the changes across the rest of the U.S. and internationally. *The work has been completed in California* and several other U.S. states, and we are on track to complete the roll out by February 2014.

Id. ¶ 31 (emphasis in original). The CAC alleges that, contrary to its stated position, Pepsi did not comply with Proposition 65 and continued selling Pepsi Beverages with levels of 4-MeI in excess of Proposition 65's safe harbor. *Id.* ¶¶ 32-33. The CAC charges that this public statement, among

others, misled consumers into thinking the Pepsi Beverages were safe and complied with all relevant California regulations. *Id.*; *see also* ¶¶ 5-6, 41-42, 44-49.

Plaintiffs Hall and Ibusuki have alleged a violation of Proposition 65. The Plaintiffs and the Class have also alleged a violation of the Consumer Legal Remedies Act, Cal. Civ. Code § 1750, *et seq.*, based on Pepsi's alleged active concealment and failure to warn that Pepsi Beverages contain 4-MeI in excess of the levels permitted by Proposition 65. Finally, the Plaintiffs and the Class have also alleged that Pepsi engaged in unfair, unlawful, and fraudulent business practices in violation of Cal. Bus. & Prof. Code § 17200, *et seq.* (the "UCL"). The Plaintiffs and Class seek an order certifying the Class, civil penalties pursuant to California Health & Safety Code § 25249.7(b), damages, restitution, and injunctive relief.

Pepsi moves to dismiss on the grounds that (1) Plaintiffs failed to comply with Proposition 65's mandatory notice provisions before filing suit, (2) the federal Food, Drug, and Cosmetic Act ("FDCA") and the Food and Drug Administration's ("FDA") regulations preempt Plaintiffs' state law claims, and (3) the Court should not adjudicate this action because (a) the FDA has primary jurisdiction over the subject matter of this lawsuit and (b) there is a pending Proposition 65 action in state court.

II. DISCUSSION

A. Legal Standard

Federal Rule of Civil Procedure 8(a) requires a plaintiff to plead a claim with enough specificity to "give the defendant fair notice of what the . . . claim is and the grounds upon which it rests." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 545 (2007) (quotation omitted). A Rule 12(b)(6) motion tests the sufficiency of the pleading. *Navarro v. Block*, 250 F. 3d 729, 732 (9th Cir. 2001). Dismissal under Rule 12(b)(6) is "proper only where there is no cognizable legal theory or an absence of sufficient facts alleged to support a cognizable legal theory." *Id.*

To survive a motion to dismiss under Rule 12(b)(6), a complaint must "contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 570). "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.; see also Twombly*, 550 U.S. at 556. A plaintiff need not plead "detailed factual allegations" to survive a motion to dismiss, but the allegations must be "enough to raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555. In deciding a motion to dismiss, the Court "accept[s] the plaintiffs' allegations as true and construe[s] them in the light most favorable to the plaintiffs." *See Siracusano v. Matrixx Initiatives, Inc.*, 585 F. 3d 1167, 1177 (9th Cir. 2009).

B. Proposition 65 Notice Requirements

California voters approved an initiative measure in November of 1986, enacting the Safe Drinking Water and Toxic Enforcement Act of 1986, which is now set forth in Health and Safety Code section 25249.5 *et seq*. and is commonly known as Proposition 65. *Cal. Chamber of Commerce v. Brown*, 196 Cal. App. 4th 233, 238 (2011). Under Proposition 65, "[n]o person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual" where the amount of exposure exceeds the "no significant risk level" established by the California Environmental Protection Agency's Office of Environmental Health Hazard Assessment ("OEHHA"). Cal. Health & Saf. Code § 25249.6; 25249.10(c); CAC ¶¶ 24-26. The OEHHA listed 4-MeI as a chemical known to the state to cause cancer on January 7, 2011. CAC ¶ 24. The OEHHA determined that the "no significant risk level" for 4-MeI is 29 micrograms per day. *Id.* ¶ 29; *see also* Cal. Code Regs. tit. 27, § 25705(b)(1).

Proposition 65's warning requirement can be enforced by a public or private enforcement action and carries the possibility of both injunctive relief and civil penalties. *Cal. Chamber of Commerce*, 196 Cal. App. 4th at 239 (citing Cal. Health & Saf. Code § 25249.7, subds. (a), (b)). Private enforcement of Proposition 65's warning requirement is permitted only if a plaintiff has provided notice to the Attorney General (and the district attorney, city attorney, or prosecutor in whose jurisdiction the violation is alleged to have occurred) and to the alleged violator. Cal. Health & Safety Code § 25249.7(d)(1). In other words, "[s]tatutory notice is a mandatory condition precedent to establishing a citizen's right to commence a Proposition 65 enforcement action in the

public interest." *Ctr. for Self-Improvement & Cmty. Dev. v. Lennar Corp.*, 173 Cal. App. 4th 1543, 1551 (2009).

In a Proposition 65 warning case, pursuant to an amendment that took effect in 2002, statutory notice must include a certificate of merit that states that the "person executing the certificate has consulted with one or more persons with relevant and appropriate experience or expertise who has reviewed facts, studies, or other data regarding the exposure to the listed chemical that is the subject of the action, and that, based on that information, the person executing the certificate believes there is a reasonable and meritorious case for the private action." *DiPirro v. Am. Isuzu Motors, Inc.*, 119 Cal. App. 4th 966, 970 (2004); Cal. Health & Safety Code § 25249.7(d)(1).

The requirement for a certificate of merit "operates as a brake on improvident citizen enforcement." *Ctr. for Self-Improvement*, 173 Cal. App. 4th at 1551. The certificate of merit informs the Attorney General as to the likelihood of success of the claims, which allows the Attorney General "to focus its efforts to discourage filing of the truly frivolous" and "to resolve the matter before a suit is filed, defense lawyers are hired and a litigation posture is developed." *DiPirro*, 119 Cal. App. 4th at 974-75. The amendment requiring a certificate of merit was "prompted by a concern that private enforcers were abusing Proposition 65 by filing meritless lawsuits alleging that businesses had failed to provide adequate warnings about chemical discharges." *Id.* at 970.

Proposition 65's pre-suit notice must be sent at least 60 days before a private person acting in the public interest "commences" an action "pursuant to this section." Cal. Health & Safety Code § 25249.7(d)(1). In warning cases, pursuant to the "unambiguous" language of Proposition 65, "notice and certificate of merit must be provided *before* the action is commenced." *DiPirro*, 119 Cal. App. 4th at 973 (emphasis in original).

1. Purpose of Notice

The provision for citizen enforcement was included to enhance enforcement of Proposition 65 and deter violations. *Yeroushalmi v. Miramar Sheraton*, 88 Cal. App. 4th 738, 748 (2001) (citing Historical and Statutory Notes, 40C West's Ann. Health & Saf. Code (1999 ed.) foll. § 25249.5, p.

279). Citizen enforcement, however, "was conditioned upon the failure of state and local government agencies to commence or diligently prosecute an action, after due notice." *Id.*

California cases make clear that the notice requirements in Proposition 65 encourage public enforcement and reduce private lawsuits by requiring a non-adversarial opportunity for public agencies to pursue investigation, settlement, and cure. The purpose of notice to the state and local government agencies was to enable the public prosecutors "to investigate and, if necessary, to institute a lawsuit against the [violator]." *Yeroushalmi,* 88 Cal. App. 4th at 748. California courts have compared the Proposition 65 notice provisions to the notice provisions in environmental statutes, such as the Resource Conservation and Recovery Act, the Clean Water Act, and the Clean Air Act, which serve "to encourage public enforcement, thereby avoiding the need for a private lawsuit altogether, and to encourage resolution of disputes outside the courts." *Id.* at 750. The Proposition 65 notice requirements "reflect the same intent to further settlement and public enforcement by requiring adequate information from which to allow the recipient to assess the nature of the alleged violation." *Id.; see also Consumer Advocacy Grp., Inc. v. Kintetsu Enterprises of Am.,* 150 Cal. App. 4th 953, 963-64 (2007) ("[Notice] provides the public prosecutor the means to assess whether to intervene on behalf of the public" and "further affords the accused an opportunity to forestall litigation by settling with the plaintiff or by curing any violation."); *Consumer Def. Grp. v. Rental Hous. Indus. Members,* 137 Cal. App. 4th 1185, 1208 (2006) (commenting that the "purpose of these [Proposition 65] notices is to enable 'meaningful investigation' by those public authorities 'prior to citizen intervention'"); *In re Vaccine Cases,* 134 Cal. App. 4th at 458-59 (quoting *Yeroushalmi,* 88 Cal. App. 4th at 750).

With these legislative purposes in mind, California cases strictly enforce the notice requirements and hold that pre-filing notice is mandatory. For example, two cases, *DiPirro v. Am. Isuzu Motors, Inc.,* 119 Cal. App. 4th 966 (2004), and *In re Vaccine Cases,* 134 Cal. App. 4th 438 (2005), have declined to permit post-litigation cure of a defective notice. These cases involved the amendment to Proposition 65 that required a certificate of merit to be filed as part of the notice. In *DiPirro* and *In re Vaccine Cases*, the respective plaintiffs sent a 60-day notice before the effective date of the legislative amendment requiring a certificate of merit, but filed their initial Proposition

65 enforcement actions after the effective date (and without providing the certificate of merit in advance). Both *DiPirro* and *In re Vaccine Cases* concluded that the complaints must be dismissed with prejudice, because allowing retroactive cure after the lawsuit was filed "would reduce the effectiveness of prelitigation efforts by the Attorney General to discourage filing the frivolous suit in the first place." *DiPirro*, 119 Cal. App. 4th at 975; *In re Vaccine Cases*, 134 Cal. App. 4th at 457; *cf. Hallstrom v. Tillamook Cnty.*, 493 U.S. 20, 26 (1989) (holding 60-day notice provision in Resource Conservation and Recovery Act was strict condition precedent to bringing suit and could not be given a pragmatic construction; *e.g.*, notice requirement was not satisfied through post-filing 60-day stay of the action).

Similarly, in *Physicians Comm. for Responsible Med. v. Applebee's Int'l, Inc.*, 224 Cal. App. 4th 166 (2014), a California court affirmed sustaining a demurrer without leave to amend where the certificate of notice in a Proposition 65 case was defective. *Id.* at 180. *Applebee's* concluded that denying leave to amend was not an abuse of discretion, because a plaintiff "cannot cure its defective certificate and notice by later conducting discovery to fill in the gaps in what it knew" when the notice was served. *Id.* at 181, 183.

2. Commencing An Action

Applying *DiPirro*, *In re Vaccines*, and *Applebee's*, if a Plaintiff commenced an action under Proposition 65 without providing suitable statutory notice, the Plaintiff should not be able to maintain that action. Dismissal with prejudice would be proper, because improper notice cannot be retroactively cured.

California courts have held that plaintiffs cannot plead around the notice requirement by characterizing their claim as a UCL claim. Cases have dismissed UCL claims predicated on Proposition 65 claims that failed for defective notice. *In re Vaccine Cases* dismissed not only the direct Proposition 65 claim for failure to serve notice, but also a derivative UCL claim alleging unlawful business practices. *In re Vaccine Cases*, 134 Cal. App. 4th at 447. While the scope of the UCL, which encompasses (in the disjunctive) unlawful, unfair, or deceptive practices, is "sweeping, [the UCL's scope] is not unlimited." *Cel-Tech Commc'ns, Inc. v. Los Angeles Cellular Tel. Co.*, 20 Cal. 4th 163, 180, 182 (1999). Specifically, the UCL may be purposefully limited by other

legislation: "If the Legislature has permitted certain conduct or considered a situation and concluded no action should lie," then a plaintiff may not "'plead around' absolute barriers to relief by relabeling the nature of the action as one brought under the unfair competition statute." *Id.* (citing *Rubin v. Green,* 4 Cal. 4th 1187, 1201 (1993)). The legislative purpose to disallow or limit a substantiated claim must be evident. *Id.* at 183 ("To forestall an action under the unfair competition law, another provision must actually 'bar' the action or clearly permit the conduct."). Thus, for instance, the mere fact that the legislature did not provide a civil cause of action to enforce a law does not necessarily preclude a UCL suit by a party with statutory standing based on an alleged violation thereof. *Stop Youth Addiction, Inc. v. Lucky Stores, Inc.,* 17 Cal. 4th 553, 576 (1998) ("We previously have held [. . .] that 'whether a private right of action should be implied under the predicate statute is immaterial since any unlawful business practice may be redressed by a private action charging unfair competition in violation of Business and Professions Code sections 17200 and 17203.'" (collecting cases)); *Cel-Tech,* 20 Cal. 4th at 183 (noting difference between "(1) not making an activity unlawful, and (2) making that activity lawful" and observing that acts in the first category may still be challenged under the UCL if they are otherwise unfair).

The purposefulness of the legislature in making notice an absolute pre-condition to suit is evident here as noted below. As applied to Proposition 65, California Health & Safety Code Section 25249.7(d)(1) therefore "prohibits plaintiffs from recasting their Proposition 65 action as an unfair competition action." *In re Vaccine Cases,* 134 Cal. App. 4th at 458. In other words, a plaintiff cannot use the UCL to "plead around" a defective notice that creates an absolute bar to relief under Proposition 65. *Id.* (citing *Cel-Tech,* 20 Cal. 4th at 184). After *In re Vaccine Cases,* "[i]t is now settled that unfair competition law claims (*see* Bus. & Prof.Code, § 17200) which are predicated on Proposition 65 warning violations must be dismissed if the underlying Proposition 65 claim is dismissed." *Consumer Def. Grp.,* 137 Cal. App. 4th at 1220.

Pepsi contends that although the initial complaints did not contain a direct Proposition 65 cause of action, the initial complaints effectively "recast" the Proposition 65 claim as CLRA, false

advertising, negligent misrepresentation, and UCL claims. Pepsi characterizes Plaintiffs' initial complaint as an exercise in artful pleading designed to circumvent the strictures of Proposition 65.

Plaintiffs respond that the actions were not commenced as Proposition 65 actions, because none of the initial complaints brought a claim directly under Proposition 65. Instead, Plaintiffs contend that they have alleged (and continue to allege) material misrepresentations and omissions that provide grounds for claims under the CLRA and UCL independent of Proposition 65. Plaintiffs argue that they amended their complaints to add a direct Proposition 65 cause of action only after the 60-day notice period had elapsed. Thus, Plaintiffs contend that they did not commence an action under Proposition 65 until after providing compliant notice.

The relevant plaintiffs are Plaintiffs Hall and Ibusuki, who are the named plaintiffs for the Proposition 65 claim in the CAC. *See Hal Roach Studios v. Richard Feiner & Co.,* 896 F.2d 1542, 1546 (9th Cir.1990) ("The fact that a party was named in the original complaint is irrelevant; an amended pleading supersedes the original."). Neither Hall nor Ibusuki alleged an action directly under Proposition 65 in their initial complaints. In this case, Ibusuki's March 7, 2014 initial complaint alleged a violation of the false advertising laws, violation of the UCL, and violation of the CLRA. *Ibusuki* ECF C-14-1193, Docket No. 1 ("Ibusuki Complaint"). Plaintiff Ibusuki sent a Proposition 65 notice on April 3, 2014, *see* Docket No. 83-8, one month after filing his complaint on March 7, 2014. Ibusuki Complaint.[2] Plaintiff Hall's March 7, 2014 complaint alleged a violation of

[2] Pepsi requests judicial notice over five categories of documents: (1) FDA guidance and explanatory materials (Docket Nos. 83-2, 83-3, 83-4); (2) Pepsi product labels (Docket Nos. 83-5, 83-6, 83-7); (3) Proposition 65 notices (Docket Nos. 83-8 (Ibusuki Letter); 83-9 (Hall Letter)) (4) citizen petitions submitted to the FDA (Docket Nos. 83-10 (Consumer Reports); 83-11 (Center for Science in The Public Interest)); and (5) records of judicial proceedings (Docket No. 83-12). Plaintiffs have filed a limited opposition to Pepsi's requests for judicial notice as to the FDA guidance and explanatory materials. Plaintiffs "do not oppose PepsiCo's request for judicial notice of [the FDA guidance documents] generally." Docket No. 87 at 2. Instead, Plaintiffs oppose noticing the truth of the contents of the FDA documents. *Id.* The Court **GRANTS** Pepsi's unopposed requests for judicial notice of the documents in categories 2 - 5. The Pepsi product labels are referred to in the CAC and placed in issue by Plaintiffs' claims. See CAC ¶¶ 1, 4, 42, 47, 48, 64. The Proposition 65 notices are also proper to consider, because they are incorporated by reference in the CAC and no party questions their authenticity. *See United States v. Corinthian Colleges,* 655 F.3d 984, 999 (9th Cir. 2011); CAC ¶ 67. The citizen petitions submitted to the FDA by Consumer Reports and the Center for Science in the Public Interest also are noticeable as "documents publicly filed with [an] administrative agency." *Tovar v. Midland Credit Mgmt.*, No. 10CV2600 MMA MDD, 2011 WL 1431988, at *2 (S.D. Cal. Apr. 13, 2011) (noticing, among other things, comments submitted to the FCC as part of rulemaking process). The existence of the citizen petitions is

the CLRA, alleged a claim of negligent misrepresentation, and alleged a violation of the UCL. *Hall* ECF C-14-1099, Docket No. 1 ("Hall Complaint"). Plaintiff Hall provided notice on March 3, 2014, four days before filing her March 7, 2014 initial complaint. *See* Docket No. 83-9. Plaintiff Ree does not allege that she provided notice; the direct Proposition 65 claim in the CAC is brought only by Hall and Ibusuki.

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noticeable to the extent that such petitions indicate that the FDA is actively deciding issues regarding labeling. *Cf. Greene v. T-Mobile USA, Inc.*, No. C07-1563RSM, 2008 WL 351017, at *2 (W.D. Wash. Feb. 7, 2008). The existence of the complaint in the parallel state case is also a matter of public record subject to judicial notice. *See Lee v. City of Los Angeles*, 250 F.3d 668, 689-90 (9th Cir. 2001). The Court also **GRANTS** Pepsi's request for judicial notice of the FDA guidance and explanatory materials with respect to the existence of these statements. A court may take judicial notice of "records and reports of administrative bodies." *Interstate Nat. Gas Co. v. S. California Gas Co.*, 209 F.2d 380, 385 (9th Cir. 1953). Such materials include guidance documents published by the FDA. *See, e.g., Anderson v. Jamba Juice Co.*, 888 F. Supp. 2d 1000, 1003 (N.D. Cal. 2012) (taking judicial notice of FDA guidance document from FDA website); *Hansen Beverage Co. v. Innovation Ventures, LLC*, No. 08-CV-1166-IEG POR, 2009 WL 6597891, at *2 (S.D. Cal. Dec. 23, 2009); *In re Amgen Inc. Sec. Litig.*, 544 F. Supp. 2d 1009, 1023-24 (C.D. Cal. 2008); *cf. County of Santa Clara v. Astra USA, Inc.*, 401 F. Supp. 2d 1022, 1024 (N.D. Cal. 2005) (taking judicial notice of information posted on a Department of Health and Human Services website); *cf. Nw. Envtl. Advocates v. U.S. E.P.A.*, 537 F.3d 1006, 1026-27 (9th Cir. 2008) (taking judicial notice of EPA's statements in its request for comments). In this case, the FDA documents are judicially noticeable, because they are guidance documents issued by a public administrative body and accessed from a government website, a source whose accuracy cannot reasonably be questioned. Fed. R. Evid. 201(b)(2). Nevertheless, when the documents to be noticed contain disputed facts, a court should notice the documents for their existence, not for the truth of the disputed facts. *Lee*, 250 F.3d at 690 ("[W]hen a court takes judicial notice of another court's opinion, it may do so not for the truth of the facts recited therein, but for the existence of the opinion, which is not subject to reasonable dispute over its authenticity."); *In re High-Tech Employee Antitrust Litig.*, 856 F. Supp. 2d 1103, 1108 (N.D. Cal. 2012) ("A court may also take judicial notice of the existence of matters of public record, such as a prior order or decision, but not the truth of the facts cited therein."); *In re Ubiquiti Networks, Inc. Sec. Litig.*, No. 12-CV-4677 YGR, 2014 WL 1254149, at *4 (N.D. Cal. Mar. 26, 2014); *Ritz Camera & Image, LLC v. SanDisk Corp.*, 772 F. Supp. 2d 1100, 1109 (N.D. Cal. 2011) *aff'd*, 700 F.3d 503 (Fed. Cir. 2012) ("While a court may take judicial notice of the existence of SEC filings, it may not take judicial notice of documents for the truth of disputed facts asserted therein."). The Court notices the fact that the FDA made the statements in the documents. *See Von Saher v. Norton Simon Museum of Art at Pasadena*, 592 F.3d 954, 960 (9th Cir. 2010) (explaining that "[c]ourts may take judicial notice of publications introduced to indicate what was in the public realm at the time, not whether the contents of those articles were in fact true"). The Court does not take notice of the FDA documents for the truth of facts subject to reasonable dispute, such as the safety or riskiness of 4-MeI. *Lee*, 250 F.3d at 689 (citing Fed. R. Civ. Proc. 201(b)).

There are facts suggestive of an initial "pleading around" Proposition 65. Plaintiffs have generally characterized the case as "a Proposition 65 action" when counsel sought to be appointed interim lead counsel.[3]

The question is whether the claims asserted in the initial complaint prior to the CAC, are entirely derivative of an unspoken Proposition 65 violation, or whether they assert claims independent of Proposition 65. If it is the former, the complaint may be treated as a "pleading around" Proposition 65. In this regard, Ibusuki's Complaint is problematic. As Plaintiffs' counsel acknowledged at the hearing, Ibusuki's initial complaint referred to no other alleged misstatements other than the failure to warn under Proposition 65. Ibusuki Complaint ¶¶ 9-11, 25-27, 37, 41-42; *see* 2/19/15 Hrg. Tr. at 8. While the Plaintiffs argue that Ibusuki's initial complaint did not arise "exclusively under Proposition 65," the paragraphs that Plaintiffs cite from the Ibusuki complaint relate only to the omission of the "health-warning label per California's Prop. 65" (Ibusuki Complaint ¶¶ 8-11) and allege but-for causation of loss, because Ibusuki "would have never purchased Pepsi One had he known it contained 4-MeI at a level that required a Proposition 65 warning." Ibusuki Complaint ¶¶ 40-45.

The Court therefore finds that the gravamen of Ibusuki's initial complaint was a Proposition 65 claim seeking to vindicate a right created by Proposition 65; all his claims were derivative of Proposition 65. Thus, where the California "Legislature did specifically conclude that 'no action should lie' unless plaintiffs provided a 60–day notice required by section 25249.7, subdivision (d)(1)" the Court concludes that Ibusuki "cannot evade the requirement of pre-suit 60-day notice in Proposition 65 by repleading [his] cause of action" as a violation of a consumer protection statute. *In re Vaccine Cases,* 134 Cal. App. 4th at 458-59 (plaintiff cannot evade notice requirements by repleading as an action for violation of the UCL); *cf. Cortina v. Goya Foods, Inc.,* No. 14-CV-169-L NLS, 2015 WL 1411336, at *4 (S.D. Cal. Mar. 19, 2015) (denying motion to dismiss based on failure to provide notice as to initial complaint where "Plaintiffs' sole mention of Proposition 65 in

[3] When counsel for Hall sought to be appointed interim lead counsel, counsel argued that it should be appointed, because "PSW and several other firms followed the necessary procedures for enforcement of Proposition 65, and their cases are now ripe for adjudication under Proposition 65." Docket No. 46 at 2.

the initial complaint lies in a quote in which a toxicologist references the Proposition 65 safe harbor level in comparison to [her] own recommended level of safe exposure").[4]

To be sure, the Ninth Circuit has characterized the rule against using the UCL to plead around an absolute bar to relief as "rather narrow." *Chabner v. United of Omaha Life Ins. Co.*, 225 F.3d 1042, 1048 (9th Cir. 2000); *cf. Yanting Zhang*, 57 Cal. 4th at 369 (concluding that UCL claims were not barred by lack of available private action under the Unfair Insurance Practices Act, because "plaintiff alleges causes of action for false advertising and insurance bad faith, both of which provide grounds for a UCL claim independent from the UIPA" even where conduct violated the UIPA); *Stop Youth Addiction*, 17 Cal. 4th at 576 (concluding that "the fact a UCL action is based upon, or may even promote the achievement of, policy ends underlying section 308 or the STAKE Act, does not, of itself, transform the action into one for the 'enforcement' of section 308"). But in this case, Ibusuki's initial claims were all totally dependent on establishing a Proposition 65 violation.

By contrast, the Hall Complaint does not plead around Proposition 65. To be sure, the Hall Complaint referred multiple times to Proposition 65. Hall alleged that "[d]uring the Class Period,

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[4] Plaintiffs have filed a statement of recent decision from the Southern District. Under Local Rule 7-3(d)(2): "*Before* the noticed hearing date, counsel may bring to the Court's attention a relevant judicial opinion published after the date the opposition or reply was filed by filing and serving a Statement of Recent Decision, containing a citation to and providing a copy of the new opinion – without argument." *Id.* (emphasis added). Pepsi objects to consideration of the recent decision, which was proffered after the hearing date. Docket No. 103. Pepsi seeks to strike the supplemental submission as unauthorized, or, alternatively, requests to submit a six-page supplemental memorandum addressing differences between this case and *Goya*. *Id.* The purpose of Local Rule 7-3(d)(2) is to "deter an endless cycle of filings and counter-filings while preserving the Court's ability to render a decision that is fully-informed by any particularly germane legal authority that may emerge." *Michael Taylor Designs, Inc. v. Travelers Prop. Cas. Co. of Am.*, 761 F. Supp. 2d 904, 909 (N.D. Cal. 2011) *aff'd*, 495 F. App'x 830 (9th Cir. 2012). The rules permit a party to submit a motion for administrative relief to seek leave to submit new authority after a hearing, although "it is a right that should be exercised sparingly." *Id.* In determining whether to permit leave to submit additional authority, the Court weighs the relevance of the authority and considers factors such as whether the decision is controlling, persuasive on an important issue, or cumulative of cases already submitted. *Id.* In this case, *Goya* is not controlling precedent, but it involves highly similar factual allegations and addresses unsettled areas of law that are in issue in the case at bar. The Court therefore exercises its discretion to construe Plaintiffs' motion as properly filed and will consider this recent decision, which the Court finds to be "particularly germane legal authority." *Michael Taylor Designs*, 761 F. Supp. 2d at 909; *see, e.g., In re Optical Disk Drive Antitrust Litig.*, No. 3:10-MD-2143 RS, 2012 WL 1366718, at *3 n.5 (N.D. Cal. Apr. 19, 2012) (construing one improperly filed statement of recent decision as properly filed). The Court also exercises its discretion to review and consider Pepsi's supplemental memorandum.

Pepsico knowingly and actively concealed the material fact that the Pepsi Beverages contain the toxic and cancer-causing chemical known as [4-MeI] at levels above the safety threshold set by the State of California in Proposition 65." Hall Complaint ¶ 1. Further, Hall's complaint continued to refer to Proposition 65 repeatedly in support of her claims. *Id.* ¶¶ 2, 5, 18, 19, 20, 21, 22, 28, 29, 62. Specifically, Hall referred to Proposition 65 as part of her allegations for the predicate wrong in support of her state law claims (*id.* ¶¶ 43a, 62, 70).

However, Hall expressly disclaimed any Proposition 65 violation in her initial complaint. *See* Hall Complaint ¶ 3 ("This Complaint does not allege a violation of Proposition 65."). Hall explained that "Proposition 65 is relevant to the extent it provides guidance as to a reasonable consumer's purchasing decisions in California." *Id.* ¶¶ 3, 29. More importantly, Hall's initial complaint proceeded under two independent theories. First, Hall's initial complaint is based not literally upon a violation of Proposition 65, but on Pepsi's public statements which allegedly misrepresented its actions. Hall Complaint ¶¶ 21-25. In particular, Hall alleged that Pepsi "feigned action" in response to the changing regulatory environment in California, misleading consumers into believing that the amounts of 4-MeI in the Pepsi Beverages were lower than they were. *Id.* The Hall Complaint alleged that Pepsi misrepresented it had "moved immediately to meet the new requirements" on 4-MeI and had "roll[ed] out . . . changes" that had been completed in California as well as several other states. Hall Complaint ¶ 22. While the alleged misstatement is related to Proposition 65, the alleged wrong is not a failure to warn under Proposition 65, but rather a separate misrepresentation to consumers regarding what actions Pepsi had taken and what levels of 4-MeI were present in the Pepsi Beverages.

Second, Hall's initial complaint and the CAC both appear to allege that Pepsi should have disclosed the presence of 4-MeI in the Pepsi Beverages irrespective of Proposition 65, including, *e.g.*, in its advertising and public statements.

The Court concludes that the Hall Complaint was not wholly derivative of a Proposition 65 warning violation. Hall did not "commence" an action "pursuant to" Proposition 65 in her initial complaint. Cal. Health & Safety Code § 25249.7(d)(1). Hall therefore only commenced a Proposition 65 action when the CAC was amended to add a direct claim under Proposition 65; that

claim was properly preceded by the requisite notice. *See Goya*, 2015 WL 1411336, at *5. The Ibusuki Complaint, on the other hand, arises exclusively from his allegations that Pepsi did not issue the warning required by Proposition 65. Consequently, the Ibusuki Complaint did not comply with Proposition 65's notice requirements and his later notice cannot retroactively cure this defect. *See DiPirro*, 119 Cal. App. 4th at 975; *In re Vaccine Cases*, 134 Cal. App. 4th at 457.

For the foregoing reasons, the Court **DENIES** Defendant's motion to dismiss Hall's claims on Proposition 65 notice grounds. The Court **GRANTS** Defendant's motion to dismiss Ibusuki's Proposition 65 claim, however, as discussed at the hearing, this dismissal has little practical effect. In this case "notice by [Hall] fulfills the true purpose of the notice requirement." *See Goya,* 2015 WL 1411336, at *5 n.2. Hall may proceed as named plaintiff for the Proposition 65 claim in the CAC.

3. Merits Argument on Safe Harbor & Exposure Limits

Pepsi repeatedly raises a factual argument throughout its motion. Pepsi argues that the Plaintiffs misconstrue both Proposition 65 and the Consumer Reports article. Pepsi contends that Plaintiffs' entire lawsuit rests on their mistaken belief that exceeding 29 micrograms in a single twelve-ounce serving constitutes a violation of Proposition 65. Pepsi argues that Plaintiffs' methodology does not align with that of Proposition 65, which calculates consumption based on lifetime exposure patterns using the average rate of intake or exposure for average users of the consumer product. *See, e.g.*, Motion at 7-8 (citing Cal. Health & Safety Code § 25249.10(c); 27 Cal. Code Regs. § 25721(d)(4)).

Viewing the pleadings in the light most favorable to Plaintiffs, the CAC adequately pleads that the Pepsi Beverages at issue did not fall within the safe harbor established by Proposition 65. In particular, the CAC alleges that studies show that consumers who drink soda consume, on average, more than one twelve-ounce serving per day. Assuming the facts alleged in the CAC to be true, it is a plausible inference that, where each serving of the Pepsi Beverages contained more than 29 micrograms of 4-MeI, the average *daily* exposure to a consumer who drinks more than one serving per day exceeds 29 micrograms. To the extent that Pepsi wishes to challenge Plaintiffs' exposure calculation methodology, it can do so at summary judgment or at trial. For purposes of surviving a

Rule 12(b)(6) motion to dismiss, Plaintiffs have adequately pled that the Pepsi Beverages did not fall within the safe harbor.

C. Preemption

Pepsi argues that federal labeling laws are the supreme law of the land, and that Congress (through the FDCA) and the FDA (through its regulations) have established a comprehensive federal system for food and beverage labeling. The FDCA and the FDA's regulations, in Pepsi's view, therefore preempt any claims arising under consumer state laws for warning labels or other disclosure of 4-MeI.

Under the Supremacy Clause, "Congress has the power to preempt state law." *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372 (2000); *see also Oneok, Inc. v. Learjet, Inc.*, No. 13-271, --- S.Ct. ----, 2015 WL 1780926, at *4 (Apr. 21, 2015). Congress may exercise this power by expressly providing for preemption. *Crosby*, 530 U.S. at 372 . Preemption need not, however, be express; it also occurs "[w]hen Congress intends federal law to occupy the field." *Id.* Additionally, federal statutes will preempt state law that conflicts with federal law. *Id.* Conflict preemption can arise where it is impossible for a party to comply with both state and federal law (*see, e.g., Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963)) or where "the challenged state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Crosby*, 530 U.S. at 373 (citing *Hines v. Davidowitz*, 312 U.S. 52, 66-67 (1941)).

Two presumptions regarding preemption guide the courts. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996). First, courts "start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress," because "the States are independent sovereigns in our federal system," *i.e.*, there is a starting presumption "that Congress does not cavalierly pre-empt state-law causes of action." *Id. See Wyeth v. Levine*, 555 U.S. 555, 565 (2009); *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 654-55 (1995); *Astiana v. Hain Celestial Grp., Inc.*, No. 12-17596, --- F.3d ---, 2015 WL 1600205, at *2 (9th Cir. Apr. 10, 2015). Second, the "ultimate touchstone" in every preemption case is Congressional purpose and intent. *Medtronic*, 518 U.S. at 485. "Congressional intent to preempt state law must be clear and manifest." *Indus.*

Truck Ass'n, Inc. v. Henry, 125 F.3d 1305, 1309 (9th Cir. 1997). *See United States v. Locke*, 529 U.S. 89, 108 (2000); *Astiana*, 2015 WL 1600205, at *2.

Proposition 65 is a consumer protection law that is within the states' historic police powers and subject to the presumption against preemption. *In re Farm Raised Salmon Cases*, 42 Cal. 4th 1077, 1088 (2008) (citation omitted); *see also Chem. Specialties Mfrs. Ass'n, Inc. v. Allenby*, 958 F.2d 941, 943 (9th Cir. 1992). The states' historic police powers included "[l]aws regulating the proper marketing of food, including the prevention of deceptive sales practices." *Id.; Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 144 (1963) ("[T]he 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." (quotation omitted)).

1. Express Preemption

The purpose of the FDCA is to "protect the health and safety of the public at large." *POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228, 2234 (2014). To that end, the "FDCA prohibits the misbranding of food and drink." *Id.*

In 1990, Congress amended the FDCA by enacting the Nutrition Labeling and Education Act ("NLEA") to "clarify and strengthen [the FDA's] authority to require nutrition labeling on foods . . . ." *Nat'l Council for Improved Health v. Shalala*, 122 F.3d 878, 880 (10th Cir. 1997) (quoting H.R. Rep. No. 101-538, at 7 (1990), reprinted in 1990 U.S.C.C.A.N. 3336, 3337); *see also Reid v. Johnson & Johnson*, 780 F.3d 952, 959 (9th Cir. 2015) ("The [NLEA] amended the [FDCA] to 'establish[ ] uniform food labeling requirements, including the familiar and ubiquitous Nutrition Facts Panel found on most food packages.'" (quoting *Lilly v. ConAgra Foods, Inc.*, 743 F.3d 662, 664 (9th Cir. 2014))). The purpose of the NLEA was "primarily to establish a national uniform labeling standard in place of the patchwork of different state standards that existed at the time." *In re Farm Raised Salmon Cases*, 42 Cal. 4th at 1091 n.12.

To create the desired national uniformity, the NLEA amended the FDCA to include a provision preempting state laws on misbranding. The NLEA added the preemption provision as section 403A of the Federal Food, Drug, and Cosmetic Act, which was codified at 21 U.S.C. § 343-1(a). *See POM Wonderful*, 134 S. Ct. at 2235. This provision provides that no state may

directly or indirectly establish a requirement for the labeling of food that is not "identical to" the requirements of section 403 of the FDCA (21 U.S.C. § 343), which governs misbranded food. 21 U.S.C. § 343-1(a). The FDA, in its implementing regulations, has commented that the term "not identical to" captures a state requirement that "directly or indirectly imposes obligations or contains provisions . . . that . . . [d]iffer from those specifically imposed by or contained in the applicable provision (including any implementing regulation) of section 401 or 403 of the act." 21 C.F.R. § 100.1(c)(4).

The uniform system for nutrition labeling inured to the benefit of both manufacturers and consumers – manufacturers do not have to "print 50 different labels" and consumers who buy food in more than one state do not have to discern different labels. *Turek*, 662 F.3d at 426; *Nemphos v. Nestle Waters N. Am., Inc.*, 775 F.3d 616, 620 (4th Cir. 2015) (observing "manufacturers can produce and market foods consistently and cost-effectively" while "consumers can make well-informed decisions about the types and quantities of ingredients in their diets"). Inconsistent state "requirements" include not only "positive enactments like statutes and regulations" but also "common-law duties and judge-made rules." *Chacanaca v. Quaker Oats Co.*, 752 F. Supp. 2d 1111, 1118 (N.D. Cal. 2010) (citing *Bates v. Dow Agrosciences, LLC*, 544 U.S. 431, 443 (2005)).

The NLEA makes clear, however, that the NLEA does not occupy the field. *Turek*, 662 F.3d at 425. Section 6(c)(1) of the NLEA, which was enacted, but not codified as part of the FDCA provides: "The Nutrition Labeling and Education Act of 1990 shall not be construed to preempt any provision of State law, unless such provision is *expressly preempted* under section 403A [21 U.S.C. § 343-1(a)] of the Federal Food, Drug, and Cosmetic Act." Pub. L. No. 101-535, § 6(c)(1), 104 Stat. 2353, 2364 (1990) (emphasis added).[5]

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[5] At argument, Pepsi contended that an uncodified portion of the NLEA should not merit weight. While the appearance of a provision in the United States Code "is 'prima facie' evidence that the provision has the force of law, 1 U.S.C. § 204(a), it is the Statutes at Large that provides the 'legal evidence of laws,' § 112." *U.S. Nat. Bank of Oregon v. Indep. Ins. Agents of Am., Inc.*, 508 U.S. 439, 448 (1993). The NLEA's uncodified note on construction appears in the United States Statutes at Large. Pub. L. No. 101-535, § 6(c), 104 Stat. 2353, 2364 (1990). Although not codified, Congress's enacted note on construction has the "force of law" and "works together" with the statute. *Glenn v. Holder*, 690 F.3d 417, 426 n.2 (6th Cir. 2012) (applying six uncodified rules of construction included in a note to the Hate Crimes Act). The note on construction therefore provides an "express definition of the pre-emptive reach" of the NLEA. *Brod v. Sioux Honey Ass'n, Co-op.*,

The FDCA misbranding provisions subject to express preemption deem food misbranded if it is offered for sale under the name of another food (§ 343(b)), if it is an imitation of another food and does not properly state "imitation" (§ 343(c)); if the container is made, formed, or filled in a misleading manner (§ 343(d)); if it is packaged and the package does not identify the source of the food or accurately identify its contents (§ 343(e)); if required information is not printed with sufficient prominence (§ 343(f)); if it does not comply with definitions and standards, including the common names of optional ingredients (other than spices, flavoring, and coloring) (§ 343(g)); if it does not make proper representations as to quality, fill, and pasteurization (§ 343(h)); if it does not bear the common or usual name of the food or component ingredients, except that spices, flavorings, or colorings may be designated as spices, flavorings, or colorings without naming each (§ 343(i)); if it does not label artificial flavoring, artificial coloring, or chemical preservatives as such (§ 343(k)); if it does not provide certain nutrition information, such as serving size, servings per container, calories, and identification of certain nutrients, vitamins, and minerals (§ 343(q)); if it improperly characterizes nutrition levels and health-related claims (§ 343(r)); and if it does not identify certain allergens (§ 343(w; x)). *See* 21 U.S.C. §§ 343; 343-1(a).

Where there is an express preemption clause applicable to a provision of the FDCA, the Court must determine whether the state law at issue falls within the scope of that preemption. *Altria Grp., Inc. v. Good*, 555 U.S. 70, 76 (2008) ("If a federal law contains an express pre-emption clause, it does not immediately end the inquiry because the question of the substance and scope of Congress' displacement of state law still remains."). In mapping the scope of a preemption clause, the Court typically must "accept the reading that disfavors pre-emption," if such reading is plausible. *Id.* at 77.

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927 F. Supp. 2d 811, 824 (N.D. Cal. 2013) (quoting *Freightliner Corp. v. Myrick*, 514 U.S. 280, 288 (1995)). As such, many cases analyze some or all of the NLEA's note on construction in determining whether preemption is proper. *See, e.g., Brazil v. Dole Food Co.*, 935 F. Supp. 2d 947, 957 (N.D. Cal. 2013); *Bruton v. Gerber Products Co.*, 961 F. Supp. 2d 1062, 1083 (N.D. Cal. 2013); *Gustavson v. Wrigley Sales Co.*, 961 F. Supp. 2d 1100, 1119 (N.D. Cal. 2013); *Ivie v. Kraft Foods Global, Inc.*, 961 F. Supp. 2d 1033, 1038 (N.D. Cal. 2013); *Chacanaca v. Quaker Oats Co.*, 752 F. Supp. 2d 1111, 1118 (N.D. Cal. 2010); *Lockwood*, 597 F. Supp. 2d at 1032; *Turek*, 662 F.3d at 425; *Holk v. Snapple Beverage Corp.*, 575 F.3d 329, 336 (3d Cir. 2009) (discussing Section 6(c)(1) and (c)(3)); *New York State Rest. Ass'n v. New York City Bd. of Health*, 556 F.3d 114, 123 (2d Cir. 2009); *In re Farm Raised Salmon Cases*, 42 Cal. 4th 1077, 1091 (2008).

Here, the enumeration of the various sections of the FDCA that expressly preempt state law is "significant," because "the complex pre-emption provision distinguishes among different FDCA requirements," covering some, but not all, of the FDCA's misbranding subsections. *POM Wonderful,* 134 S. Ct. at 2238. Relevant to the case at bar, the NLEA only preempts state-law requirements "that are of the type but not identical to only certain FDCA provisions with respect to food and beverage labeling." *Id.*

In other words, the NLEA's preemption provisions do not reflect an intent to preempt every state law requirement with some conceivable relationship to the labeling of food. Instead, express preemption applies only to requirements "of the type" enumerated.[6] 21 U.S.C. § 343-1(a); *see Medtronic,* 518 U.S. at 501 (holding that where state requirements were not specifically developed "with respect to" a specific medical device, they were not "the kinds of requirements that Congress and the FDA feared would impede the ability of federal regulators to implement and enforce specific federal requirements" under the Medical Device Amendments); *Bates,* 544 U.S. at 444-45 (concluding that common law rules governing product design, due care in testing, marketing, and enforcing express warranties are not preempted under FIFRA, because they are not requirements for labeling or packaging).[7] *Cf. New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.,* 514 U.S. 645, 654-56 (1995) (construing "relate to" in ERISA preemption

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[6] In contrast to the NLEA, the express preemption provision included in the Medical Device Amendments to the FDCA contains more expansive language. The Medical Device Amendments provided that no state "may establish or continue in effect with respect to a device . . . any requirement relating to safety or effectiveness that is different from, or in addition to, federal requirements. *Riegel v. Medtronic, Inc.,* 552 U.S. 312, 327-28 (2008) (quoting 21 U.S.C. § 360k(a)(2)). Similarly, the express preemption provision in the Federal Drug Administration Modernization Act, which amended the FDCA in 1997, broadly references any state requirement that is "different from or in addition to, or that is otherwise not identical with, a requirement under this chapter, the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.), or the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.)." 21 U.S.C. § 379r(a). Proposition 65 was specifically saved from the preemption provision of the Modernization Act; it is the only state enactment that falls within the savings clause. *Dowhal v. SmithKline Beecham Consumer Healthcare,* 32 Cal. 4th 910, 919, 924 (2004); 21 U.S.C. § 379r(d)(2) ("This section shall not apply to a State requirement adopted by a State public initiative or referendum enacted prior to September 1, 1997."). *See* 21 U.S.C. § 379r(a)(1) (The preemption provision of the Modernization Act applies only to OTC drugs.).

[7] FIFRA's preemption provision provides: "Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter." *Id.* at 443.

provision and concluding that "infinite relation" and "infinite connection" cannot be the measure of preemption). If the label statements at issue do not involve the enumerated labeling requirements, "then the NLEA's express preemption provision would not in the ordinary circumstance come into play." *Chacanaca*, 752 F. Supp. 2d at 1119.

a. Violation of Proposition 65 Warning Requirements

Plaintiffs allege that Pepsi failed to include a health warning even though exposure to 4-MeI from the coloring of Pepsi Beverages was at a level above Proposition 65's safe-harbor level. CAC ¶¶ 1, 4–6, 8, 40, 49, 63–65, 69, 76, 85. Pepsi argues that mandating a Proposition 65 warning would impose a labeling requirement that is not identical to requirements of the FDCA and is thus subject to the NLEA's express preemption provision. Motion at 16-18.

i. No Conflict with NLEA Labeling Requirements

In asserting preemption, Pepsi refers generally to 21 U.S.C. §§ 343-1(a)(2),[8] (a)(3).[9] Of the substantive misbranding provisions covered by express preemption under Section 343-1, the only potentially relevant provisions are those which require that artificial coloring be labeled (21 U.S.C. § 343(k)), which require a label bearing the common or usual name of the food (21 U.S.C. § 343(i)(1)), and which permit multiple spices, flavorings, or colorings to be designated as spices, flavorings, or colorings without naming each (21 U.S.C. § 343(i)(2)). *See* 21 U.S.C. § 343-1(a)(2); (a)(3). Pepsi cites a number of the FDA's related implementing regulations regarding how caramel coloring should be identified in labeling. *See* 21 C.F.R. §§ 70.25; 101.4; 101.22. Under FDA regulations, caramel color may be labeled as "Colored with Caramel" or "Caramel color." *See id.* § 101.22(k)(2). Alternatively, caramel color "may be declared as 'Artificial Color,' 'Artificial Color Added,' or 'Color Added' (or by an equally informative term that makes clear that a color additive has been used in the food)." *Id.*[10]

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[8] Section 343-1(a)(2) preempts state requirements that are not identical to sections 343(c), 343(e), 343(i)(2), 343(w), or 343(x).

[9] Section 343-1(a)(3) preempts state requirements that are not identical to sections 343(b), 343(d), 343(f), 343(h), 343(i)(1), or 343(k).

[10] A more detailed list of color additive ingredients is required when caramel color is a "mixture." *Id.* § 70.25 (color additives must include "[t]he name of the straight color or the name of each ingredient comprising the color additive, if it is a mixture."). Under the FDA's implementing

In this case, a Proposition 65 warning is not a statement explicitly covered by the misbranding provisions subject to express preemption. Proposition 65 does not directly or indirectly establish a requirement that differs from the FDCA's requirement that artificial coloring be labeled (21 U.S.C. § 343(k)). Nor does Proposition 65 disturb the permissive provision in the FDCA that allows multiple colors to be designated as "colorings" without naming each (21 U.S.C. § 343(i)(2)). Similarly, Proposition 65 does not require caramel color to be called a name different from the common or usual names approved by the FDA in its implementing regulations, *e.g.*. "caramel color."[11]

Thus, the misbranding provisions subject to express preemption under the NLEA do not in an obvious facial manner cover the warning required by Proposition 65, because the duties imposed by Proposition 65 are not "of the type" of those imposed under the misbranding provisions subject to preemption; *i.e.*, §§ 343(i) (common or usual name for food or ingredients) and 343(k) (labeling of any artificial coloring). Proposition 65 does not take issue with the use of the term "caramel color" for the color additive at issue here. Instead, it addresses the safety of the compound that is a byproduct of the additive. *Cf. Altria,* 555 U.S. at 82-83 (distinguishing between fraudulent labeling statements and warnings and holding that while warnings were preempted, a general consumer protection act claim that merely encompassed *harms* related to smoking and health was not expressly preempted by the amended Federal Cigarette Labeling and Advertising Act, which

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regulations, a "mixture" is defined as "a color additive made by mixing two or more straight colors, or one or more straight colors and one or more diluents." *Id.* § 70.3(k). 4-MeI, which, as alleged in the CAC and recognized by the FDA is "a byproduct" of the manufacturing process for Caramel Color III and IV, does not appear to be a mixed, separate ingredient requiring specific listing under the FDA's regulations. CAC ¶¶ 19, 22; Docket No. 83-2, Ex. A.

[11] Plaintiffs' opposition to the Motion raises the argument that their claims are based, at least in part, on the premise that Pepsi Beverages were "misbranded" within the meaning of the FDCA. See Docket No. 86, Opp. at 13. Section 343-1, by its terms, allows states to establish requirements identical to FDCA requirements that are otherwise subject to express preemption. *See In re Farm Raised Salmon Cases*, 42 Cal.4th at 1086. In that respect, California has enacted the "Sherman Law," which prohibits the misbranding of food using language which is identical scope as that of the FDCA. *Id.* The Sherman Law incorporates all food regulations adopted pursuant to the FDCA. *Id.* (citing Cal. Health & Saf. C. § 110100(a)). Plaintiffs do not mention misbranding anywhere in the CAC. In this case, Plaintiffs have not brought claims for misbranding arising under or based on California's Sherman Law. *Cf. Astiana,* 2015 WL 1600205, at *3; *In re Farm Raised Salmon Cases*, 42 Cal.4th at 1086. To the extent Plaintiffs now seek to raise a misbranding claim based on the use of the use of the term "Caramel color," that claim fails, as the Pepsi Beverages complied with the FDCA's requirements on the identification of caramel color and Plaintiffs have failed to allege or show how the Pepsi Beverages' labels would be misbranded under the FDCA.

expressly preempted requirements that were "based on smoking and health . . . with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions" of the act; state law claim based on statements did not create a requirement based on smoking and health).

The lack of a specific FDA labeling requirement which conflicts with the Proposition 65 warning sought by the plaintiffs distinguishes this case from others, wherein the alleged statement or omission was specifically sanctioned by particular federal labeling regulations. *Cf. In re Bisphenol-A (BPA) Polycarbonate Plastic Products Liab. Litig.*, No. 08-1967-MD-W-ODS, 2009 WL 3762965 at *5 (W.D. Mo. Nov. 9, 2009) (noting FDA specifically exempted BPA from disclosure in its implementing regulations).[12]

Furthermore, the intent of the NLEA (and the misbranding provisions) was to cover "only nutrients or substances in food that 'nourish,'" and the NLEA "does not in any way regulate carcinogens or other, non-nutritive substances in foods." H.R.Rep. No. 101-538, at 7 (1990), reprinted at 1990 U.S.C.C.A.N. 3336, 3337. As Congress's statement of intent sets forth: "This section [the savings clause in Section 6(c)(2)] may be unnecessary because section 403 [*i.e.* 21

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[12] For example, cases involving nutrient and disease prevention claims under Section 343(r) are distinguishable. *See Chacanaca*, 752 F. Supp. 2d at 1121 ("The statement would not be misbranded under subsection (r) and the plaintiffs' state law claims therefore seek to impose a non-identical burden."); *Turek*, 662 F.3d at 427 ("The disclaimers that the plaintiff wants added to the labeling of the defendants' inulin-containing chewy bars [distinguishing inulin from "natural" fiber] are not identical to the labeling requirements imposed on such products by federal law, and so they are barred."); *Gustavson v. Wrigley Sales Co.*, 961 F. Supp. 2d 1100, 1123 (N.D. Cal. 2013) (dismissing calorie-related claims as expressly preempted, because statements regarding calories "appear to comply with all applicable federal regulations," and therefore "any finding that these claims are unlawful and deceptive would impose requirements not identical to the FDA's regulations");*Trazo v. Nestle USA, Inc.*, No. 5:12-CV-2272 PSG, 2013 WL 4083218, at *6 (N.D. Cal. Aug. 9, 2013) ("If Nestle's products are compliant with the FDCA, Plaintiffs' claims on those products are expressly preempted by Section 343-1(a)."). As part of the NLEA, Congress directed the FDA to promulgate regulations defining terms regarding the characterization of nutrient levels. Pub.L. No. 101–535, § 3(b)(1)(A). The FDA's regulations on those terms dictate whether a food is deemed misbranded. 21 U.S.C. § 343(r) (deeming food misbranded if a label characterizes certain nutrients using terms other than those defined in the FDA's regulations). In other words, Section 343(r) addresses a broad range of statements with detailed regulations enacted pursuant to formal rule-making, balancing various interests and specifically circumscribing labeling statements. *See, e.g.*, Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms, 56 Fed. Reg. 60,421, 60,423 (November 27, 1991) (noting in proposed rule that "[t]o ensure that consumers are not misled and are given reliable information, Congress found, and FDA agrees, that it is appropriate for the agency to establish specific definitions to standardize the terms used by manufacturers to describe the nutrient content of foods.").

U.S.C. § 343, the misbranding provision subject to the express preemption provisions of the NLEA] *does not require health warnings* and therefore, by the terms of section 403A [*i.e.* 21 U.S.C. § 343-1(a), the preemption provisions added by the NLEA], state laws requiring health warnings would not be preempted." 136 Congressional Record, 101st Congress, 2nd Session at 20419 (July 30, 1990) (emphasis added). Hence, Proposition 65's regulation of carcinogenic warnings which do not alter FDA sanctioned labels on coloring is not inconsistent with the letter or purpose of the NLEA. *Cf. Wyeth*, 555 U.S. at 570 (finding that "strengthening the warning" regarding antihistamine would not have rendered it "misbranded" under the FDCA's provisions regarding misbranded drugs and devices).

ii. The Savings Clause Under Section 6(c)(2)

Even if a Proposition 65 warning somehow improperly added a non-identical burden on labeling or conflicted with the FDA's listing of caramel color in a way that implicated Section 343-1, Section 6(c)(2) saves from express preemption state laws such as Proposition 65 requiring food safety warnings for *e.g.*, cancer. The NLEA specifically provides that the express preemption provision "shall not be construed to apply to any requirement respecting a statement in the labeling of food that provides for a warning concerning the safety of the food or component of the food." Pub.L. No. 101–535, § 6(c)(2) (21 U.S.C. § 343-1 note). Thus, the NLEA carves out an exemption from its express preemption clause where *warnings* concerning the *safety* of food or component of food are at issue.

The Proposition 65 warning[13] and the cancer risks alleged in the CAC unambiguously implicate safety concerns. Thus, unlike cases in which no safety concerns are raised, the Section 6(c)(2) exemption from preemption applies where, as here, such concerns are manifest.

In this regard, Pepsi's reliance on two cases it cites is inapposite. These cases grappled with the initial question of whether the safety of food was sufficiently implicated to invoke the Section 6(c)(2) exemption. *Mills v. Giant of Maryland, LLC*, 441 F. Supp. 2d 104 (D.D.C. 2006) *aff'd*, 508 F.3d 11 (D.C. Cir. 2007), concluded that the Section 6(c)(2) exemption did not apply in a case where

[13] "WARNING: This product contains a chemical known to the State of California to cause cancer." 27 Cal. Code Regs. § 25603.2.

the safety concern hinged on the risk of gastrointestinal discomfort, *e.g.*, flatulence and bloating, associated with lactose intolerance. *Id.* at 109. *Mills* found that the FDA did not recognize this type of gastrointestinal irritation as a safety concern. *Id.* Unlike *Mills*, as discussed more fully *infra* with respect to the Delaney Clause, this case involves the risk of cancer, which the FDA and Congress recognize as a risk implicating food safety.

Pepsi also points to *In re Bisphenol-A (BPA) Polycarbonate Plastic Products Liab. Litig.*, No. 08-1967-MD-W-ODS, 2009 WL 3762965 (W.D. Mo. Nov. 9, 2009) for the proposition that if the FDA finds that a substance is "safe," the exemption from express preemption cannot apply. *Id.*, at *6. At the outset, *In re BPA* found no implied conflict preemption based on the FDA's safety determination, specifically observing that the FDA's "approval of BPA as safe without labeling requirements establishes only a regulatory *minimum;* nothing on these regulations either required or prohibited Defendants from providing the disclosures sought by Plaintiffs." *Id.*, at *4 (emphasis in original). Where the safety determination sets only a floor it does not preclude state law causes of action, particularly in view of the presumption against preemption. *Wyeth*, 555 U.S. at 573-74. Nevertheless, the court in *BPA* found express preemption, pursuant to a misbranding regulation under Section 343(i)(2). *In re BPA* declined to give effect to the safety exception to the NLEA's preemption clause, because the FDA had concluded by another regulation that the use of BPA in epoxy liners was "safe". *In re BPA*, 2009 WL 3762965, at *6. *In re BPA* reasoned that it was appropriate to defer to the FDA's determination of safety to apply the safety exception, because otherwise a state could "impose almost any requirement on food labeling that conceivably could concern food safety, a result Congress surely did not intend." *Id.* Thus, the court rejected application of the savings clause of Section 6(c)(2).

The Court disagrees with *In re BPA's* conclusion that a safety determination by the FDA precludes application of Section 6(c)(2), the NLEA's savings clause. Instead, this Court concludes that state law warning requirements as to food safety are saved from express preemption under Section 6(c)(2) of the NLEA. This conclusion is faithful to the plain language, legislative history, and purpose of the NLEA as set forth by Section 6(c)(2). *See Lockwood*, 597 F. Supp. 2d at 1033

(observing "the NLEA – including the savings clause (no preemption unless the law is expressly preempted) – shall not be construed to affect preemption of food safety laws").

First, the language of the Section 6(c)(2) exemption is plain. Congress specifically determined that the express preemption provision shall not be construed to apply to "any requirement" that provides for a warning concerning the "safety" of a food component. Pub.L. No. 101–535, § 6(c)(2) (21 U.S.C. § 343-1 note). Its wording applies to all such state laws, without regard to whether the FDA has made a finding to the contrary. Proposition 65 is such a law.

Second, the legislative history supports a broad construction of the savings clause. The NLEA was sponsored by Representative Henry Waxman. When the House considered and passed the NLEA, Congressman Waxman addressed certain changes made to the bill's language since it had been initially reported – changes that arose in the course of negotiations within the Committee on Energy and Commerce and in connection with input from private parties. *See* 136 Congressional Record, 101st Congress, 2nd Session at 20414-21 (July 30, 1990) (statement of Mr. Waxman). These changes added the provision regarding construction, which narrowed the scope of the preemption provision contained in the bill from when it was first reported by the Committee. *Id.* In particular, Congressman Waxman explained why the original, more expansive preemption provision was explicitly narrowed. *Id.* He deemed "most important[]" the principle that "the most compelling argument for State regulation is where the States have adopted laws to protect the safety of their citizens." *Id.* at 20419. He explained that "[t]herefore, the [amended] preemption provisions in H.R. 3562 explicitly permit the States to adopt requirements for warning about the ingredients or components of food." *Id.* Hence, the sponsor of the NLEA made clear the importance of exempting state safety laws from federal preemption.

The legislative intent behind the changes to the preemption provision was also memorialized in a separate statement of intent. *Id.* at 20418. That statement provides:

> Section 403A(b)(1) [later enacted as Section 6(c)(2)] states that section 403(a) does not apply to any requirement for a statement in food labeling (including statements on the label) that provides a warning concerning the safety of the food or a component of the food. This section may be unnecessary because section 403 does not require health warnings and therefore, by the terms of section 403A, state laws requiring health warnings would not be preempted. Nevertheless,

> section 403A(b)(1) has been included to *underscore* that State laws requiring warnings pertaining to the safety of foods are *not preempted*.

Id. at 20419 (emphasis added). Following Congressman Waxman's comments, Representative Tom McMillen rose in support of passage of the bill, which he viewed as a "positive step toward national uniformity in food labeling," but also voiced his "disappointment that this legislation is silent on the issue of health warnings." *Id.* at 20423. He explained that "[w]ithout national uniformity requirements for health warnings on food labels, manufacturers are forced to continue operating in a system of patchwork regulations." *Id.* Notwithstanding Congressman McMillen's statements regarding the pitfalls of a patchwork of health warning regulations, the House passed the amended bill. *Id.* Health warnings were never incorporated into the NLEA or the related FDCA misbranding provisions.

The Senate hearings addressed the scope of preemption as well. Senator Metzenbaum discussed the "uniformity question" with the then-Commissioner of the FDA. Hearing on S. 1425, Before the Senate Comm. on Labor and Human Resources, 101st Cong., 1st Sess. 13 at 24 (November 13, 1989). Senator Metzenbaum observed that while the NLEA included specific preemption of nutrition provisions, it did "not preempt State labeling laws in other areas, including pesticides and cancer warnings." *Id.* Senator Metzenbaum indicated his view that uniformity in food safety standards should be dealt with in a separate bill on food safety issues. *Id.* The FDA Commissioner responded by acknowledging the benefits and challenges with achieving uniformity. *Id.* He specifically commented on Proposition 65, observing that at that time he did not see any particular area that was out of compliance. *Id.* He indicated that the FDA would proceed on a "case-by-case basis" and deferred to a letter from Jay Plager of the Executive Office of the President. *Id.* That letter communicated to Congress that the Reagan administration had formally established a position (in collaboration with FDA Commissioner Young) that there would be "no Federal preemptive action – either by regulation or otherwise" with respect to Proposition 65. *Id.* at 42. The administration of then-president Bush had revisited and adopted this position without change. *Id.*

Later, during Senate consideration and passage of the NLEA, Senator Hatch stated:

> [T]he carefully crafted uniformity section of this legislation is limited in scope. That section does not preempt or affect a requirement respecting a statement in the labeling of food that provides for a warning concerning the safety of a food or a component of a food. . . . [A]lthough the provisions of this bill may not preempt a State warning requirement . . . that very same State warning may be preempted by virtue of the Constitution, another statutory provision, or agency action. . . . [T]he limited preemption in this bill [is] only one step toward expanding uniformity of labeling laws and food safety requirements through existing law as well as future legislation.

136 Congressional Record, 101st Congress, 2nd Session at 33429 (October 24, 1990) (statement of Mr. Hatch).

This legislative history weighs strongly against preemption. "'The case for federal pre-emption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to stand by both concepts and to tolerate whatever tension there [is] between them.'" *Wyeth*, 555 U.S. at 575 (quoting *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 166-167 (1989)).

Third, preemption is particularly disfavored where state laws in exercise of traditional and historic police powers to protect health and safety are rendered ineffective, *Allenby*, 958 F.2d at 943 (cautioning that courts should be "especially unlikely" to find preemption of state laws that regulate health and safety), a point underscored by the legislative history of § 6(c)(2).

Finally, it is noteworthy that food manufacturers have petitioned Congress to enact legislation expressly preempting state warning requirements as to ingredients that the FDA has deemed safe. *See* Peter Barton Hutt, Richard A. Merrill & Lewis A. Grossman, Food and Drug Law 315 (4th ed. 2014). Such legislation was reported in 2000, 2004, and 2006, but no such legislation has been passed. *Id.*

In sum, the plain language of the NLEA, which is uncontradicted by its legislative history, excludes state law safety warning requirements from the scope of the NLEA's express preemption provision. The legislative history illustrates that Congress specifically considered preempting state causes of action that require health warnings, such as Proposition 65 particularly as applied to carcinogens. Congress explicitly declined to do so through express preemption. Pub.L. No. 101–535, § 6(c)(2) (21 U.S.C. § 343-1 note). Even if a case of express preemption could otherwise

be made, the Proposition 65 warning here is saved from express preemption under the NLEA under Section 6(c)(2) because Proposition 65 unquestionably involves food safety and in particular suspected carcinogens.

b. The FDA's Regulatory Finding That Caramel Color is Safe Does Not Expressly Preempt Proposition 65

Defendant argues that the "identical to" standard encompassed in the FDA misbranding provisions applies with particular vigor here, because as explained below, the FDA authorization of the descriptive term "caramel color" arguably encompasses the FDA's predicate determination that caramel color is safe which allowed caramel color to be listed as a color additive exempt from certification. Importantly, that FDA determination was made under the Color Additive Amendments, which predated the NLEA.

In 1960, thirty years before the enactment of the NLEA, the FDCA was amended to add the Color Additive Amendments, which "establish[ed] an elaborate system for regulation of color additives in the interests of safety." *Pub. Citizen v. Young,* 831 F.2d 1108, 1109 (D.C. Cir. 1987). The Color Additive Amendments, like the sections of the FDCA concerning food additives and new animal drugs, contains what is commonly known as the "Delaney Clause." *Id.* In relevant part, the color additive Delaney Clause provides:

> A color additive [. . .] shall be deemed unsafe, and shall not be listed, for any use which will or may result in ingestion of all or part of such additive, if the additive is found by the Secretary to induce cancer when ingested by man or animal, or if it is found by the Secretary, after tests which are appropriate for the evaluation of the safety of additives for use in food, to induce cancer in man or animal[.]

21 U.S.C. § 379e(b)(5)(B).

Thus, under the Color Additive Amendments, a "color additive may be used only after the [FDA] has published a regulation listing the additive for such uses as are safe." *Pub. Citizen,* 831 F.2d at 1109. As part of listing the additive as safe, the FDA may prescribe the conditions of safe use and must either batch certify the additive or exempt the additive from the certification requirement. 21 U.S.C. § 379e(a). This includes a determination of safety. § 379(e)(b)(4)(5).

Here the FDA made a safety determination under the Color Additive Amendments in permitting caramel color to be listed and exempt from certification. 21 C.F.R. §§ 73.85; 182.1235; 21 U.S.C. § 379e(b)(4); 21 U.S.C. § 379e(b)(5)(B). Plaintiffs allege that Class IV caramel coloring is found in the Pepsi Beverages and is created through an ammonia-sulfate process. CAC ¶¶ 18-19. The CAC identifies 4-MeI as a byproduct of the manufacturing of caramel color IV. CAC ¶¶ 19, 22. The FDA has determined that the additive described as caramel color includes caramel manufactured with ammonium- and sulfate-containing compounds, such as that used in the Pepsi Beverages. *See* 21 C.F.R. § 73.85(a)(2)(iii). Nonetheless, the FDA specifically approved "caramel" for use as a color additive after the agency concluded that caramel color is "generally recognized as safe when used in accordance with good manufacturing practice" and does not induce cancer in man or animals at any level. 21 C.F.R. §§ 73.85 (identifying the "color additive caramel" as the dark-brown material "resulting from the carefully controlled heat treatment" of certain food-grade carbohydrates and subject to the use of food-grade acids, alkalis, and salts that may be employed to assist caramelization, finding "Caramel may be safely used for coloring foods generally, in amounts consistent with good manufacturing practice," and exempting caramel from certification), 70.25 ("All color additives shall be labeled with sufficient information to assure their safe use and to allow a determination of compliance with any limitations imposed by this part and parts 71, 73, 74, 80, and 81 of this chapter."); 182.1235 (Caramel "is generally recognized as safe when used in accordance with good manufacturing practice"); 21 U.S.C. § 379e(b)(4) ("The Secretary shall not list a color additive under this section for a proposed use unless the data before him establish that such use, under the conditions of use specified in the regulations, will be safe."); 21 U.S.C. § 379e(b)(5)(B).

In contrast with the NLEA, however, the Delaney Clause does *not* have a preemption provision. *Riegel,* 552 U.S. at 341 (Ginsburg, J., dissenting) (observing, more than 15 years after the enactment of the NLEA, that the Color Additive Amendments, along with other FDCA amendments requiring premarket approval, were not subject to any preemption clause).[14] *Compare* 21 U.S.C. § 379e *with* § 343-1(a). Hence, express preemption does not apply to the specific safety determination made by the FDA under Color Additive Amendments.

[14] Indeed, Pepsi cites no preemption provision other than that provided under the NLEA.

Even if the lack of a preemption provision in the Color Additive Amendments did not complete the inquiry and the Court was to give effect to the more general preemption provisions of the subsequently enacted NLEA, the Court finds that the FDA's regulatory finding regarding the safety of caramel coloring does not expressly preempt Proposition 65 under the NLEA. The FDA's safety determination is itself not a regulation of "the labeling of food," 21 U.S.C. 343-1(a). Instead it was a subsidiary finding predicate to a labeling determination. The ultimate preemption question turns on whether Proposition 65 conflicts with that ultimate labeling determination. As noted above, Proposition 65 is not a requirement for the "labeling of food of the type required by" Section 343(i) or 343(k). Furthermore, as discussed above, Congress intended the NLEA (and the misbranding provisions) to cover "only nutrients or substances in food that 'nourish[;]'" the NLEA "does not in any way regulate carcinogens or other, non-nutritive substances in foods." H.R.Rep. No. 101-538, at 7 (1990), reprinted at 1990 U.S.C.C.A.N. 3336, 3337. Proposition 65 is therefore not subject to express preemption under the NLEA. 21 U.S.C. 343-1(a); *see POM Wonderful,* 134 S. Ct. at 2238 (noting "[i]t is significant that the complex pre-emption provision distinguishes among different FDCA requirements" and preempts "only certain FDCA provisions"); *see also* 21 C.F.R. § 100.1(c)(4) (discussing preemption of regulations that implement 21 U.S.C. §§ 341, 343 and not preemption by implementing regulations of other FDCA provisions, such as the Color Additive Amendments).

In sum, considering (1) the plain language of the government statutes, (2) the presumption against preemption of the states' historic police powers, *Medtronic,* 518 U.S. at 485, (3) the related requirement to accept, when plausible, the reading of an express preemption clause that disfavors preemption, *see Altria,* 555 U.S. at 77, (4) the evidence of Congress's intent not to regulate carcinogens or include state warning laws under the NLEA's express preemption provision, (5) the inclusion of a provision specifically saving state law claims based on warnings as to safety, and (6) Congress's consideration and lack of action as to specific legislation that would expressly preempt warning requirements such as those under Proposition 65, the Court concludes that it was *not* Congress's clear and manifest intent to include Proposition 65 warning claims within the scope of the NLEA's express preemption clause. Moreover, the Color Additive Amendments and the

Delaney Clause under which the FDA issued its safety finding contain no express preemption clause.

c. Material Misrepresentations

The CAC alleges a material misstatement in the form of a public statement regarding steps that Pepsi had taken to conform its beverages to state regulations. CAC ¶¶ 31; 40; 47-48. In the light most favorable to Plaintiffs, the misstatement or omissions that Pepsi made in its public statements and/or on its website is a deceptive claim regarding a consumer product. Pepsi has pointed to no provision of the FDCA or FDA regulations that preempts claims based on such alleged misrepresentations, which are not alleged to be included on product labels or packaging. As noted above, the alleged misstatements are independent of Proposition 65 compliance. The Court concludes that these claims are not preempted, expressly or otherwise. *Astiana,* 2015 WL 1600205, at *3 (holding claims of "deception as a result of advertising statements that contradicted the true ingredients listed on the FDA-mandated label" are not preempted).

2. Implied Preemption

Having found that the NLEA does not expressly preempt Proposition 65, the Court addresses implied preemption. In particular, the Court addresses field and conflict preemption; as to conflict preemption, the Court examines both impossibility and obstacle preemption.

a. Field Preemption

As discussed *supra,* the NLEA provides that it "shall not be construed to preempt any provision of State law, unless such provision is expressly preempted." 21 U.S.C. § 343-1. The NLEA's savings clause reflects that Congress "disavow[ed] any implied preemption." *Lockwood,* 597 F. Supp. 2d at 1032; *see also Turek,* 662 F.3d at 425. Instead, "Congress has explicitly stated that it does not intend to occupy the field of food and beverage nutritional labeling; [] it permits states to regulate subject matters covered by the NLEA and its regulations provided that such state laws do not fall within the FDCA's express preemption provisions." *Lockwood*, 597 F. Supp. 2d at 1032.

Moreover, Congress enacted the FDCA to protect consumers and was cognizant of the existence of state law causes of action. *Wyeth,* 555 U.S. at 574; *Riegel,* 552 U.S. at 341 (Ginsburg,

J., dissenting) (observing that the Color Additive Amendment was enacted with common law tort litigation, such as personal injury lawsuits, as "a prominent part of the legal landscape"). There is no federal private consumer remedy to enforce the FDCA. 21 U.S.C. § 337(a) ("[A]ll such proceedings for the enforcement [of the FDCA] . . . shall be by and in the name of the United States"); *POM Wonderful,* 134 S. Ct. at 2235 (2014); *Buckman Co. v. Plaintiffs' Legal Comm.,* 531 U.S. 341, 349 n.4 (2001) ("The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance . . . ."). The absence of such a remedy evidences Congress's determination "that widely available state rights of action provided appropriate relief for injured consumers." *Wyeth,* 555 U.S. at 574; *cf. Cipollone,* 505 U.S. at 518 ("That Congress requires a particular warning label does not automatically pre-empt a regulatory field."). The Court concludes that Plaintiffs' claims are not barred by field preemption.

b. Conflict Preemption

The NLEA left open the possibility that warning requirements regarding food safety may be preempted by federal law not amended by the NLEA. *See* Pub. L. No. 101-535, § 6(c)(3) (21 U.S.C. § 343-1 note); *see also Reid,* 780 F.3d at 967 n. 2. In general, "Congress' enactment of a provision defining the pre-emptive reach of a statute implies that matters beyond that reach are not pre-empted." *Cipollone,* 505 U.S. at 517. Here, however, Section 6(c)(3), the third and final provision of the NLEA's construction note, provides:

> The amendment made by subsection (a), the provisions of subsection (b) and paragraphs (1) and (2) of this subsection shall not be construed to affect preemption, express or implied, of any such requirement of a State or political subdivision, which may arise under the Constitution, any provision of the Federal Food, Drug, and Cosmetic Act not amended by subsection (a), any other Federal law, or any Federal regulation, order, or other final agency action reviewable under chapter 7 of title 5, United States Code.

Pub.L. No. 101-535, § 6(c)(3). Arguably then, Plaintiffs' safety warning assertedly required under California law may be subject to implied preemption by a federal law that pre-dates (and was left unamended by) the NLEA.

As discussed above, there are two types of conflict preemption: (1) impossibility preemption and (2) obstacle preemption. Federal law preempts state law "where compliance with both federal

and state regulations is a physical impossibility." *Florida Lime,* 373 U.S. 132, 142-43. A finding of impossibility requires more than a showing of differences between federal and state standards; impossibility arises only where there is an "inevitable collision between the two schemes of regulation" that results in "impossibility of dual compliance." *Id.*; *Mut. Pharm. Co. v. Bartlett,* 133 S. Ct. 2466, 2485 (2013) ("Impossibility pre-emption is a demanding defense, that requires the defendant to show an irreconcilable conflict between federal and state legal obligations." (internal citations omitted)); *PLIVA, Inc. v. Mensing,* 131 S. Ct. 2567, 2577 (2011) (finding impossibility where it was "not lawful under federal law for the Manufacturers to do what state law required of them."). Obstruction preemption arises where "the challenged state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Crosby,* 530 U.S. at 373 (citing *Hines,* 312 U.S. at 67). "What is a sufficient obstacle is a matter of judgment, to be informed by examining the federal statute as a whole and identifying its purpose and intended effects." *Id.*

Pepsi alleges that the Proposition 65 warning claim is preempted by the FDA's listing of caramel color pursuant to the Delaney Clause.[15] As discussed above, the color additive Delaney Clause provides:

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[15] *Public Citizen* analyzed a challenge to the FDA's decision to list two color additives for which the FDA's scientific review panel concluded the "lifetime cancer risks of the substances [were] extremely small," ranging from one in nine million to one in 19 billion. *Id.* at 1111. *Public Citizen* concluded that the Delaney Clause was not subject to *de minimis* exceptions even for "exceedingly small (but measurable) risks." *Id.* at 1113; *cf. Les v. Reilly,* 968 F.2d 985, 990 (9th Cir. 1992) (holding no *de minimis* exception in provision of Delaney clause prohibiting food additives that induce cancer). *Public Citizen* did not discuss preemption.

Public Citizen distinguished *Scott v. Food & Drug Administration,* in which the Sixth Circuit determined that the Delaney Clause "did not bar the permanent listing of D & C Green No. 5" even where p-toluidine, a known carcinogen, was present in minute quantities as a chemical impurity in the color additive. *Scott v. Food & Drug Admin.,* 728 F.2d 322, 323 (6th Cir. 1984). *Scott* reasoned that "Congress distinguished between 'pure dye' and its 'impurities' in its list of factors for the FDA to consider under the General Safety Clause, but omitted 'impurities' as a factor under the Delaney Clause." *Id.* at 325. *Public Citizen* did not disagree with *Scott,* finding meaningful the fact that the dye "as a whole" had not been found to induce cancer. *Pub. Citizen,* 831 F.2d at 1118. Thus, while it is clear that *Public Citizen* concluded that there was no *de minimis* exception to the FDA's determination that the additive itself is generally safe, *Public Citizen* concluded that "[a]pplication of a *de minimis* exception for *constituents* of a color additive [ ] seems to us materially different from use of such a doctrine for the color additive itself." *Id.* at 1119 (emphasis in original). In other words, Public Citizen acknowledges that *de minimis* exceptions persist "on the periphery of the Delaney Clause[]," *e.g.,* where the carcinogen in question is a constituent impurity and the FDA has not "squeezed the scientific trigger" with respect to the dye as a whole. *Id.* at 1116-17, 1119.

> A color additive [. . .] shall be deemed unsafe, and shall not be listed, for any use which will or may result in ingestion of all or part of such additive, if the additive is found by the Secretary to induce cancer when ingested by man or animal, or if it is found by the Secretary, after tests which are appropriate for the evaluation of the safety of additives for use in food, to induce cancer in man or animal[.]

21 U.S.C. § 379e(b)(5)(B).

Specifically, Pepsi argues that Proposition 65's warning requirement for 4-MeI is inconsistent with the FDA's finding that caramel color is safe even though it contains 4-MeI. As discussed above, the Delaney Clause is not subject to an express preemption provision. There is a reason for this. The D.C. Circuit in *Public Citizen v. Young*, 831 F.2d 1108 (D.C. Cir. 1987) discussed the legislative history of the Delaney Clause at length. That legislative history reveals that, unlike the NLEA, the Delaney Clause did not seek to resolve a patchwork of state requirements. Instead, the Delaney Clause was borne out of "intense congressional concern over cancer risks from man-made substances." *Pub. Citizen,* 831 F.2d at 1113. Congress acted out of an apparent intent to "do everything possible to put persons in a position where they will not unnecessarily be adding residues of carcinogens to their diet." *Id.* at 1114 (quoting hearing testimony of Arthur S. Flemming, Secretary of Health, Education, and Welfare). Thus, the safety determination and related decisions not to set limitations on caramel color's use under the Delaney Clause were intended to set only a regulatory floor, not a ceiling, that does not bar state law remedies. *See Wyeth,* 555 U.S. at 582 (Breyer, J., concurring) (agreeing that the FDA's regulation governing the content and format of prescription drug labels, which expressly maintained that the FDA's premarket label approval established a regulatory ceiling with preemptive effect, did not reflect a lawful specific regulation that determined and described when the FDA's premarket label approval served as both a regulatory floor and a ceiling); *see also In re BPA,* 2009 WL 3762965, at *4 ("[T]he FDA's approval of BPA as safe without labeling requirements establishes only a regulatory *minimum*; nothing in these regulations either required or prohibited Defendants from providing the disclosures sought by Plaintiffs." (emphasis in original)).

As for implied conflict preemption, it is not impossible for Pepsi to comply with the FDA's labeling regulation allowing use of the term "caramel color" while at the same time including a

Proposition 65 warning. It can do both. Thus, there is no impossibility conflict preemption under *Florida Lime*. *Crosby*, 530 U.S. at 372; *cf. Allenby*, 958 F.2d at 949 (stating "the proper approach is to reconcile the operation of both statutory schemes with one another rather than holding that one has been completely ousted" and compliance with both FIFRA and Proposition 65 was possible).

Nor is there obstruction preemption; Proposition 65 is not an "obstacle to the accomplishment and execution" of Congress's "full purposes and objectives" in enacting the Delaney Clause. *Crosby*, 530 U.S. at 373. Proposition 65's warning requirement does not ban affected compounds permitted by the FDA; it merely requires a warning. *See* Cal. Health & Saf. Code § 25249.6. The purpose of the Proposition 65 warning requirement is to allow consumers to make informed choices. *See Dowhal*, 32 Cal. 4th at 934-35. The fact that Proposition 65 might require safety warnings more protective of the public as to potential carcinogens would not obstruct the purposes and objectives of the Delaney Clause. As noted above, the Delaney Clause sets a minimum floor, not a ceiling, on consumer protection from carcinogens. *In re BPA*, 2009 WL 3762965, at *4. *Cf. Wyeth*, 555 U.S. at 570 ("And the very idea that the FDA would bring an enforcement action against a manufacturer for strengthening a warning . . . is difficult to accept – neither Wyeth nor the United States has identified a case in which the FDA has done so."); *cf. Allenby*, 958 F.2d at 947 (9th Cir. 1992) ("It seems implausible that the EPA would prosecute a company for, in essence, complying with Proposition 65.").

The more protective warning requirement of Proposition 65 does not prevent the Delaney Clause from achieving its vigorous anti-cancer purpose, reflecting Congress's "willingness to take extreme steps to lessen even small risks [of cancer]." *See Pub. Citizen*, 831 F.2d at 1117; *see also Wyeth*, 555 U.S. at 574, 581 (declining to find that state failure-to-warn claims obstruct the federal regulation of drug labeling where, among other things, "Congress enacted the FDCA to bolster consumer protection against harmful products").

In undertaking "extreme steps" to prevent cancer through the passage of the Delaney Clause, Congress eschewed any attempt to strike a particular balance between the safety interests of the public and the financial interests of industry. *See Pub. Citizen*, 831 F.2d at 1113. Congress considered the opposing views of various industry and manufacturing interests (*e.g.*, the Toilet

Goods Association, the Manufacturing Chemists Association, the Pharmaceutical Manufacturers Association, the Certified Color Industry Committee, and Eli Lilly & Co.) and specifically declined to yield on its position on public safety. *See generally* Hearings on H.R. 7624 & S. 2197, Before the House Comm. on Interstate and Foreign Commerce, 86th Cong., 2nd Sess. (January 26, 27, 29, February 10, 11, March 11, April 5, 6, and May 9, 1960); *see also* H.R.Rep. No. 1761, 86th Cong., 2d Sess. at 13 (1960) (noting that industry witnesses had objected to and proposed changes to the "anticancer clause" and "all of the proposed changes were rejected by the committee" because the proposals would "weaken the present anticancer clause"); *Pub. Citizen*, 831 F.2d at 1114-15 & n.7 (discussing same). Therefore the driving impetus of the Delaney Clause was not concern for manufacturers, but rather the overriding "imperative" to "protect the public from deliberate introduction of additional carcinogenic materials into the human environment." H.R.Rep. No. 1761, 86th Cong., 2d Sess. at 12 (1960) (quoting hearing testimony of Arthur S. Flemming); *Pub. Citizen*,831 F.2d at 1114 (discussing same).

Hence, this is not a case where Proposition 65 interferes with a more nuanced balance struck by Congress or by delegation to the FDA acting under the Delaney Clause. *See Wyeth*, 555 U.S. at 575 (rejecting argument that FDA's determination "that a drug is safe and effective under the conditions set forth in its labeling" requires a presumption that the agency "performed a precise balancing of risks and benefits and [. . .] established a specific labeling standard that leaves no room for different state-law judgments"). *Cf. Local 20, Teamsters, Chauffeurs & Helpers Union v. Morton*, 377 U.S. 252, 259-60 (1964) ("If [state law] can be applied to proscribe the same type of conduct which Congress focused upon but did not proscribe [. . .] the inevitable result would be to frustrate the congressional determination to leave this weapon of self-help available, and to upset the balance of power between labor and management expressed in our national labor policy."); *Lodge 76, Int'l Ass'n of Machinists & Aerospace Workers, AFL-CIO v. Wisconsin Employment Relations Comm'n*, 427 U.S. 132, 141 n.4 (1976) ("[In the NLRA and LMRA] Congress struck a balance of protection, prohibition, and laissez-faire in respect to union organization, collective bargaining, and labor disputes that would be upset if a state could also enforce statutes or rules of decision resting upon its views concerning accommodation of the same interests." (quotation omitted)). Nor is this a

case where the FDA has required a more refined warning requirement that state law would dilute. *Cf. Dowhal,* 32 Cal. 4th at 934-35; *Nemphos,* 775 F.3d at 623 (finding preemption where FDA's regulations specifically indicate when manufacturers must provide warnings about fluoride in bottled water). Hence, the Proposition 65 warning at issue here is entirely consistent with the Delaney Clause's purpose of eliminating the risk of cancer caused by foods. Obstacle preemption does not apply.

Finally, as noted above, where the "regulated conduct touche[s] interests so deeply rooted in local feeling and responsibility," preemption will not be inferred absent clear congressional intent. *Sears, Roebuck & Co. v. San Diego Cnty. Dist. Council of Carpenters,* 436 U.S. 180, 183 (1978)). California's exercise of its police power to protect the health and safety of its citizens is a matter deeply rooted in local feeling and responsibility. The Delaney Clause should not lightly be construed to "sweep away" state laws concerning health and safety, which are matters traditionally subject to state regulation. *Id.*; *Allenby*, 958 F.2d at 943.[16]

For the foregoing reasons, the Court **DENIES** Pepsi's motion to dismiss the state law claims alleged in the CAC under a theory of preemption.

D. Primary Jurisdiction Doctrine

Primary jurisdiction "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; in such a case the judicial process is suspended pending referral of such issues to the administrative body for its views." *United States v. W. Pac. R. Co.*, 352 U.S. 59, 63-64 (1956).

Primary jurisdiction is a "prudential" doctrine "under which a court determines that an otherwise cognizable claim implicates technical and policy questions that should be addressed in the first instance by the agency with regulatory authority over the relevant industry rather than by the judicial branch." *Clark v. Time Warner Cable,* 523 F.3d 1110, 1114 (9th Cir. 2008); *Reid,* 780 F.3d

[16] If Congress thought Proposition 65 suits as to safety warnings "posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA's 70-year history." *Wyeth*, 555 U.S. at 574 (holding federal drug labeling laws under the FDCA did not preempt state tort claim based on failure to warn). As discussed above, it has not done so.

at 966. As such, application of the doctrine is "committed to the sound discretion of the court." *Syntek Semiconductor Co. v. Microchip Tech. Inc.*, 307 F.3d 775, 781 (9th Cir. 2002).

There is not a "fixed formula" for when to apply the doctrine of primary jurisdiction. *W. Pac. R. Co.*, 352 U.S. at 64. Nevertheless, the Ninth Circuit considers the following four factors in applying the primary jurisdiction doctrine: "(1) [a] need to resolve an issue that (2) has been placed by Congress within the jurisdiction of an administrative body having regulatory authority (3) pursuant to a statute that subjects an industry or activity to a comprehensive regulatory authority that (4) requires expertise or uniformity in administration." *Clark*, 523 F.3d at 1115 (quoting Syntek, 307 F.3d at 781); *Davel Commc'ns, Inc. v. Qwest Corp.*, 460 F.3d 1075, 1086-87 (9th Cir. 2006) (quoting *United States v. Gen. Dynamics Corp.*, 828 F.2d 1356, 1363 (9th Cir.1987)). The Ninth Circuit has recently emphasized that "efficiency" is a "deciding factor" in whether primary jurisdiction applies. *Astiana*, 2015 WL 1600205, at *5*; Reid*, 780 F.3d at 967.

If primary jurisdiction applies, a district court should enable a "referral" of the issue to the relevant agency. *Clark*, 523 F.3d at 1115. In practice, this does not require an agency ruling; "the court merely stays or dismisses proceedings to allow the plaintiff to pursue administrative remedies." *Id.; see also Syntek*, 307 F.3d at 782 (noting that where there is primary jurisdiction "the case should be dismissed without prejudice so that the parties may pursue their administrative remedies"). A stay, rather than a dismissal, is required where "further judicial proceedings are contemplated" or where prejudice – *e.g.*, the potential running of the statute of limitations during administrative proceedings – may unfairly disadvantage the parties. *Astiana*, 2015 WL 1600205, at *6.

The circumstances requiring application of the primary jurisdiction doctrine have been described as "limited." *Clark*, 523 F.3d at 1114; *Astiana*, 2015 WL 1600205, at *5. In general, before "finding that judicial deferral is warranted" a court should ensure that there was "Congressional intent to place the initial consideration of an issue with an agency." *Gen. Dynamics Corp.*, 828 F.2d at 1370 n.13. The Ninth Circuit has cautioned that "the doctrine is not designed to 'secure expert advice' from agencies 'every time a court is presented with an issue conceivably within the agency's ambit.'" *Clark*, 523 F.3d at 1114 (quoting *Brown v. MCI Worldcom Network*

Servs., Inc., 277 F.3d 1166, 1172 (9th Cir. 2002); *see also Reid*, 780 F.3d at 966. Primary jurisdiction "is to be used only if a claim requires resolution of an issue of first impression, or of a particularly complicated issue that Congress has committed to a regulatory agency." *Id.*; *Astiana*, 2015 WL 1600205, at *5; *Davel*, 460 F.3d at 1086. At the motion to dismiss stage the "question is whether any set of facts could be proved which would avoid application of the doctrine." *Davel*, 460 F.3d at 1088.

In this case, Pepsi stresses that the FDA has stated that it is currently considering whether more stringent guidelines are needed regarding exposure to 4-MeI from Class III and Class IV caramel coloring. In a document available on the FDA's website and entitled "Questions & Answers on Caramel Coloring & 4-MeI" the FDA has stated:

> [The FDA] is currently reviewing all available data on the safety of 4-MEI and is reassessing potential consumer exposure to 4-MEI from the use of Class III and Class IV caramel coloring in food products. This safety analysis will help FDA determine what, if any, regulatory action needs to be taken. Such actions could include setting a limit on the amount of 4-MEI that can be present in caramel coloring. However, in the interim, FDA is not recommending that consumers change their diets because of concerns about 4-MEI.

Docket No. 83-2, RJN, Ex. A. The FDA has also stated that it plans to "further investigate[]" 4-MeI exposures by, among other things, conducting analysis of general exposures, including from other food products, and analyzing 4-MeI in caramel color samples. Docket No. 83-4, RJN, Ex. B2. The FDA has also stated that it is considering citizen petitions, such as those from Consumer Reports and the Center for Science in The Public Interest, which have advocated for more restrictive regulations, particularly as to how caramel color is permitted to be processed and labeled. *Id.; see also* Docket Nos. 83-10, 83-11.

Nevertheless, the Court concludes that Plaintiffs' allegations regarding Pepsi's materially misleading public statements as well as its failure to warn under Proposition 65 do not clearly fall within the labeling jurisdiction of the FDA. This is particularly so where Congress has stated that

the NLEA labeling requirements, which Plaintiffs primarily rely upon,[17] do not regulate carcinogens. *See* H.R.Rep. No. 101-538, at 7 (1990), reprinted at 1990 U.S.C.C.A.N. 3336, 3337.

More importantly, to the extent the FDA has stated any intent to take action, the FDA appears to have stated that it is solely considering tightening its restrictions on 4-MeI. Consequently, dismissing or staying as a matter of primary jurisdiction is not indicated here because even "if the FDA were to [take action to regulate the labeling and permitted amounts of 4-MeI more stringently,] federal law would not dispose of plaintiffs' state law claims." *Lockwood,* 597 F. Supp. 2d at 1035. Moreover, as noted above, states are free to impose stricter warnings regarding carcinogens than those required under federal law. The Court thus concludes that Pepsi has not shown that "efficiency," which is the "deciding factor" in primary jurisdiction referrals, would be served by a stay. *Rhoades v. Avon Products, Inc.*, 504 F.3d 1151, 1165 (9th Cir. 2007).

Moreover, with respect to the FDA's authority as to the FDCA's Color Additive Amendments, at least one of the citizen petitions at issue was submitted to the FDA more than four years ago. *See* Docket No. 83-11 (CSPA citizen petition, dated February 16, 2011). Consequently, there does not appear to be any imminent FDA rule-making that would create a risk of inconsistent rulings. *See Reid,* 780 F.3d at 966 (declining to invoke the FDA's primary jurisdiction where the FDA had not indicated it would issue a new rule in over a decade); *see also Astiana,* 2015 WL 1600205, at *5 ("Common sense tells us that even when agency expertise would be helpful, a court should not invoke primary jurisdiction when the agency is aware of but has expressed no interest in the subject matter of the litigation.").

Furthermore, the issues raised by Plaintiffs' claims, particularly its state law misrepresentation claims, do not clearly require the FDA's expertise or benefit from uniformity in administration. *See Reid,* 780 F.3d at 967 ("The issue that this case ultimately turns on is whether a reasonable consumer would be misled by [Defendant's] marketing, which the district courts have reasonably concluded they are competent to address."); *see also Chacanaca v. Quaker Oats Co.*, 752 F. Supp. 2d 1111, 1124 (N.D. Cal. 2010) (rejecting application of primary jurisdiction doctrine as to

[17] Defendant has cited two regulations purportedly governing warnings, (21 C.F.R. §§ 101.2, 101.4), yet these regulations appear to pertain to standards of identity under the NLEA.

claims that of misleading marketing, because "courts are well-equipped to handle" such state-law challenges in the food labeling arena); *Lockwood*, 597 F. Supp. 2d at 1035 (declining to apply primary jurisdiction doctrine because definition of "all natural" was not "technical"); *Jones v. ConAgra Foods, Inc.*, 912 F. Supp. 2d 889, 898-99 (N.D. Cal. 2012); *Leonhart v. Nature's Path Foods, Inc.*, No. 5:13-CV-0492-EJD, 2014 WL 1338161, at *7 (N.D. Cal. Mar. 31, 2014) ("Defendant has not demonstrated that this Court could not determine whether such claims are misleading without FDA expertise."); *Goya*, 2015 WL 1411336, at *12 (holding resolution of state law claims does not require FDA expertise or undercut uniformity in regulation).

Finally, although both the Proposition 65 claim and FDA regulations do involve some scientific analysis of the actual health and safety risk of 4-MeI in Pepsi beverages, invoking the primary jurisdiction doctrine would frustrate positive state law on this precise subject. The state of California has evaluated and made a public safety determination. Dismissing or staying the enforcement action at bar, preventing an adjudication on the merits, would be inconsistent with Congress's desire to leave to the states room to enact food safety warning laws as discussed above. The Court therefore **DENIES** Pepsi's request to dismiss or stay the action under a theory of primary jurisdiction.

E. Abstention in Favor of Pending State Action

Pepsi also seeks to dismiss based on abstention. Abstention in favor of a parallel state action may be proper due to considerations of "[w]ise judicial administration giving regard to conservation of judicial resources and comprehensive disposition of litigation." *Nakash v. Marciano*, 882 F.2d 1411, 1415 (9th Cir. 1989) (quoting *Colorado River Water Conserv. Dist. v. United States*, 424 U.S. 800, 817 (1976)). Such cases are "rare," "limited," and "exceptional," with "only 'the clearest of justifications,'" supporting abstention. *R.R. St. & Co. v. Transp. Ins. Co.*, 656 F.3d 966, 977–78 (9th Cir. 2011) (quoting *Colorado River*, 424 U.S. at 818-19).

In determining whether to stay a case pursuant to Colorado River,[18] courts in the Ninth Circuit consider eight factors:

[18] "We generally require a stay rather than a dismissal." *R.R. St.*, 656 F.3d at 983 n.8 (9th Cir. 2011).

> (1) which court first assumed jurisdiction over [the case]; (2) the inconvenience of the federal forum; (3) the desire to avoid piecemeal litigation; (4) the order in which the forums obtained jurisdiction; (5) whether federal law or state law provides the rule of decision on the merits; (6) whether the state court proceedings can adequately protect the rights of the federal litigants; (7) the desire to avoid forum shopping; and (8) whether the state court proceedings will resolve all issues before the federal court.

R.R. St., 656 F.3d at 978–79. In this analysis, "[n]o one factor is necessarily determinative; a carefully considered judgment taking into account both the obligation to exercise jurisdiction and the combination of factors counseling against that exercise is required." *Colorado River,* 424 U.S. at 818-19. In other words, the decision does not "rest on a mechanical checklist, but on a careful balancing of the important factors as they apply in a given case, with the balance heavily weighted in favor of the exercise of jurisdiction." *Moses H. Cone Mem'l Hosp. v. Mercury Const. Corp.,* 460 U.S. 1, 16 (1983).

Nevertheless, certain of the eight factors are "dispositive." *Intel Corp. v. Advanced Micro Devices, Inc.*, 12 F.3d 908, 913 (9th Cir. 1993). In particular, "substantial doubt as to whether the state proceedings will resolve the federal action precludes the granting of a stay." *Id.; see also Holder v. Holder,* 305 F.3d 854, 868 (9th Cir. 2002) ("Because there is substantial doubt that a final determination in the custody proceeding will resolve all of the issues in Jeremiah's federal Hague Convention petition, we conclude that the district court abused its discretion in staying proceedings."). Where there is such doubt as to resolution of the federal action, a *Colorado River* stay is precluded, and the additional factors need not be considered. *Intel,* 12 F.3d at 915 n.7.

In this case, Pepsi argues that the Court should abstain from adjudicating this action in light of a pending state action, *Center for Environmental Health v. Pepsi Beverages Co.*, et al., No. RG14-711020 (Alameda Super. Ct., filed Jan. 23, 2014); see Docket No. 83-12 ("CEH Complaint"). The state case, however, only alleges a claim for violation of Proposition 65, and does not allege any other misstatements or violation of the UCL and CLRA. *Compare* CAC ¶¶ 71-90 with CEH Complaint. Correspondingly, the CEH action seeks recovery of civil penalties under Proposition 65, and does not seek monetary damages and restitution on a class basis as this action does. *Id.* Under Ninth Circuit law, "even when a concurrent state proceeding might address issues relevant to a

federal action, the rule is that the federal proceeding should go forward." *United States v. Rubenstein*, 971 F.2d 288, 293-94 (9th Cir. 1992). "Abstention is the exception." *Id.* Given the fact of the broader remedies sought herein and the fact that certain of Plaintiffs' claims that are not based directly on Proposition 65, the Court concludes that there is substantial doubt that the state proceedings will resolve the federal action; this precludes a *Colorado River* stay. *Intel*, 12 F.3d at 913.

It is true that a partial stay is permissible and does not run afoul of *Intel* or *Holder*. *See Daugherty v. Oppenheimer & Co.*, No. 06-7725-PJH, 2007 WL 1994187, at *5 (N.D. Cal. July 5, 2007) (staying third through eleventh causes of action as "substantially similar" to state claims, because the dispute concerns the same core factual issues of proper classification of employees and whether employer denied overtime pay and meal and rest breaks); *In re Countrywide Fin. Corp. Derivative Litig.*, 542 F. Supp. 2d 1160, 1172 (C.D. Cal. 2008) (agreeing with Daugherty and staying only "state law merger-related class action claims that are proceeding in nearly identical form in Delaware, under the same laws" and not derivative claims); *ScripsAmerica, Inc. v. Ironridge Global, LLC*, ---F. Supp. 3d---, 2014 WL 5638045, at *12 (C.D. Cal. Nov. 3, 2014). Nonetheless, a partial stay can affect the balance of other factors under *Colorado River*. In particular, the third factor, the desire to avoid piecemeal litigation, is not well-served in this case by a partial stay. Moreover, in light of the federal courts' "virtually unflagging obligation to exercise the jurisdiction conferred upon them by the coordinate branches of government and duly invoked by litigants" abstention, even on a partial basis, is not warranted in this case. *United States v. Rubenstein*, 971 F.2d 288, 293 (9th Cir. 1992) (quotation omitted). The Court **DENIES** Pepsi's request that it abstain from adjudicating this action.

III. CONCLUSION

For the reasons discussed herein, the Court **GRANTS** Defendant's motion to dismiss Plaintiff Ibusuki's Proposition 65 claims on notice grounds. Otherwise, the Court **DENIES** Pepsi's motion to dismiss. Plaintiff Hall's Proposition 65 notice was timely, because she did not commence a Proposition 65 action until she added a direct claim under Proposition 65 in the CAC after giving notice. Plaintiffs' claims arising out of material misrepresentation in Pepsi's public statements and

out of the alleged violation of Proposition 65 are not preempted. The Court **DENIES** Defendant's motion to stay or dismiss under primary jurisdiction and abstention doctrines.

This order disposes of Docket No. 82.

IT IS SO ORDERED.

Dated: June 5, 2015

EDWARD M. CHEN
United States District Judge