IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF FLORIDA TALLAHASSEE DIVISION

ANDREW E. STANSFIELD and MICHAEL STEPHEN MATHEWS, individually and on behalf of all others similarly situated,

Plaintiffs,

v. **Case No. 4:14cv290-MW/CAS**

THE MINUTE MAID COMPANY, a division of the Coca-Cola company, and THE COCA-COLA COMPANY,

Defendants.

_____/

ORDER OF DISMISSAL

In this proposed class action, Plaintiffs Andrew E. Stansfield and Michael Stephen Matthews assert that the label of a juice drink produced by Minute Maid Company and the Coca-Cola Company ("Defendants") is misleading. Defendants moved to dismiss the first amended complaint. This Court considered the matter without hearing. This order grants the motion to dismiss the first amended complaint because these state-law claims are preempted by federal law.

I

The standards for considering a motion to dismiss are well-established. Federal Rule of Civil Procedure 8(a) requires that a complaint contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Rule 12(b)(6) calls for a dismissal of a complaint if it fails "to state a claim upon which relief can be granted."

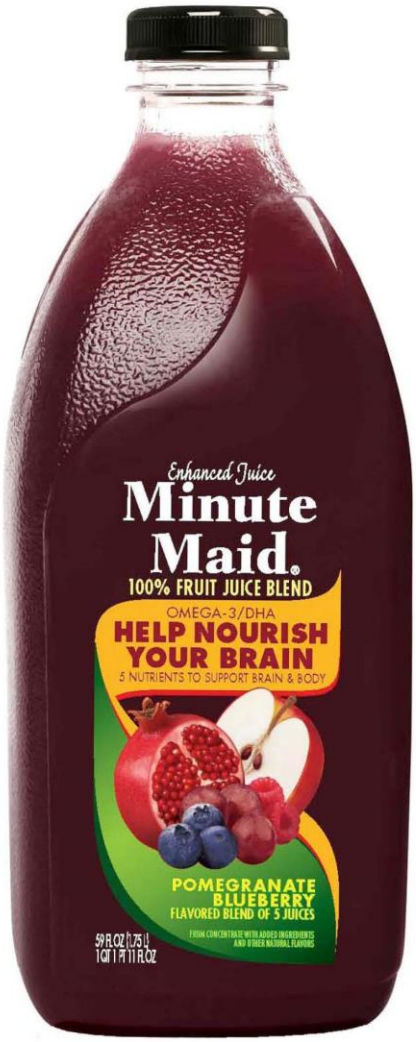
When considering a motion to dismiss, courts must "accept[] the allegations in the complaint as true and construe[] them in the light most favorable to the plaintiff." *Spain v. Brown & Williamson Tobacco Corp.*, 363 F.3d 1183, 1187 (11th Cir. 2004). To survive dismissal, a complaint's "[f]actual allegations must be enough to raise a right to relief above the speculative level." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). It must also 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) (internal quotation marks omitted). "A claim is facially plausible when the court can draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 662.

II

Defendants produce a beverage which is labeled as a pomegranate and blueberry flavored blend of five juices. The five-juice blend is 99.4% apple and

grape juices, 0.3% pomegranate juice, 0.2% blueberry juice, and 0.1% raspberry juice.

The front of the bottle has a "principal display panel." *See* 21 C.F.R. § 101.1. The back has an "information panel." *See id*. § 101.2. Plaintiffs do not assert that anything on the information panel is untrue. But Plaintiffs say that the principal display panel is misleading—that it suggests that the product is predominantly pomegranate and blueberry juice. This is the product and its principal display panel:



ECF No. 35-2.

Within the four years preceding the filing of this action (which was on June 13, 2014), Plaintiffs each bought more than $25.00 worth of this product. They point to various health benefits associated with pomegranate and blueberry juice. They say they had cheaper juice options available and paid more for Defendants' five-juice blend because they did not know it was almost entirely apple and grape juice.

Plaintiffs seek recovery on the theory that the primary display panel is misleading. They assert claims under the Florida Deceptive and Unfair Trade Practices Act (§§ 501.201–501.213, Florida Statutes), the Florida false advertising statute (§ 817.44, Florida Statutes), and breach of express and implied warranties, negligence,[1] and unjust enrichment. ECF No. 22.

Defendants moved to dismiss the amended complaint, arguing that all the claims are preempted by federal law and are otherwise deficient.

III

The amended complaint alleges that this juice label implies that the product is predominantly pomegranate and blueberry juice when it is not. Plaintiffs say this violates state laws that mirror federal laws and seek to recover damages. Defendants argue that those claims are preempted by federal law.

The existence of an affirmative defense such as preemption will not usually support a motion to dismiss. *See Quiller v. Barclays Am./Credit, Inc.*, 727 F.2d 1067, 1069 (11th Cir. 1984), *aff'd*, 764 F.2d 1400 (11th Cir. 1985) (en banc). But there is an exception allowing dismissal under Rule 12(b)(6) when the affirmative defense "clearly appears on the face of the complaint." *Id*. at 1069. If the

[1] In their response to the motion to dismiss, Plaintiffs abandoned their negligence claim and their request for injunctive relief. ECF No. 38, at 3.

"complaint itself demonstrates" that the claims are preempted, then dismissal is proper. *Id*.

Under the Constitution's Supremacy Clause, state laws that "interfere with, or are contrary to," federal law "must yield." *Gibbons v. Ogden*, 22 U.S. (9 Wheat.) 1, 211 (1824). Congress has the authority to expressly preempt state law by statute. *E.g.*, *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372 (2000). When there is an express preemption clause, a court must consider "the substance and scope of Congress' displacement of state law." *See Altria Group, Inc. v. Good*, 555 U.S. 70, 76 (2008). The effect of a presumption against preemption is "to support, where plausible, a narrow interpretation of an express pre-emption provision." *CTS Corp. v. Waldburger*, 134 S. Ct. 2175, 2189 (U.S. 2014) (internal quotation marks omitted).

On these alleged facts, this Court concludes that Plaintiffs' claims are expressly preempted by federal statute.

A

The Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301–399f, prohibits "misbranded" food in interstate commerce. *See* 21 U.S.C. § 331.[2] There are many ways in which a product might be misbranded. Three are relevant here.

[2] The term "food" means "articles used for food or drink for man or other animals." 21 U.S.C. § 321(f).

A food is misbranded if its label does not bear "the common or usual name of the food, if any there be," *id*. § 343(i), or if information required to appear on its label "is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use." *Id*. § 343(f). A third provision is something of a catch-all, deeming a product misbranded if its labeling is "false or misleading in any particular." *Id*. § 343(a)(1). The Food and Drug Administration ("FDA") is authorized to promulgate regulations to enforce the FDCA. 21 U.S.C. § 371(a).[3]

In a recent case, *Pom Wonderful LLC v. Coca-Cola Co.* 134 S. Ct. 2228 (U.S. 2014), the Supreme Court considered this very product in a different context. POM sued Coca-Cola under the Lanham Act, 15 U.S.C. § 1125, which allows one competitor to hold another liable for unfair competition arising from false or misleading product descriptions. *Id*. at 2233. The suit alleged that Coca-Cola's juice blend misled consumers and that the ensuing confusion caused POM to lose

[3] For example, "[w]henever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable a reasonable definition and standard of identity, a reasonable standard of quality, or reasonable standards of fill of container." 21 U.S.C. § 341.

sales. *Id.* In part, Coca-Cola argued that the product complied with regulations implementing the FDCA and that compliance precluded a Lanham Act claim.

The Supreme Court held that the FDCA did not preclude a Lanham Act claim challenging food and beverage labels that are regulated by the FDCA. *Id*. The Court did not decide whether the product's label complied with regulations implementing the FDCA. The Court said the FDA could not, through those regulations, displace statutory rights under the Lanham Act. *Pom Wonderful* thus addressed the horizontal relationship between complementary federal laws.

This case concerns the vertical relationship between federal requirements and state laws.[4] In the FDCA's preemption provision, Congress has established "[n]ational uniform nutrition labeling." *See* 21 U.S.C. § 343-1. The Nutrition Labeling & Education Act of 1990 ("NLEA"), Pub. L. 101–535, 104 Stat. 2353 (Nov. 8, 1990), amended the FDCA to expressly preempt state requirements within certain categories that are not identical to federal requirements. 21 U.S.C. § 343-1. A state may not "directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce . . . any requirement for the labeling of food of the type required by" § 343(i) or (f) "that is not identical to the

[4] It should be noted that there is another class action pending before same district judge who decided *Pom Wonderful*. *See Saedian v. The Coca Cola Co.*, No. 2:09cv06309-SJO-JPR (C.D. Cal.) (Otero, J.). The plaintiffs there bring claims against what appears to be the same product. The instant case was stayed pending a decision by the Judicial Panel on Multidistrict Litigation ("JPML") on whether to transfer or consolidate it with the *Saedian* case. ECF No. 30. This Court lifted the stay after the JPML denied the Defendants' motion. ECF No. 31.

requirements of such section." *Id.* § 343-1(a)(2) & (3).[5] According to the FDA, "Not identical to" means the requirements "concerning the . . . labeling of food . . . '(i) Are not imposed by or contained in the applicable provision [or regulation]; or (ii) Differ from those specifically imposed by or contained in the applicable provision [or regulation].' " 21 C.F.R. § 100.1(c)(4).

By its plain terms the NLEA does not preempt state requirements that are *identical* to federal requirements in the applicable sections of the FDCA and its implementing regulations. *See, e.g., Koenig v. Boulder Brands, Inc*, 995 F. Supp. 2d 274, 283 (S.D.N.Y. 2014). "The state thus can impose the identical requirement or requirements, and by doing so be enabled, because of the narrow scope of the preemption provision in the Nutrition Labeling and Education Act, to enforce a violation of the Act as a violation of state law." *Turek v. Gen. Mills, Inc.*, 662 F.3d 423, 426 (7th Cir. 2011) (Posner, J.). A private plaintiff may bring a state-law claim that parallels federal requirements. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315, 330 (2008); *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 447 (2005); *Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1301 (11th Cir. 2011). This means that if the product violates an implementing regulation, and so is

[5] The preemption clause makes no mention of § 343(a).

misbranded under § 343, Plaintiffs may bring a parallel claim under state law to impose an identical requirement.[6]

Defendants argue that the challenged aspects of this product's label are authorized by these juice-labeling regulations and Plaintiffs are attempting to impose requirements that are not identical to those imposed by federal law. In response, Plaintiffs argue that they are trying to enforce state law that mirrors two of the misbranding provisions of the FDCA.

The first theory is that the label does not bear the "common or usual name of the food" under § 343(i) because it violates one of the implementing regulations, 21 C.F.R. § 102.33(d)(1). Plaintiffs want to enforce an identical requirement under state law.

The second theory is that the statute does not preempt challenges brought to the label under § 343(a)(1). They say there are aspects of this label that are not required or permitted by the FDCA and its implementing regulations, and a valid claim under § 343(a)(1) exists on that basis. And even if that were not so, Plaintiffs say that they can challenge the label "as a whole."

[6] It is true that not every violation of the FDCA will support a state-law claim. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 353 (2001) (holding fraudulent representations to the FDA could not sustain state-law claims); *cf. Papas v. Upjohn Co.*, 985 F.2d 516, 518-19 (11th Cir. 1993) (holding claim based on failure to disclose information to the EPA preempted). The claims here are nothing like those in *Buckman* or *Papas*.

Although state law does indeed mirror federal requirements,[7] this Court concludes that none of those theories holds water. Plaintiffs' claims are expressly preempted by the FDCA as amended by the NLEA.

B

Plaintiffs' argue that the product is misbranded under § 343(i) and an implementing regulation. This argument rests on a misunderstanding of the requirements of the regulation. The product does not violate the regulation. So there is no parallel claim to bring on that basis. Any claim on the specific facts alleged is expressly preempted.

The name of the food may be established by common usage or regulation. 21 C.F.R. § 102.5(d). It must "accurately identify or describe, in as simple and direct terms as possible, the basic nature of the food or its characterizing properties or ingredients." *Id*. § 102.5(a). If the proportion of a characterizing ingredient "has a material bearing on price or consumer acceptance or when the labeling or the appearance of the food may otherwise create an erroneous impression that such

[7] The Florida Food Safety Act adopts § 343(i) and (a)(1) in state law. *See* §§ 500.11(a)(1), (i), 500.02(2), Fla. Stat. (explaining the purpose of the FFSA is to "[p]rovide legislation which shall be uniform, as provided in this chapter, and administered so far as practicable in conformity with the provisions of, and regulations issued under the authority of, the Federal Food, Drug, and Cosmetic Act"); *see also* Fla. Admin. Code. r. 5K-4.002(1)(d) (adopting FDCA regulations). A violation of the FFSA is actionable by a private party under causes of action such as FDUTPA. *See, e.g.*, *Bohlke v. Shearer's Foods, LLC*, No. 9:14-CV-80727, 2015 WL 249418, at *6 (S.D. Fla. Jan. 20, 2015).

ingredient[] . . . is present in an amount greater than is actually the case," the regulation presumes that the percentage of that ingredient will be declared unless a more specific rule says otherwise. *Id*. § 102.5(b).

The more specific regulation is 21 C.F.R. § 102.33, which sets requirements for multiple-juice beverages. For a product like this one, "where one or more, but not all, of the juices are named on the label other than in the ingredient statement, and where the named juice is not the predominant juice, the common or usual name for the product shall . . . [i]ndicate that the named juice is present as a flavor or flavoring." *Id*. § 102.33(d)(1). The reason the FDA gave for this rule is that "it is not necessary to require that each juice in a beverage be named to ensure that the label is not [] misleading." Food Labeling; Declaration of Ingredients; Common or Usual Name for Nonstandardized Foods; Diluted Juice Beverages, 58 Fed. Reg. 2897, 2919 (1993). The regulation gives an example of a compliant statement: "e.g., 'Rascranberry'; raspberry and cranberry flavored juice drink." 21 C.F.R. § 102.33(d)(1).

Plaintiffs argue that the label violates § 102.33(d) and so the product is misbranded under § 343(i). They do not suggest the product does not taste like pomegranate and blueberry juice. Rather, Plaintiffs assert that because there is so little pomegranate and blueberry juice in the beverage, as a causal matter it is not getting a pomegranate and blueberry flavor from those juices, but rather from

"other natural flavors." ECF No. 38, at 17. Plaintiffs rely primarily on FDA's explanation for the rule. In promulgating § 102.33(d), FDA said it "believes that using the term 'flavor' with the name of the characterizing juice will inform the consumer that the juice is present in an amount sufficient to flavor the beverage but will not imply that the content of that juice is greater than is actually the case." 58 Fed. Reg. at 2921. Plaintiffs say pomegranate juice and blueberry juice are not present "in an amount sufficient to flavor this beverage, as § 102.33(d)(1) requires." ECF No. 38, at 17. So, according to Plaintiffs, § 102.33(d)(1) allows a company to name minority juices on the label if those named minority juices actually provide the taste. As they would have it, § 102.33(d)(1) means only that if a named minority juice actually flavors the beverage, then the label may say as much.

That is not what this regulation requires. It says that "where the named juice is not the predominant juice, the common or usual name for the product *shall* . . . [i]ndicate that the named juice is present as a flavor or flavoring." *Id.* § 102.33(d)(1) (emphasis added). The FDA's explanation of its choice of the terms "flavor" or "flavoring" for such a circumstance (where a juice is *present,*

though not predominant)—questionable though that choice may be—does not graft a requirement of gustatory causation onto *this* regulation.[8]

On the facts in the complaint, the product complies with § 102.33(d)(1). The amended complaint alleges that pomegranate juice and blueberry juice are present in this product along with three other juices. Of the five juices in the product, only pomegranate and blueberry are named on the principal display panel. That is not a violation, because §102.33(d)(1) expressly allows for it. But because these juices are not predominant juices, Defendants were required to state on the label that those juices are "present as a flavor or flavoring." *Id*. By stating "Pomegranate" on one line, "Blueberry" below it, and "Flavored Blend of 5 Juices" below that, Defendants complied with this requirement to the letter. *See, e.g.*, *Bell v. Campbell Soup Co.*, No. 4:14CV291-RH/CAS, 2014 WL 6997611, at *3 (N.D. Fla. Dec. 11, 2014).

The first amended complaint does not state a violation of 21 C.F.R. § 102.33(d)(1). So there is no valid parallel claim on that basis. A claim challenging that aspect of the label is expressly preempted by the NLEA.

[8] A different regulation is implicated when "the amount of a characterizing ingredient" is "insufficient to independently characterize the food." *See* 21 C.F.R. 101.22(i)(1)(i); *see also* Part III.C.1.

C

The second preemption-avoidance theory is that the NLEA does not block challenges brought under 21 U.S.C. § 343(a)(1) to the label "as a whole" or "in a respect not specifically required or authorized by a federal preemptive regulation." ECF No. 38, at 14.

Plaintiffs say that a state-law claim parallel to § 343(a)(1) is not preempted because it is not one of those requirements "identified by Congress as having preemptive effect." ECF No. 38, at 12. While that is true, it is not the end of it. If the requirement is "of the type required by" § 343(f) or (i), the text of § 343-1(a)(2) and (3) limits what requirements the state may enforce about the product's name or placement of information on the label to the requirements of "such section," meaning § 343(f) or (i).

This Court recently held that the preemption clause, § 343-1(a), does not bar a parallel state claim premised on a violation of § 343(a)(1). *Reynolds v. Wal-Mart Stores, Inc.*, No. 4:14CV381-MW/CAS, 2015 WL 1879615, at *12 (N.D. Fla. Apr. 23, 2015); *see also Saedian v. The Coca Cola Co.*, No. 2:09cv06309-SJO-JPR, ECF No. 171, at *8 (C.D. Cal. Jul. 6, 2015) (holding § 343-1 does not preempt substantially the same § 343(a)-based claim as this case). In *Reynolds*, the label for a similar product said "100% Cranberry Pomegranate." 2015 WL 1879615, at *1. The use of "100%" in that manner was not required or authorized by

regulations implementing the FDCA. Because it implied the product is entirely cranberry juice and pomegranate juice, a reasonable jury could find such a label misleading under § 343(a)(1). This Court concluded that § 343-1 did not preempt such a claim.

The reason for that conclusion is that a "requirement" to be imposed under a parallel claim mirroring § 343(a)(1) is not "of the type required by" § 343(f) or (i). 2015 WL 1879615, at *12.[9] It is a requirement of a different type. This is so because the misbranding categories in § 343 work together. Aspects of labels that are *required* or *permitted* by a more specific provision "by definition, are not considered 'false or misleading' under federal law." *See, e.g., Red v. The Kroger Co.*, No. CV 10-01025 DMG MANX, 2010 WL 4262037, at *5 (C.D. Cal. Sept. 2, 2010).[10] But if some aspects of a label are required or permitted, and so by

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[10] This point must be qualified in light of *POM Wonderful*. The government asserted in that case that "compliance with one aspect of [FDA's] juice-naming regulations does not, by itself, render a juice label non-misleading . . . [b]ut compliance with FDA's juice-naming regulations does make the juice's *name* nonmisleading." Brief for United States as Amicus Curiae Supporting Neither Party, *POM Wonderful LLC v. The Coca-Cola Company*, 2014 WL 827980, at *19 (U.S. 2014) ("SG Brief"). The government said the FDA "could not (and would not) bring an enforcement action against a manufacturer under 21 U.S.C. [§] 343(a)(1) or (i) for naming its product "Raspcranberry; raspberry and cranberry flavored juice drink," if raspberry and cranberry juices were present as flavors, even if the drink was primarily white grape juice." *Id.* at *17. These points were made in support of the government's argument that a Lanham Act claim by a competitor is precluded "to the extent the FDCA or FDA regulations specifically require or authorize the challenged aspects of [the] label." *Id.* at *11. The Supreme Court rejected the government's position that compliance with FDA regulations could preclude a Lanham Act claim. 134 S. Ct. at 2241. The Court said "Congress intended the Lanham Act and the FDCA to complement each other with respect to food and beverage labeling." The Court explained that "[a]n agency may not reorder federal statutory rights without congressional authorization." *Id.*

definition not false or misleading under the FDCA, the rest of the label must still comply with § 343(a)(1) and not be "false or misleading in any particular." *See United States v. An Article of Food Labeled Nuclomin*, 482 F.2d 581, 583 (8th Cir. 1973) ("*Food Labeled Nuclomin*") ("[E]ven though the . . . label is technically accurate and further meets the regulations' disclosure requirements, it must also comply with [§ 343(a)] and not be misleading."). "Congress presumably chose to include § 343(a) in the statutory scheme in order to allow the FDA to target specific false or misleading labels without having promulgated regulations that address the specific false or misleading aspect of the particular label." *Zupnik v. Tropicana Products, Inc.*, No. CV 09-6130 DSF RZX, 2010 WL 6090604, at *2 (C.D. Cal. Feb. 1, 2010). *Reynolds*'s holding was thus based in part on § 343(a)(1)'s "distinct function in the statutory framework," which is "to address false or misleading labels when the FDA has not set specific requirements addressing the challenged aspect of the name, the placement of information, or any other category of requirements." 2015 WL 1879615, at *12.

Apart from compliance with regulations making that aspect non-misleading under § 343(a)(1), it also brings the conduct within the preemptive reach of the statute. "In circumstances where challenged conduct is expressly required or

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But that part of *Pom Wonderful* has no applicability to the FDA's interpretation of what is or is not misleading under the FDCA, which the FDA is charged to enforce.

permitted by FDA regulations, the claims fall within the core of the preemption provision because they would 'impose different requirements on precisely those aspects . . . that the FDA had approved.' " *Id*. at *11 (quoting *Altria Group, Inc.*, 555 U.S. at 86). A good example is *Red v. The Kroger Co.*, where the court held that "[b]ecause Plaintiffs challenge the use of terms that the FDA, through its regulations, has defined and permitted, Plaintiffs' claims fall with the scope of the FDA's preemption clause." 2010 WL 4262037, at *7; *see also Carrea v. Dreyer's Grand Ice Cream, Inc.*, 475 F. App'x 113, 115 (9th Cir. 2012) (holding claims preempted where plaintiffs sought "to enjoin and declare unlawful the very statement that federal law permits and defines" because "[s]uch relief would impose a burden through state law that is not identical to the requirements under section 343(r)"); *Peviani v. Hostess Brands, Inc.*, 750 F. Supp. 2d 1111, 1119 (C.D. Cal. 2010) ("Plaintiff's claims seek to enjoin the use of the very term permitted by the NLEA and its accompanying regulations. Plaintiff's claims must therefore fail because they would necessarily impose a state-law obligation for trans fat disclosure that is not required by federal law."). So, to state a parallel claim under § 343(a)(1) and escape preemption, Plaintiffs must point to some aspect of this product's label that is not required or permitted by the regulations which a reasonable jury could find makes the label "false or misleading."

Plaintiffs argue that many of the challenged features of the label are not required or permitted by the regulations, and these provide a basis to find the label "false or misleading" under § 343(a)(1). They specifically point to the depiction of fruit on the label, the placement, lettering, type-size, and spacing of the juice name and other labeling statements. Each of these is addressed in logical order.

1

Plaintiffs say that the label is misleading because of the miniscule amount of pomegranate and blueberry juice in the product. More specifically, in their response to the motion to dismiss, Plaintiffs assert that the first amended complaint "plausibly alleges that Pomegranate and Blueberry are present in only trace amounts and fortified by other natural flavors." ECF No. 38, at 13. Assuming that is properly alleged, it does not amount to a violation of any of the implementing regulations.[11] A careful analysis of regulations governing such a product shows that some of the challenged aspects of the label are required in those circumstances.

The first requirement is that if the name of the product leads consumers to expect it will contain a "characterizing ingredient," say "strawberries in a 'strawberry shortcake,' " but the product does not have enough of that ingredient to

[11] The response does not cite any part of the first amended complaint alleging fortification with other natural flavors, only allegations that label contains the statement "and other natural flavors." ECF No. 22 ¶ 32.

"independently characterize" the food, the word "flavored" has to be used in letters at least half as big as those of the characterizing ingredient—in this instance pomegranate and blueberry juice. 21 C.F.R. § 101.22(i)(1)(i). *See Reynolds*, 2015 WL 1879615, at *5 n.6; *Bell v. Campbell Soup Co.*, 2014 WL 6997611, at *3; *POM Wonderful LLC v. Coca Cola Co.*, 727 F. Supp. 2d 849, 871 (C.D. Cal. 2010), *aff'd in part, vacated in part, remanded*, 679 F.3d 1170 (9th Cir. 2012), *rev'd*, 134 S. Ct. 2228, (U.S. 2014).

Plaintiffs rely on part of the government's *Pom Wonderful* brief where it stated that § 101.22(i)(1)(i) "has no logical application here." SG Brief, 2014 WL 827980, at *31. The government reasoned that § 102.33(d)(1) already required the declaration "that the juice is pomegranate blueberry 'flavored.' " *Id*. It said "having the phrase 'pomegranate and blueberry flavored' stated again to 'accompan[y]' the 'name of the food' would be at best duplicative and at worst confusing." *Id*.

Those statements are at odds with the government's earlier observation that "a juice can be 'present as a flavor or flavoring' under 21 C.F.R. 102.33(d)(1) and still be insufficient to '*independently* characterize the food' under 21 C.F.R. 101.22(i)(1)(1)." SG Brief, 2014 WL 827980, at *22. Section 102.33(d)(1) says the label must indicate that a named minority juice is "present as a flavor or flavoring." Section 101.22(i)(1)(i) more specifically requires that if the minority

juice is not enough to provide the characterizing flavor, then the word "flavored" has to be a certain size. Nothing about these requirements implies that the word "flavored" must appear twice. Common sense suggests that the statement "flavored" required by § 101.22(i)(1)(i) might also satisfy the requirement in § 102.33(d)(1) to indicate that the minority juice is "present as a flavor or flavoring."[12] Indeed, the FDA explained how these two provisions work in concert:

> However, both §§ 101.22 and 102.33 are intended to ensure that the label communicates essential information to consumers. These provisions are intended to provide manufacturers with flexibility for labeling products while providing consumers with information that they need to determine the nature of the product. The agency concludes that both kinds of label information discussed here are essential to adequately describe the nature of the product.

58 Fed. Reg. at 2920. The regulations thus make plain that §§ 102.33(d)(1) and 101.22(i)(1)(i) are not mutually exclusive; they are complementary.[13]

The requirement in § 101.22(i)(1)(i) is implicated by Plaintiffs' assertion that pomegranate and blueberry juice are not present in an amount sufficient to characterize the beverage. A review of this label, as it is alleged in the complaint, reveals that the word "FLAVORED" is at least as big as it must be, if not more so.

[12] It is also worth noting that the use of a vignette triggers also the requirements of § 101.22(i)(1)(i).

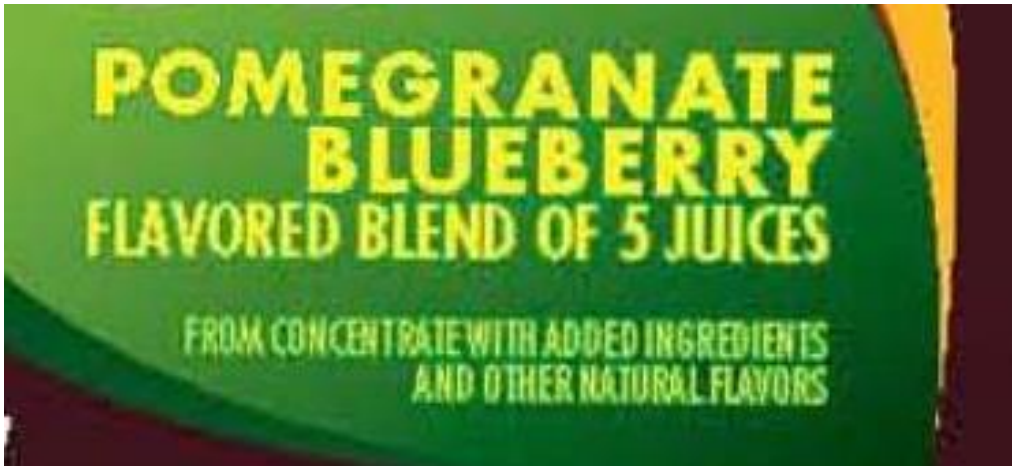
[13] To the extent the FDA took views inconsistent with its regulations in *Pom Wonderful*, it is not entitled to deference. *See Chase Bank USA, N.A. v. McCoy*, 562 U.S. 195, 208 (2011).

The second requirement is that if other natural flavors[14] reinforce the characterizing flavor, then "the name of the food shall be immediately followed by the words 'with other natural flavor' in letters not less than one-half the height of the letters used in the name of the characterizing flavor." *Id*. § 101.22(i)(1)(iii); *see also id.* § 102.33(b) ("[T]he presence of added natural flavors is not required to be declared in the name of the beverage unless the declared juices alone do not characterize the product before the addition of the added flavors.").[15]

This is a close-up of that part of the principal display panel with the product's name:

[14] A "natural flavor" means "the essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, or any product of roasting, heating or enzymolysis, which contains the flavoring constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, seafood, poultry, eggs, dairy products, or fermentation products thereof, whose significant function in food is flavoring rather than nutritional." 21 C.F.R. § 101.22(a)(3).

[15] Other requirements apply when there are *artificial* flavors. *See* 21 C.F.R. § 101.22(i)(1)(ii) ("If none of the natural flavor used in the food is derived from the product whose flavor is simulated, the food in which the flavor is used shall be labeled either with the flavor of the product from which the flavor is derived or as 'artificially flavored.'"); *id.* § 101.22(i)(2) (setting requirements "[i]f the food contains any artificial flavor which simulates, resembles or reinforces the characterizing flavor").



ECF No. 35-2. Under § 102.33(g)(1), "[i]f one or more juices in a juice beverage is made from concentrate, the name of the juice must include a term indicating that fact, such as 'from concentrate,' or 'reconstituted.' " So it appears that placing the statement "AND OTHER NATURAL FLAVORS" where it was in that type size amounts to substantial compliance with § 102.33(g) and § 101.22(i)(1)(iii).[16]

[16] Two aspects of this label are potentially deviations from those requirements. When including "from concentrate" as part of the "name of the juice" there are two alternatives for a producer. One is to include it in the name of each individual juice: "e.g., 'cherry juice (from concentrate) in a blend of two other juices.'" *Id.* § 102.33(g)(1). The second is to place the term "adjacent to the product name so that it applies to all the juices"; e.g., "cherry juice in a blend of 2 other juices (from concentrate)." *Id.* It has been suggested elsewhere (though not by Plaintiffs) that where the second method is invoked, as it apparently is here, tagging the statement "AND OTHER NATURAL FLAVORS" after it is a violation. The argument is that in such circumstances the declaration of other natural flavoring is not "immediately following" the "name of the food." The regulation does not say how to order the statements when *both* are required; the first "adjacent to the product name" and the other "immediately following" the "name of the food." Another potential discrepancy is that the label says "WITH ADDED INGREDIENTS AND OTHER NATURAL FLAVORS" rather than "with other natural flavor," as § 101.22(i)(1)(iii) requires.

Plaintiffs do not assert that the product is misbranded because these statements *violate* these regulations. And these statements in the label are similar enough to the requirements of the regulations to conclude that any differences are not sufficient to make the label false or misleading. *See Cytyc Corp. v. Neuromedical Sys., Inc.*, 12 F. Supp. 2d 296, 301 (S.D.N.Y. 1998).

Apart from the size and placement of the term "FLAVORED," Plaintiffs attack the size of the remainder of the statement: "BLEND OF 5 JUICES."

Under § 102.33(c) "[i]f a juice is present and listed only on the ingredient statement (that is, on the back of the label), it is an 'unrepresented juice.' " If that is so, then the name must indicate "that the represented juice is not the only juice present." *Id*. § 102.33(c). The example given by the FDA is to use the terms "Apple blend" or "apple juice in a blend of two other fruit juices." *Id*. The words of the statement in question plainly satisfy that requirement.

Plaintiffs argue that the FDA "has not adopted presentation standards for every word in a juice name" such as "blend." Because it has not, Plaintiffs assert that this is a basis to challenge the size of the statement "BLEND OF 5 JUICES" on this label.

The flaw with this theory is that parts of a juice-labeling regulation do not exist in isolation; according to the FDA they must be read and construed together. The requirement in § 101.22(i)(1)(i) is to use the term "flavored." *See also id*. § 102.33(d)(1) (requiring that the label indicate these two juices presence as a flavor or flavoring). The requirement in § 102.33(c) is to use the term "blend." The FDA said an "acceptable description" of a product where both requirements ("flavored" and "blend") are implicated is "cranberry flavored juice in a blend of

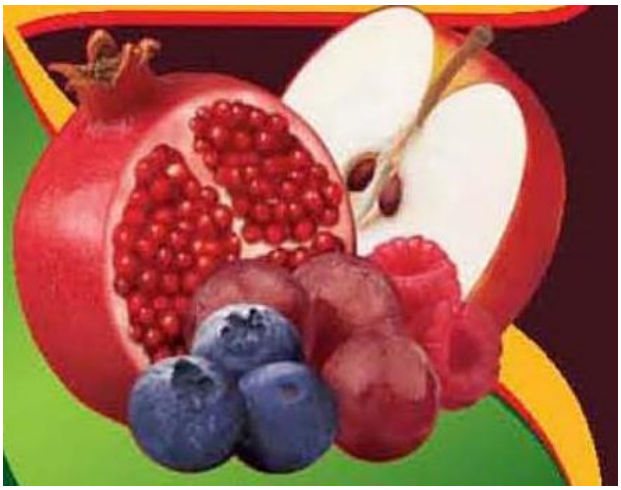
two other juices." 58 Fed. Reg. at 2920. Another "adequately descriptive term" is "cranberry flavored juice in a blend of two other juices, with added cranberry flavor." *Id*.

In the same breath, the FDA expressly advised reading the "flavoring" and "blend" requirements in concert with § 101.22. 58 Fed. Reg. at 2920 ("[B]oth §§ 101.22 and 102.33 are intended to ensure that the label communicates essential information to consumers . . . both kinds of label information discussed here are essential to adequately describe the nature of the product."). The size of the term "FLAVORED" is governed by § 101.22(i)(1)(i), which this label complies with. Given that context, to say that the label is misleading because the term "BLEND OF 5 JUICES" is merely the same size as "FLAVORED" is absurd.[17]

3

The depiction of fruits on the label is called a "vignette." *See* 21 C.F.R. § 101.22(i). This is a close-up of the vignette from the label:

[17] According to FDA, all text on the primary display panel must be at least 1/16 of an inch in height. 21 C.F.R. § 101.3(d). Plaintiffs do not suggest that this product violates that requirement.



ECF No. 35-2. According to Plaintiffs, the image is of an apple, pomegranate, grapes, and blueberries. ECF No. 38, at 7.[18]

The source of authority for any use of a vignette is § 101.22(i). If the label of a food "makes any direct or indirect representations with respect to the primary recognizable flavor(s), by word, *vignette*, e.g., depiction of a fruit, or other means," then "such flavor shall be considered the characterizing flavor and shall be declared" in certain ways. *Id*. (emphasis added). For a product like this one, the use of a vignette triggers the requirement that the characterizing flavor—in this instance blueberry and pomegranate—be "followed by the word 'flavored' in letters not less than one-half the height of the letters in the name of the characterizing flavor." *Id*. § 101.22(i)(1)(i). Defendants complied with these specifications to the letter.

[18] Presumably the fifth visible fruit is raspberry.

Yet Plaintiffs argue that the vignette is misleading because "it displays oversized pomegranate and blueberries at least as prominently as an apple and grapes, even though there is virtually no pomegranate or blueberry juice in this product." ECF No. 38, at 22. Relying on the FDA's statements about vignettes, Plaintiffs say Defendants "cannot establish on a motion to dismiss that [the] vignette is non-misleading as a matter of federal law." ECF No. 38, at 23.

As Plaintiffs stress, the FDA has not promulgated a formal regulation governing the content of fruit vignettes. Rather, in the preamble to the juice-labeling regulation, the FDA explained its reasoning about fruit vignettes.

"[A]gencies normally address problems in a detailed manner and can speak through a variety of means, including regulations . . . [and] preambles." *See Hillsborough Cnty., Fla. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 718 (1985). A preamble "is not a binding portion of the regulations, but is instead an advisory opinion" "represent[ing] the formal position of FDA on a matter" which "obligates the agency to follow it until it is amended or revoked." 21 C.F.R. § 10.85 (d)(1),(e), (g); *see Perry v. Novartis Pharma. Corp.*, 456 F. Supp. 2d 678, 683 (E.D. Pa. 2006). Such agency "rulings, interpretations and opinions of the [FDA], while not controlling upon the courts, do constitute a body of experience and informed judgment to which courts and litigants may properly resort for guidance." *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944); *see also United States v. Mead*

Corp., 533 U.S. 218, 228 (2001); *see e.g. In re Zyprexa Products Liab. Litig.*, 489 F. Supp. 2d 230, 273 (E.D.N.Y. 2007) (applying *Skidmore* deference to a different FDA preamble). "The weight of such a judgment in a particular case will depend on the thoroughness evident in its consideration, the validity in its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control." *Skidmore*, 323 U.S. at 140.

In the main, the FDA gave a non-exhaustive opinion in the preamble on what is or is not, and what might or might not be a misleading fruit vignette under § 343(a)(1). It is quoted here at length:

> The agency did not propose a specific requirement regarding the relative amounts of the various fruits depicted in a label vignette but solicited comments on whether it should require that the vignette accurately reflect the quantity of the fruit present or the taste of the product, or whether some other requirement is appropriate.
>
> . . . Some comments, from both consumers groups and manufacturers, stated that vignettes should depict all juices in a product. Other comments stated that such a provision is not necessary because a descriptive name together with declaration of each juice by order of predominance in the ingredient list and the percent of total juice would provide enough information to ensure that the consumer is adequately informed.
>
> The agency agrees that it is not always necessary that the label of a multiple-juice beverage depict each juice in a vignette. The agency believes that a vignette that pictures only some of the fruit or vegetables in the beverage would not be misleading where the name of the food adequately and appropriately describes the contribution of the pictured juice. For example, a 100 percent juice product consisting of apple, grape, and raspberry juices, in which the raspberry juice provides the characterizing flavor, a vignette depicting raspberries would not

necessarily be misleading if the statement of identity were "raspberry juice in a blend" or "raspberry juice in a blend of two other juices, 3 to 8 percent raspberry juice." Moreover, if these three juices were in a beverage containing 50 percent total juice, a vignette picturing raspberries would not be misleading in the presence of a name like "raspberry flavored juice beverage."

Accordingly, FDA is not requiring that vignettes depict the fruit or vegetables for all juices present. However FDA believes that a vignette that pictures the fruit or vegetable sources of all juices present in a product would provide useful information and thus encourages manufacturers to use such vignettes.

Conversely, vegetables or fruits not present in the beverage cannot be depicted in vignettes or other pictorial representations on the label. The agency considers that depicting a fruit or vegetable in a vignette on a juice beverage implies that the fruit or vegetable is in the product, either in the form of a juice or of a natural or artificial flavor of the depicted fruit or vegetable. A vignette that pictures a fruit or vegetable that is not present in the product results in a label that is false and misleading and therefore in violation of section 403(a) of the act.

. . . Some comments that wanted all fruits and vegetables pictured in the vignette also requested that the fruits and vegetables be depicted in proportion to the amount of each juice present. However, most comments requested that the agency not impose a specific requirement regarding the relative amounts of the various fruits or vegetables because the relative size and shape of various fruits and vegetables make it difficult to portray by vignette. They stated that both the relative size and the quantity of those fruits and vegetables are difficult to represent in a manner that would allow the consumer to readily recognize the quantity relationship.

The agency did not propose a specific requirement regarding the relative amounts of the various fruits depicted in a vignette but solicited comments on whether it should require that the vignette accurately reflect the quantity of the fruit present or the taste of the product, or whether some other requirement is appropriate. While information in comments emphasized the difficulties in displaying fruits and

> vegetables quantitatively, there was no information on how useful quantitative displays could be devised.
>
> The agency, therefore, is not requiring that fruits and vegetables pictured in vignettes be depicted in proportion to the amount of each juice present.
>
> . . . Several comments requested that the agency not make specific requirements regarding flavor characterizations in vignettes. They stated that the taste of a product is best communicated to the consumer through means other than the label vignette alone, and that any requirement should rely on wording to describe product flavor, e.g., "raspberry (flavor) in a blend of ————————other juices."
>
> The agency agrees with the comments that vignettes alone should not be required to communicate the flavor characteristics of the beverage and is not establishing such requirements. It also agrees that more explicit information is provided by the wording on the label, especially in the statement of identity of the product. However, FDA advises that in order for a beverage label to not be misleading, it is necessary that the vignette and other label statements on the beverage not conflict in any way. The agency has discussed above the circumstances under which the name of the beverage may be misleading. It will determine on a case-by-case basis whether a vignette is misleading because it is not consistent with other label information or for other reasons.

58 Fed. Reg. at 2921-22.

Applying that guidance, it thus appears that, with respect to this fruit vignette, Defendants did precisely what the FDA said to do. Even though, according to the FDA, it would *not* have been misleading to only have pomegranate and blueberry depicted in the vignette (if the name "adequately and appropriately describes the contribution of the picture juice" under the applicable regulations, as this one does), this label goes further and depicts all five fruits.

Indeed, in considering this very product, the *Pom Wonderful* district court concluded the vignette "clearly complies with FDA requirements relating to the depiction of vignettes" and is "therefore, clearly not misleading." *See*, 727 F. Supp. 2d at 873 (Otero, J.).[19]

A fruit vignette could conceivably be misleading for "other reasons." *See* 58 Fed. Reg. at 2922. But none of the uses of a fruit vignette which the FDA identified as potentially misleading are present here. That is, there is no allegation that the fruit vignette depicts a fruit that is not present in the beverage. Nor is there is any conflict between the depiction of all five fruits and the statements "POMEGRANATE BLUEBERRY FLAVORED BLEND OF 5 JUICES." The

[19] In a parallel case involving this same product, the district court retreated from that position when denying the defendant's summary-judgment motion. *See Saedian v. The Coca Cola Co.*, Case No. CV 09-06309 SJO (JPRx), ECF No. 148, at *9 (C.D. Cal. July 6, 2015) (Otero, J.). The court cited the wiggle room the FDA left itself in the preamble and explained that "the FDA's findings do not necessarily constitute 'a standard with the force of law that would foreclose the public protections under state law labeling and false advertising claims.' " *Id*. (quoting *Reid v. Johnson & Johnson*, 780 F.3d 952, 965 (9th Cir. 2015)). In *Reid*, the court held that an FDA letter did not have the force of law or preemptive effect. 780 F.3d at 964–65.

This Court has a slightly different take on the effect of the preamble. The NLEA, 21 U.S.C. § 343-1, preempts claims concerning food labels imposing requirements of the type required by sections of the misbranding statute, § 343, and the implementing regulations. Under *Reynolds*, a state-law claim parallel to § 343(a)(1) goes forward only to the extent the FDA could bring a § 343(a)(1) claim. The implementing regulations have preemptive force (by defining what state law *can* impose) and also limit the scope of a § 343(a)(1) claim. This Court assumes that this preamble does not have preemptive force. Even so, the preamble still limits the scope of a § 343(a)(1) claim by defining what is false or misleading under that provision. If Plaintiffs do not have a cognizable state-law claim paralleling § 343(a)(1), then the challenge to the label is preempted by § 343-1.

best example FDA gave cuts against Plaintiffs' argument. In declining to propose or adopt a requirement that the vignette reflect the relative fruit content of the beverage, FDA said "this representation could be misleading to consumers who might expect a different taste than was reflected by such a vignette." Food Labeling; Declaration of Ingredients; Common or Usual Name for Nonstandardized Foods; Diluted Juice Beverages, 56 Fed. Reg. 30452-01, 30462 (Jul. 2, 1991); *see also* 58 Fed. Reg. at 2922 ("The agency, therefore, is not requiring that fruits and vegetables pictured in vignettes be depicted in proportion to the amount of each juice present.").

Plaintiffs have not articulated any other basis on which a jury might find this fruit vignette misleading. Instead they fall back on the solicitor general's brief in *Pom Wonderful*, which stated in a footnote:

> To the extent petitioner challenges the fruit vignette as misleading . . . nothing in the FDCA or its implementing regulations precludes that claim. The district court relied on the preamble to the final rule . . . , but FDA specifically considered whether to formally regulate the content of such vignettes and ultimately opted for a case-by-case assessment.

SG Brief, 2014 WL 827980, at *30 n.14. The statement is correct; nothing in the FDCA or its implementing regulations precludes a Lanham Act claim based on the fruit vignette.

Plaintiffs are attempting to bring a claim parallel to the requirements of

§ 343(a)(1). In the preamble, FDA gave guidance on misleading aspects of fruit vignettes. According to FDA's advisory opinion—which it has not revoked—the challenged aspects of this fruit vignette are not in themselves misleading. Defendants could properly rely on that advisory opinion in designing the label of this product. And Plaintiffs have not given any "other reasons" why this fruit vignette is supposedly misleading under § 343(a)(1).

4

Having concluded that certain challenged aspects of this label are either required or permitted by the juice-labeling regulations, or are otherwise not misleading, the remaining consideration is whether there is still a basis to find the label misbranded "as a whole" under § 343(a)(1) such that Plaintiffs' claims are not preempted by § 343-1.

A brief review of the challenged aspects of this label is appropriate. Recall that Plaintiffs argue that they were misled by the vignette and the "placement, lettering, type-size, and spacing of the juice name and other labeling statements such as 'Flavored Blend of Five Juices.' " ECF No. 38, at 20. Section 102.33 in some ways required and otherwise authorized Defendants to use this name. The FDA's advisory opinion on vignettes explained that if the label adequately described the contribution of the named juices, a vignette depicting the only named minority juices (as opposed to this product, which has all five constituent juices)

would not be misleading. And § 101.22(i) sets type-size requirements for certain required statements *in relation* to "POMEGRANATE" and "BLUEBERRY" on the lines above. Because the FDA endorsed combining the required "flavored" and "blend" declarations, using the same type size for the latter as the former is no basis to find the label misleading.

The basic flaw in Plaintiffs' claims is this. The regulations require or permit the use of certain statements and depictions. The FDA has given some guidance on misleading use, which this label tracks. Conceivably, labeling aspects that are generally permitted might specifically be used in a misleading way. But the requirements in the regulations necessarily contemplate that they *will* be used, and—as cross references between the rules make plain—often in conjunction with each other. *See, e.g.*, 21 C.F.R. § 102.33(b) (referencing *id*. § 101.22(i)(1)(iii)).

Consider, for example, the FDA's assertion in *Pom Wonderful* that it "could not (and would not) bring an enforcement action against a manufacturer under 21 U.S.C. [§] 343(a)(1) or (i) for naming its product 'Raspcranberry; raspberry and cranberry flavored juice drink,' if raspberry and cranberry juices were present as flavors, even if the drink was primarily white grape juice." 2014 WL 827980, at *17. Rather, the FDA admitted it would have to point to something else on the label that was misleading aside from the actual words of the name. Transcript of Oral Argument at 20, *Pom Wonderful LLC v. The Coca Cola Co.*, 134 S. Ct. 2228

(U.S. 2014). That point applies with equal force to Plaintiffs' attempt to aggregate aspects of the label that comply with applicable requirements and complain the sum is misleading.

In support of their argument that the label is misleading as a whole, Plaintiffs cite a warning letter sent by the FDA to another juice manufacturer. *See* Letter of Roberta Wagner, FDA, to Brad Alford, Nestle U.S.A. ("Nestle Letter") (Dec. 4, 2009) (http://www.fda.gov/iceci/enforcementactions/warningletters/ucm194122.htm (last visited Jun. 23, 2015)). It points to more than just regulation-compliant conduct.

In the Nestle Letter, the FDA determined that two roughly similar products were misbranded under § 343(a)(1). The principal display panel for each product identified them, respectively, as "Orange Tangerine" or "Grape." The labels said each product was "All Natural-100% Juice." They had vignettes of oranges or grapes. Each of those aspects of the Nestle label complied, individually, with FDCA regulations. In combination, the FDA found the label misleading. *See* 21 U.S.C. § 321(n) (explaining the misbranding determination includes "not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations"). This was so because the flavoring statement (e.g., "Orange Tangerine") was in "large bold lettering," and in

"close proximity" to the statement "All Natural-100% Juice" and the vignettes of oranges or grapes.

Defendants' juice is different. The statement "100% FRUIT JUICE BLEND" is closer to the top of the label, while the name is near the bottom. Rather than being in "close proximity" to each other, the components are spread evenly across the label. Perhaps most importantly, the vignette is not just of the named juices, but all five juices present in the product.

In contrast to the Nestle labels, Plaintiffs cannot point to anything beyond regulation-compliant conduct on this label. There is no reason why this combination of material is objectionable in a way that is not necessarily contemplated and accepted by the regulations and the advisory opinions about them. So there is no proper basis to find the label misleading under § 343(a)(1), either in part or as a whole.

In conclusion, a state-law claim challenging this label is expressly preempted by the NLEA, 21 U.S.C. § 343-1.

IV

Plaintiffs say that if the motion to dismiss is granted, they should be given leave to amend their complaint. But any attempt to amend would be futile. *See, e.g.*, *Bell*, 2014 WL 6997611, at *4.

V

On August 11, 2015, the parties filed a joint motion for an order setting mediation. ECF No. 48. The parties wish to mediate this case on September 9, 2015, together with mediation in the *Saedian* case. *Id*.

The motion asserts that this case is stayed. That is not so. This Court lifted the stay of the case on February 6, 2015. ECF No. 31. Discovery is stayed pending this order on the motion to dismiss. *See* ECF No. 34.

This order was imminent when the parties filed their joint motion. Because this order grants the motion to dismiss, the joint motion for a mediation order will be denied. Nothing in this Court's orders prevents these parties from mediating their dispute with the *Saedian* plaintiffs.

For these reasons,

IT IS ORDERED:

1. Defendants' motion to dismiss, ECF No. 35, is **GRANTED**.
2. The joint motion for a mediation order, ECF No. 48, is **DENIED**.
3. The Clerk must enter judgment stating "This action is dismissed with prejudice."
4. The Clerk must close the file.

SO ORDERED on August 13, 2015.

s/Mark E. Walker
United States District Judge