

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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In re: PEPSICO, INC., BOTTLED WATER
MARKETING AND SALES PRACTICES LITIGATION

MDL No. 1903
08-MD-1903 (CS)
07-CV-6815 (CS)
07-CV-6874 (CS)

This Document Relates to All Actions

**MEMORANDUM DECISION
AND ORDER**

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Before the Court is Defendants' Motion to Dismiss Plaintiffs' Consolidated Class Action Complaint pursuant to Fed. R. Civ. P. 12(b)(6). (Doc. 8.)

I. Background

Plaintiffs Brian Fielman, Carmen Collado, Michael Jones, Regina P. Kelly, and Amanda Litschke, as individuals and on behalf of a class consisting of all individuals in the United States who purchased *Aquafina* bottled water from the date of its introduction through the present, filed

a Consolidated and Amended Class Action Complaint¹ on May 8, 2008 (the “Complaint”) (Doc. 4), alleging that Defendants PepsiCo, Inc., The Pepsi Bottling Group, Inc., and Pepsi Bottling Ventures LLC (collectively, “Pepsi” or “Defendants”), fraudulently misrepresented the source of *Aquafina* water by using a label designed to create the impression that the water came from a mountain source and failing to inform consumers that the true source of *Aquafina* water was public drinking supplies commonly known as “tap water.” (Compl. ¶ 1.) Plaintiffs assert three causes of action: (1) unfair and deceptive trade practices in violation of state consumer protection statutes;² (2) unjust enrichment; and (3) violation of the Song-Beverly Consumer Warranty Act, Cal. Civ. Code §1790, *et seq.*³ The allegations in the Complaint can be summarized as follows.

¹ The Judicial Panel on Multidistrict Litigation (“JPML”) issued an Order on February 14, 2008, centralizing these cases in the Southern District of New York pursuant to 28 U.S.C. § 1407, and transferring putative statewide class action lawsuits pending in Tennessee (*Anderson v. PepsiCo*, No. 07-CV-2514) and Texas (*Villa v. PepsiCo*, No. 07-CV-3060) for coordination and consolidation with the actions pending in this Court (*Fielman v. PepsiCo*, No. 07-CV-6815, and *Collado v. PepsiCo*, No. 07-CV-6874). The JPML issued another Order on February 28, 2008, transferring a “tag-along” action pending in the Eastern District of California (*Litschke v. PepsiCo*, No. 07-CV-2100) to this Court for further coordination and consolidation. By Order dated May 29, 2008, the late Judge Charles L. Brient consolidated these actions for all pretrial proceedings pursuant to Fed. R. Civ. P. 42. (Doc. 6.)

² Plaintiffs cite “N.Y. Gen. Bus. Law §§ 349, *et seq.*; Tenn. Code Ann. §§ 47-18-101, *et seq.*; Tex. Bus. & Com. Code [Ann.] § 17.41, *et seq.*; and Cal. Civ. Code § 1770, *et seq.* and Cal. Bus. & Prof. Code § 17200, *et seq.*, as well as substantially similar statutes in effect in the other States and the District of Columbia.” (Compl. ¶ 51.)

³ The first two causes of action are asserted by all Plaintiffs. The third cause of action is asserted only by Plaintiff Litschke, individually and on behalf of all class members residing in California.

Aquafina was first introduced in 1994 and gained national distribution with Pepsi in 1997. The label on *Aquafina* bottled water contains certain graphics, including a cartoon-like blue squiggle that evokes a mountain range, overlaid on a red-orange circle that evokes a rising or setting sun. The front of the label contains the slogan “Pure Water – Perfect Taste” and the product description “Purified Drinking Water.” The back of the label contains the ambiguous statement “BOTTLED AT THE SOURCE P.W.S.” The label does not indicate the source or state the meaning of “P.W.S.,” but Plaintiffs contend it is an abbreviation for “Public Water Supply.”

On or about July 27, 2007, Pepsi disclosed that, since its introduction to the market, the water used in *Aquafina* has been sourced from public drinking supplies. At this time, Pepsi allegedly agreed to re-label *Aquafina* to include information clarifying the source of the water, releasing a statement saying: “If this helps to clarify the fact that the water originates from public sources, then it’s a reasonable thing to do.” (Compl. ¶ 40.) Nevertheless, Plaintiffs contend that since July 27, 2007, Pepsi has continued to sell or permitted the continued selling of *Aquafina* with the labeling unchanged.

Plaintiffs allege that they were frequent purchasers of *Aquafina* water in the years prior to the public disclosure, and that they were “shocked and surprised to learn . . . that the true source of the water in *Aquafina* [was] tap water and that they had paid a premium price for tap water.” (*Id.* ¶ 8.) Prior to the disclosure, Plaintiffs claim that they believed that “the true source for *Aquafina* was mountain spring water.” (*Id.* ¶¶ 3-8.) Plaintiffs allege that Defendants intentionally created this “false impression” through its misleading marketing and labeling scheme in order to benefit from the higher prices they could obtain by misrepresenting *Aquafina*

as mountain spring water. In support of this allegation, Plaintiffs note that prior to July 2007, *Aquafina* was the best-selling brand of bottled water in the United States based on sales volume, and Defendants received revenues of approximately \$2.17 billion on sales of *Aquafina* in 2006 alone.

On June 16, 2008, Defendants filed the present Motion to Dismiss, and a Memorandum of Law in Support of their Motion to Dismiss. (Doc. 9.) Defendants argue that Plaintiffs' claims should be dismissed on the grounds that: (1) Plaintiffs' claims are expressly preempted by Section 403A of the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 343-1(a)(1); (2) Plaintiffs' claims are preempted under the doctrine of implied conflict preemption; and (3) Plaintiffs' claims fail to satisfy the pleading requirements of the various state law or common law claims alleged.

Plaintiffs filed a Memorandum of Law in Opposition to Defendants' Motion to Dismiss on August 8, 2008 ("Pls.' Opp'n"). (Doc. 14.) Defendants filed their Reply Memorandum of Law in Support of their Motion to Dismiss on September 26, 2008. (Doc. 18.) Oral argument was held on November 7, 2008.

II. Discussion

A. Preemption

Defendants move to dismiss on the grounds that Plaintiffs' state law claims are preempted by federal law, both explicitly, by the FDCA's express preemption provision, and impliedly, because they conflict with the statutory scheme related to the labeling of purified water. Express preemption is "present when Congress's intent to preempt state law is 'explicitly stated in the statute's language.'" *Mills v. Giant of Md., LLC*, 441 F. Supp. 2d 104, 106 (D.D.C.

2006) (quoting *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977)). Implied preemption is “applicable ‘where compliance with both federal and state regulations is a physical impossibility, or where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.’” *Id.* (quoting *Gade v. Nat’l Solid Wastes Mgmt. Ass’n*, 505 U.S. 88, 98 (1992)).

“Preemption is always a matter of congressional intent.” *Wachovia Bank, N.A. v. Burke*, 414 F.3d 305, 314 (2d Cir. 2005) (citing *Fid. Fed. Sav. & Loan Ass’n v. De la Cuesta*, 458 U.S. 141, 152 (1982)). “Since the existence of preemption turns on Congress’s intent, we are to ‘begin as we do in any exercise of statutory construction[,] with the text of the provision in question, and move on, as need be, to the structure and purpose of the Act in which it occurs.’” *McNally v. The Port Auth. of N.Y. & N.J.*, 414 F.3d 352, 371 (2d Cir. 2005) (alteration in original) (quoting *N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 655 (1995)). Accordingly, courts apply the following analytical framework in determining Congressional intent to preempt state law:

If the statute contains an express pre-emption clause, the task of statutory construction must in the first instance focus on the plain wording of the clause, which necessarily contains the best evidence of Congress’ pre-emptive intent. Where the language of the statute plainly indicates that Congress intended preemption, we must give effect to the plain language unless there is good reason to believe Congress intended the language to have some more restrictive meaning. If the text of the statute is ambiguous, either as to Congress’s intent to preempt at all or as to the extent of an intended preemption, the meaning of the statute may be gleaned from its context and from the statutory scheme as a whole, or by resort to the normal canons of construction and legislative history.

Id. (internal quotation marks and citations omitted).

1. Express Preemption

In the interest of promoting honesty and fair dealing, Congress has provided the Food and Drug Administration (“FDA”) with the power to “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.” 21 U.S.C. § 341. Here, Defendants’ Motion to Dismiss hinges on the “standard of identity” for “purified drinking water” and the express preemption provision of Section 403A of the FDCA, passed as part of the Nutrition Labeling and Education Act of 1990 (“NLEA”), Pub. L. No. 101-535, 104 Stat. 2353. The standard of identity for bottled water establishes definitions for several different types of bottled water, including “purified water,” “artesian water,” “ground water,” “mineral water,” and “spring water.” 21 C.F.R. § 165.110(a). Purified water is defined as follows:

The name of water that has been produced by distillation, deionization, reverse osmosis, or other suitable processes and that meets the definition of “purified water” in the United States Pharmacopeia, 23d Revision, January 1, 1995 . . . may be “purified water” or “demineralized water.”

Id. § 165.110(a)(2)(iv). Section 403A of the FDCA provides that:

(a) [N]o State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce - -

(1) any **requirement** for food which is the subject of a standard of identity established under section 401 [21 U.S.C. § 341] that is **not identical to** such standard of identity or that is not identical to the requirement of section 403(q) [21 U.S.C. § 343(q)].

21 U.S.C. § 343-1(a)(1) (emphasis added).

Under the FDCA’s misbranding provision, a food (including bottled water) purporting to be a food for which a definition and standard of identity has been prescribed is deemed

“mislabeled” if: (1) it does not conform with the applicable standard of identity; or (2) its label does not bear the name of the food specified in the definition and standard. 21 U.S.C. § 343(g). The FDCA “does not provide a private right of action.” *Savalle v. Nestle Waters N. Am., Inc.*, 289 F. Supp. 2d 31, 33 (D. Conn. 2003) (citing *Merrell Dow Pharm., Inc. v. Thompson*, 478 U.S. 804, 812 (1986)). Accordingly, Plaintiffs do not claim misbranding under § 343(g), but instead claim that Defendants are liable under various state consumer protections laws for misleadingly and deceptively suggesting that *Aquafina* has a mountain source. Plaintiffs argue that their state law claims are not preempted either because: (1) Defendants’ alleged labeling misrepresentations “went beyond the FDCA’s prescription” (in other words, notwithstanding compliance with the FDCA, Defendants may be held liable under state law for misrepresentations regarding the source of purified water because federal law is silent on the subject) (Pls.’ Opp’n 5); or (2) Defendants’ alleged labeling misrepresentations did not comply with the FDCA’s labeling requirements (in other words, Defendants can be held liable for state law claims that create a private right of action for noncompliance with the FDCA). (*Id.* 8.)

2. Relevant Law

Section 403A preempts state law “requirement[s].” 21 U.S.C. § 343-1(a)(1). In the context of express preemption provisions, “the term ‘requirements’ . . . reaches beyond positive enactments, such as statutes and regulations, to embrace common-law duties.” *Bates v. Dow Agrosciences L.L.C.*, 544 U.S. 431, 443 (2005); accord *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1008 (reaffirming that common-law causes of action for negligence and strict liability impose “requirements”). In contrast, an “occurrence that merely motivates an optional decision”—such as the threat of a state law damages remedy for violation of an existing federal

requirement—does not itself qualify as a requirement. *Bates*, 544 U.S. at 443, 448; *see Medtronic, Inc. v. Lohr*, 518 U.S. 470, 513 (1996) (O’Connor, J., concurring in part and dissenting in part) (“[T]he threat of a [state law] damages remedy” does not impose a “requirement” where “the requirements imposed on [defendants] under state and federal law do not differ.”). In other words, state law causes of action are not preempted where they merely provide a damages remedy for claims premised on a violation of federal law that does not itself provide a private right of action, but are preempted where they impose obligations not imposed by federal law. *Riegel*, 128 S. Ct. at 1011 (affirming dismissal of claims that medical device violated state law notwithstanding compliance with relevant federal requirements).

Accordingly, the mere fact that Plaintiffs’ state law claims threaten private liability that does not exist under the FDCA is not sufficient to bring those claims within the preemptive scope of Section 403A. Rather, preemption under Section 403A requires that state liability be based on a requirement that is “not identical to” the federal requirements. 21 U.S.C. § 343-1(a)(1). Thus I must look to whether the duties imposed by Plaintiffs’ state law claims are “identical” to those imposed by the standard of identity for purified drinking water.

In establishing a standard of identity for bottled water, the FDA intended that “the only State requirements that are subject to preemption are those that are affirmatively different from the Federal requirements on matters that are covered by the Section 403A(a) of the [NLEA].” *Beverages: Bottled Water*, 60 Fed. Reg. 57,076, 57,120 (Nov. 13, 1995). The federal regulation concerning the requirements for State petitions for exemption from Section 403A provides further clarification on the intended scope of express preemption under the FDCA:

“Not identical to” does not refer to the specific words in the requirement but instead means that the State requirement *directly or indirectly imposes*

obligations or contains provisions concerning the composition or labeling of food, or concerning a food container, that:

(i) *Are not imposed by* or contained in the applicable provision (including any implementing regulation) of section 401 or 403 of the act; or

(ii) *Differ 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)(i)-(ii) (emphasis added). Thus, state law cannot impose obligations beyond, or different from, what federal law requires.

This interpretation is not disturbed by the NLEA’s rule of construction concerning the scope of preemption, which provides in relevant part that, “[t]he [NLEA] shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under section 403A of the [FDCA].” NLEA, Pub. L. No. 101-535, § 6(c)(1), 104 Stat. 2353, 2364. That rule of construction applies only where preemption is sought under provisions other than Section 403A of the FDCA.⁴

The principle that state law cannot impose obligations other than what federal law requires is supported by *Bates*, 544 U.S. at 452, in which the Supreme Court, in addressing the narrower express preemption provision of the Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA”), 7 U.S.C. §§ 136 *et seq.*, held that “competing state labeling standards” creating potential liability under state law are preempted where the manufacturer would not also be held

⁴ The Court disagrees with Plaintiffs’ position that the term “expressly preempted” in the NLEA’s rule of construction modifies the scope of preemption under Section 403A of the FDCA. (Pls.’ Opp’n 7.) To the contrary, this provision – a rule of construction against preemption – refers to the express preemption provision of Section 403A solely for the purpose of exempting it.

liable under federal law.⁵ Finding that the plaintiffs’ state law fraud and negligent-failure-to-warn claims were premised on common law rules that qualify as “requirements” within the scope of the preemption provision, the Court held that state-law labeling requirements were not preempted to the extent they were “equivalent to, and fully consistent with, FIFRA’s misbranding provisions.” *Bates*, 544 U.S. at 447. Thus, the critical determination (for which the Court remanded the case) was whether the state law claims “imposed a broader obligation than [federal law].” *Id.* at 453. In language strikingly similar to the regulation explaining the meaning of the phrase “not identical to” in the FDCA’s express preemption provision, 21 C.F.R. § 100.1(c)(4)(i)-(ii) (“‘Not identical to’ does not refer to the specific words in the [federal] requirement but instead means that the State requirement directly or indirectly imposes obligations . . . that: [a]re not imposed by or . . . [d]iffer from those specifically imposed by [the federal requirement] . . .”), the Supreme Court instructed that courts undertaking a “parallel requirements” preemption analysis at the pleadings stage of a case “should bear in mind the concept of equivalence” rather than requiring that the state law requirements “be phrased in the *identical* language as its corresponding [federal] requirement” in order to survive preemption. *Bates*, 544 U.S. at 453 (emphasis in original).

⁵ In *Bates*, the Supreme Court addressed the extent to which FIFRA preempted state law claims by Texas peanut farmers alleging that their crops were severely damaged by a weed killer that was labeled with Environmental Protection Agency approval as “recommended in all areas where peanuts are grown,” although the manufacturer knew and failed to disclose on the label that the weed killer would stunt the growth of peanuts in soils with pH levels of 7.0 or greater. 544 U.S. at 434-35. The preemption provision at issue provided that: “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 439 (citing 7 U.S.C. § 136v(b)). The express preemption provision at issue here is arguably broader, because it preempts any state law claims imposing requirements that are “not identical to” the relevant federal law requirements. 21 U.S.C. § 343-1(a)(1).

Following *Bates*, the court in *Vermont Pure Holdings, Ltd. v. Nestle Waters North America, Inc.*, followed a similar approach, holding that the plaintiff's claims that the defendant misleadingly marketed Poland Spring water as "spring water" were "not preempted to the extent that they [were] based solely on state laws that provide private rights of action and have adopted the FDA definition of 'spring water.'" No. 03-11465, 2006 U.S. Dist. LEXIS 13683, at *22 (D. Mass. Mar. 28, 2006). The court reasoned that the "spring water" claims were "distinct from a situation in which a state enacts a statute that substantively adds to federal labeling requirements," because Vermont Pure did "not seek either to challenge or add to the FDA's definition of 'spring water.'" *Id.* at *20. In other words, the claim was not preempted because the plaintiff did not seek to impose a requirement beyond or different from federal law. Regarding Vermont Pure's claims that Nestle misleadingly marketed Poland Spring as "pure" when it was allegedly aware of contamination, the court held that such claims were not preempted because "[n]o federal standards of identity for bottled water purity exist." *Id.* at *30. Thus, state law claims based on issues addressed by federal regulation were permitted only to the extent they were based on or parallel to federal regulations, but if federal law did not address the issue at all, the claims were permitted to go forward. The *Vermont Pure* court thus construed the regulation that prohibits state requirements that "[a]re not imposed by" the act, 21 C.F.R. § 100.1(c)(4)(i), as permitting the states to impose requirements where the FDA has been silent.⁶

More recently, in *Mills*, 441 F. Supp. 2d at 106, the court, noting that the "scope of the FDCA's preemption clause is much broader than FIFRA's," *id.* at 108, which was at issue in

⁶ This Court finds that construction questionable, but – as discussed below – it is irrelevant in this case because the FDA has not been silent on the issues Plaintiff wishes to address via this lawsuit.

Bates, held that the plaintiffs' claims that milk should have a warning label for lactose intolerance were preempted because their proposed warning label "would far exceed" the "carefully delineated list of information" required under the standard of identity for milk labels. *Id.*

3. Application

In order to resolve this dispute, the Court must first analyze the FDCA's labeling requirements for bottled water meeting the standard of identify for "purified water," and then determine whether Plaintiffs' state law causes of action impose any "requirement . . . that is not identical to" those of the FDCA. 21 U.S.C. § 343-1(a)(1). If it is determined that Plaintiffs' state law causes of action "impose[] a broader obligation than [federal law]," then they are preempted. *Bates*, 544 U.S. at 453.

What is commonly referred to as "tap water" is known in FDCA terminology as a "community water system" and defined as "a public water system which serves at least 15 service connections used by year-round residents or regularly serves at least 25 year-round residents." 40 C.F.R. § 141.2. The parties agree that although bottled water originating from a community water system generally must be labeled "from a community water system" or "from a municipal source," the applicable standard of identity explicitly exempts from this source disclosure requirement water meeting the definition of purified drinking water. 21 C.F.R. § 165.110(a)(3)(ii). Nevertheless, Plaintiffs contend that Defendants may be held liable under state law for failing to disclose the source of *Aquafina* water because: (1) the FDCA is silent on whether the exemption of purified water from the source disclosure requirement is applicable where misrepresentations as to source are made on the label; and (2) notwithstanding the

exemption provision, the FDCA prohibits misrepresentations as to the source of all bottled water, including water meeting the definition of purified water. (Pls.’ Opp’n 8.) These arguments cannot prevail in light of the FDCA’s statutory framework and regulatory history, which reveal that the FDA specifically addressed the disclosure of source information and determined, in its expert opinion, that representations of source are immaterial in the context of purified water.

Prior to the enactment of the current standard of identity for the various types of bottled water products, all such products, with the exception of “mineral water” and “soda water,” were known as “bottled water,” and were subject to the same quality standards as set forth by the Environmental Protection Agency in its general requirements for drinking water. *Beverages: Bottled Water*, 58 Fed. Reg. 393, 393 (Jan. 5, 1993). On January 20, 1988, the International Bottled Water Association submitted a petition requesting that the FDA revise the standards of quality for bottled water to include mineral water and more closely regulate the labeling, production, and distribution of bottled water by providing definitions for “artesian water,” “distilled water,” “mineral water,” “purified water,” “spring water,” and “well water.” *Id.* at 394. On January 6, 1989, the FDA published a final rule in which it commented that it “[d]id not believe it necessary to include definitions for bottled waters from various water sources and produced by different treatments in the standard of quality for bottled water” because the existing statutory authority was deemed “sufficient to provide for regulatory action in instances where false and misleading statements concerning the source or treatment of bottled water [were] made” *Id.* (quoting *Nonalcoholic Beverages: Repeal of Soda Water Standard of Identity; Amendment of Bottled Water Quality Standard*, 54 Fed. Reg. 398 (Jan. 6, 1989)).

The FDA reversed its position on January 5, 1993, announcing its intent to move the definition for bottled water from the existing quality standard to a standard of identity including definitions for the various types of bottled water in order to address, among other concerns, the bottled water industry's stated "need for uniform labeling standards to prevent or eliminate inconsistent State labeling requirements." *Id.* at 395. In discussing the justifications for the proposed rule, the FDA noted the potential for misleading source representations made or implied by bottled water product labeling:

Often marketing and advertising associated with bottled water suggest that the "water comes from a tranquil, distant, utopian source" []. For example, a picture of a blue-green mountain spring on a label of a bottled water product may indicate to consumers that the water comes from a mountain spring. Such a label is misleading to consumers if the water actually comes from the municipal water supply of an urban area located far from any mountains

Id.

Later in the same proposed rule, however, the FDA described, in consecutive paragraphs, the justification for the proposed "municipal water supply" source disclosure requirement and the reasoning behind the proposed exemption to that requirement for purified water:

FDA is proposing to require in § 165.110(a)(3)(ii) that the phrase "from a municipal source" appear on the principal display panel or panels as a part of the name of the food if the water is obtained from a municipal water supply, ***except if the water has been treated to meet the definitions of distilled water or purified water and is labeled as such***. Information about the actual source of a bottled water product is a material fact in light of the either explicit (e.g., use of terms such as "spring" or "well") or implied (the presentation of the product in a bottle) representation made by a bottled water product that it is not tap water. Information about the source of the water is necessary to ensure that consumers do not incorrectly assume that because water is sold in a bottle, it does not come from a municipal water supply.

FDA is exempting municipal water that has been treated to meet the definition of "purified" or "distilled water" and is labeled as such because ***consumers purchase this water because of its treatment and subsequent purity rather than***

because of its source. In addition, there are no significant compositional differences among purified and distilled waters, regardless of the source of the water.

Id. at 399 (emphasis added).

After soliciting feedback on its proposed rule and receiving approximately 430 responses over the course of a six-month comment period from various trade and retail associations, government organizations, manufacturers, consumers, health care professionals, retailers, consumer groups, State groups, private organizations, the U.S. Congress, professional societies, and universities, the FDA published its final rule on bottled water on November 13, 1995.

Beverages: Bottled Water, 60 Fed. Reg. 57,076 (Nov. 13, 1995). Responding to a comment stating that “it would be misleading if a country setting is shown on the label, including lakes or ponds, and the product is drinking water processed from municipal supplies via reverse osmosis systems [i.e., purified water],” the FDA responded:⁷

FDA agrees that the use of certain graphics on a label of bottled water may be misleading to consumers if the source of the water is different than the source depicted or implied. For example, a country setting on a label may mislead consumers into believing that the product is spring water when it is not. Section 403(a) of the act specifically states that a food shall be deemed to be misbranded if its labeling is false or misleading in any particular. ***If a product is from a community water system, the label must clearly disclose this fact except as provided in § 165.110(a)(3)(ii).***

⁷ It is appropriate for Courts to consider the FDA’s published responses to commentators during the rule drafting process in determining the meaning of FDA regulations promulgated in furtherance of the FDCA. *See, e.g., Schering Corp. v. FDA*, 51 F.3d 390, 399-400 (3d Cir. 1995) (deferring to FDA’s stated disagreement with commentators regarding appropriate measurement of bioequivalence).

Id. at 57,104 (emphasis added).⁸ Section 165.110(a)(3)(ii) is the section that explicitly exempts purified water from the source disclosure requirement. Thus, while it is clear that the FDA contemplated that marketing techniques could potentially mislead consumers into believing that bottled water sourced from municipal supplies was actually “spring water,” it is also evident that the FDA determined that such concerns are irrelevant in the context of purified water. Indeed, the final rule is replete with evidence that, in contrast to spring water, the FDA concluded that because purified water, from whatever source, has been treated to meet purity standards, its source is immaterial to reasonable consumers. *See, e.g.*, 60 Fed. Reg. at 57088 (“[W]ater that is labeled as ‘purified water’ should meet stricter standards than other types of bottled water because the term ‘purified’ asserts that the product has been processed to be of a purer quality than other types of water.”); *id.* at 57089 (“[P]urified water . . . is chemically pure.”); *id.* at 57103 (“Source information for purified waters is not a material fact because the water may be significantly different in composition than other water from that particular source.”); *id.* at 57104 (“[T]here are no significant compositional differences between purified and distilled waters, regardless of the source of the water.”).

In sum, the FDA never intended or required that purified water include the “municipal water supply” disclosure required for certain other types of water, including spring water, and was not concerned with any misleading potential of graphics on bottles of purified water, based

⁸ Plaintiffs provided the Court with a handout at oral argument containing this quotation but omitting the sentence here emphasized. The omission is a significant one, because while Plaintiffs portrayed this response as evidence that the FDA shared the commentator’s concern that consumers would be misled by a country setting depicted on a bottle of purified water originating from a municipal source, the full response makes clear that the FDA shared that concern only as to products, such as spring water, for which the source is important to consumers, but specifically rejected that concern as to purified water.

on its conclusion that with respect to purified water, the purification, and not the source, is the reason consumers buy it.⁹ Consequently, Plaintiffs' claims are expressly preempted under both of their theories because: (1) federal law is not silent on the subject of implied labeling misrepresentations regarding the municipal source of bottled water; and (2) given that the *Aquafina* label fits within the exception for purified water and thus complies with the FDCA's requirements, Plaintiff's state law claims by necessity are premised on requirements that are not parallel to those imposed by federal law. Thus, because the state causes of action Plaintiffs wish to pursue would impose requirements in addition, and not identical, to federal requirements, they are preempted under Section 403A of the FDCA. *See Riegel*, 128 S.Ct. at 1011 (state damages remedy permitted only to extent state duties parallel federal requirements).

Plaintiffs' rely heavily on *Vermont Pure* in their attempt to persuade the Court that their state law claims are not preempted. This reliance on that case, which is not binding in any event, is misplaced for multiple reasons:

First, unlike the source location claims at issue in *Vermont Pure*, Plaintiffs' state law claims alleging that Defendants' misrepresented the source of *Aquafina* water impose requirements that are not identical to the applicable standard of identity. In *Vermont Pure*, the court correctly held that Vermont Pure's state law claims regarding Nestle's alleged misrepresentations of the source of the "spring water" at issue could only survive preemption to the extent that they adopted the FDA definition of spring water. 2006 U.S. Dist. LEXIS 13683,

⁹ The Court takes no position on the wisdom of the FDA's belief that label graphics are not a concern with respect to purified water or its policy decision to exempt purified water from the source disclosure requirement. All that matters for the purposes of this preemption analysis is that Congress provided that the FDA's standards would govern and that the FDA decided that purified water bottles need not disclose the source of the water even if the label might depict an idyllic setting.

at *22. Indeed, the FDA standard of identity imposes detailed requirements on the use of the “spring water” nomenclature, including “the location of the spring.” 21 C.F.R. § 165.110(a)(2)(vi). In contrast, the standard of identity for purified water is based solely on the “distillation, deionization, reverse osmosis or other suitable processes” applied to the water, *id.* § 165.110(a)(2)(iv), and purified water is explicitly exempted from the “community water system” disclosure requirement. *Id.* § 165.110(a)(3)(ii). Thus, all the *Vermont Pure* court did was apply the “parallel requirements” test set forth in *Bates*: the federal regime for spring water had requirements for source disclosure, and the plaintiffs were permitted to proceed with a state cause of action to enforce those requirements. Here the standard of identity for purified water does not require the disclosure of source information, and therefore Plaintiffs’ state law claims seeking to impose liability on these grounds are expressly preempted.

Second, unlike the “purity” claims regarding the “spring water” at issue in *Vermont Pure*, which the court concluded were unaddressed by federal law, the federal standard of identity for “purified water” explicitly regulates purity requirements. *Id.* § 165.110(a)(2)(iv). Thus, the “purity” field is not open as to purified water, as the *Vermont Pure* court held it was as to spring water. Here, Plaintiffs claim that Defendants’ use of the term “pure” in the *Aquafina* labeling slogan “Pure Water – Perfect Taste” is misleading to consumers because, when viewed in connection with the graphics on the label, it “results in misleading consumers into believing the source of the water is springs from snow-capped mountains, as opposed to public tap water.” (Pls.’ Opp’n 10.) This argument fails to appreciate that although the FDA has “discouraged” the use of the term “pure,” it did so out of concern that consumers may be misled into believing that bottled water labeled as “pure” meets the processing standards required by the standard of

identity for purified water. Beverages: Bottled Water, 60 Fed. Reg. 57,076, 57,099. Consumers cannot be misled in that fashion here, because *Aquafina* is purified water. In any event, Plaintiffs do not quarrel with the purity of *Aquafina*. (Pls.' Opp'n 6.) Their focus on purity here is merely an attempt to re-cast their source argument, but the attempt is unavailing because: (1) the term "pure" has no source-specific meaning; and (2) source claims are, as discussed above, expressly preempted.

Finally, I reject Plaintiffs' reading of *Vermont Pure* to stand for the principle that state requirements are permitted as long as the federal standard does not specifically address the terms or images at issue. Where federal requirements address the subject matter that is being challenged through state law claims, such state law claims are preempted to the extent they do not impose identical requirements. Thus, although the standard of identity does not define the term "pure" or specify when it is permissible to place a cartoon-like image of a mountain range on a purified water label, the FDA considered misrepresentations regarding source and chose to regulate the labeling requirements for the disclosure of source information, and in so doing it determined that purified water should be exempted. Accordingly, any state law claims premised on a misrepresentation about the source of purified water are preempted.¹⁰

In essence, Plaintiffs would have me construe the term "not identical to" in Section 403A as permitting state requirements that go beyond federal law as long as federal law does not expressly prohibit or permit the specific labeling at issue. I construe the term according to its

¹⁰ This is not to say that state law claims cannot survive preemption where they are premised on misrepresentations concerning subject matter that the FDA has not endeavored to regulate. Defendants acknowledged this limitation on express preemption at oral argument, providing the examples of potentially actionable state law claims in the hypothetical circumstances of labeling misrepresentations concerning purified water's ability to clear up the drinker's acne or increase the drinker's intelligence. Hr'g Tr. 58:15-24, 63:9-15, Nov. 7, 2008.

