

NATURALLY CONFUSING CONSUMERS: EXPRESS FEDERAL PREEMPTION OF STATE CLAIMS REGARDING FALSE AND MISLEADING FOOD PRODUCT LABELS

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I. INTRODUCTION

When choosing a box of cereal at the grocery store, consumers are bombarded with food product packaging proclaiming its contents “all natural,” “whole grain,” “good source of calcium,” and the like. Many consumers rely on these claims to make informed decisions concerning their diets. In the midst of the current obesity epidemic, consumers have become increasingly conscious of eating nutritious food.¹ About two-thirds of American adults are overweight, and a study by the Centers for Disease Control and Prevention (CDC) found the health-care cost of obesity is approximately \$147 billion annually.² According to the Center for Science in the Public Interest, nutrition and health information such as food product-labeling information could help lower the obesity rate.³ Food companies benefit from consumers confusing foods labeled “natural” with those labeled “organic.”⁴ Organic foods have specific United States Department of Agriculture (USDA) certifying criteria, whereas “Natural” food labeling laws are non-existent and foods with a “natural” label are generally misleading.⁵ Consumers’ health conscious craze has created a \$22.3 billion market for foods labeled as “Natural,” causing an increase in class action lawsuits claiming such food labeling is false and misleading.⁶ Foods such as Snapple, Healthy Choice pasta sauce, Skinnygirl Cocktails, Ben and Jerry’s

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¹ BRUCE SILVERGLADE & ILENE RINGEL HELLER, CTR. FOR SCI. IN THE PUBLIC INTEREST, *FOOD LABELING CHAOS: THE CASE FOR REFORM* (2010) [hereinafter *FOOD LABELING CHAOS*], available at http://cspinet.org/new/pdf/food_labeling_chaos_report.pdf

² *Id.* at I-1.

³ *Id.*

⁴ *Major Agribusiness Competing with Organics on the Cheap, “Natural” Food Products with Toxic Chemicals and GMOs Deceiving Consumers*, CORNUCOPIA INST. (Oct. 12, 2011), <http://www.cornucopia.org/2011/10/cerealcrimes-pressrelease>.

⁵ *Id.*

⁶ “Natural” Beats “Organic” in Food Sales According to Nielsen’s Healthy Eating Report, NIELSENWIRE (Jan. 21, 2009), <http://blog.nielsen.com/nielsenwire/consumer/natural-beats-organic-in-food-sales-according-to-nielsen-s-healthy-eating-report/>; Ashby Jones, *Is Your Dinner ‘All Natural’?* WALL ST. J. (Sep. 20, 2011), <http://online.wsj.com/article/SB10001424053111903374004576580671156407598.html>.

ice cream, and Wesson cooking oils have all had their "Natural" status questioned.⁷

It may seem more likely that Kellogg's Froot Loops and General Mills' Trix cereals are falsely claiming to be "Natural," but cereals with a healthier reputation, like Kashi, confuse consumers with their food label claims as well.⁸ A recent lawsuit filed against Kashi and its parent company, Kellogg, claims that Kashi's labels are intentionally misleading because the labels contain synthetic and unnaturally processed ingredients.⁹ Specifically, the plaintiff claims Kashi added "synthetic substances listed as prescription drugs to its foods, irradiated substances, pesticides that are a by-product of uranium mining, and federally declared hazardous substances."¹⁰ Kashi's brand image is centered around a healthy and eco-friendly lifestyle, and the company uses its website to educate consumers about natural food ingredients, organic farming, and the environment.¹¹ The District Court for the Southern District of California concluded that the plaintiff's claims were not expressly preempted because the "[d]efendants did not specify which subsection of [21 U.S.C.] § 343 would be violated, and because there is no subsection of section 343 listed under section 343-1(a) that addresses labeling food items as 'natural.'"¹² The lawsuit against Kashi is an example that illustrates the framework courts should apply when deciding whether a "natural" food-labeling claim is expressly preempted.

The increase in litigation surrounding "natural" food product labeling has stemmed largely from the Food and Drug Administration's (FDA) failure to adequately define the term "natural."¹³ In 1991, the FDA considered defining the term to mean "nothing artificial or synthetic (including colors regardless of source) is included in, or has been added to, the product that would not normally be expected to be there."¹⁴ However, in 1993, the FDA refused to adopt a formal definition of the term or prohibit

⁷ See *Holk v. Snapple Beverage Corp.*, 575 F.3d 329, 333 (3rd Cir. 2009); See also *Lockwood v. Conagra Foods*, 597 F. Supp. 2d 1028, 1031 (N.D. Cal. 2009); Jones, *supra* note 6.

⁸ Bonnie Rochman, *The Sugary Brands Doing the Most Kid-Chasing*, TIME MAG. (Oct. 23, 2009), http://www.time.com/time/specials/packages/article/0,28804,1931891_1931889_1931887,00.html (showing cereal box contains "Natural" food labeling claim).

⁹ *Bates v. Kashi*, No. 3:11-cv-01967-H-BGS, 2011 WL 3821651 (S.D. Cal. Aug. 24, 2011).

¹⁰ *Id.* ¶ 2.

¹¹ *Id.* ¶ 6.

¹² *Id.* ¶ 6-7.

¹³ Jones, *supra* note 6; See *Holk v. Snapple Beverage Corp.*, 575 F.3d 329, 333 (3rd Cir. 2009); See also April L. Farris, *The "Natural" Aversion: The FDA's Reluctance to Define a Leading Food-Industry Marketing Claim, and the Pressing Need for a Workable Rule*, 65 Food Drug L.J. 403 (2010).

¹⁴ *Holk*, 575 F.3d at 340 (quoting Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms, 55 Fed. Reg. 60,421, 60,466 (Nov. 27, 1991)).

its use.¹⁵ Currently, the FDA's informal policy is still in place, allowing use of the term unless the food contains added color, artificial flavors, or synthetic substances.¹⁶ On November 16, 2011, the FDA issued a warning letter to a potato company stating the food label may be misleading because the food product contains a synthetic preservative.¹⁷ The warning letter included the FDA's informal policy definition, indicating the likelihood that this is the preferred definition of the term.¹⁸ As a result of the FDA failing to define the term and enforce an official "natural" food labeling policy, courts have found that federal law does not preempt state law claims based on false and misleading labeling.¹⁹

Overall, recent cases have failed to find preemption for various unclear reasons.²⁰ In order to ensure more uniformity in the food product labeling express preemption analysis, courts should follow a two-step approach similar to the analysis the U.S. Supreme Court used in *Riegel v. Medtronic* concerning medical devices. First, courts should analyze the level of premarket approval and FDA regulations to determine whether there is a federal "requirement." Second, courts should compare the federal "requirement" to the state claim to determine whether they are "identical." Additionally, states may provide a cause of action based on an "identical" state law, and those claims would not be preempted.

The first part of this note explains the defense of federal preemption generally. The second part summarizes and explains the current status of the law concerning "natural" food product labeling cases and related lawsuits. The third part discusses recent U.S. Supreme Court cases concerning federal preemption under the Federal Food, Drug, and Cosmetic Act, (FDCA), regarding medical devices and prescription drugs. The fourth part analyzes the current FDA regulations regarding food labeling and determines whether they could be expressly preempted. Lastly, the fifth part explains the impact of the current food labeling laws on consumer behavior.

¹⁵ *Holk*, 575 F.3d at 340-41 (citing Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms: Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food, 58 Fed. Reg 2,302, 2,397, 2,407 (Jan. 6, 1993)).

¹⁶ *FDA Basics: What is the Meaning of 'Natural' on the Label of Food?*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm214868.htm> (last updated Apr. 4, 2012).

¹⁷ *Litigation Law Alert: "All Natural" Class Action Litigation in California and What's In Store for 2012?*, STOLE RIVES LLP (Dec. 20, 2011), <http://www.stoel.com/showalert.aspx?Show=8971>.

¹⁸ *Id.*

¹⁹ *E.g.*, *Holk*, 575 F.3d at 339.

²⁰ *See id.* at 339 (finding the claim was not impliedly preempted because the FDA has not officially defined the term); *Lockwood v. Conagra Foods*, 597 F. Supp. 2d 1028, 1031 (C.D. Cal. 2009) (failing to find the claims expressly preempted because the claims did not allege artificial ingredients).

II. THE DEFENSE OF FEDERAL PREEMPTION GENERALLY

Litigation involving “natural” food product labeling claims over the past few years has largely turned on the issue of federal preemption.²¹ Federal preemption originates in the Supremacy Clause of the U.S. Constitution.²² Federal law preempts, or supersedes, state law when any of three types of preemption is found.²³ The three types of preemption are express preemption, field preemption, and implied conflict preemption.²⁴

Preemption analysis focuses on determining Congress’ intent.²⁵ In areas traditionally regulated by the states, federal law is presumed not to preempt state law unless “Congress has made such an intention clear and manifest.”²⁶ Even though food and beverage labeling has been regulated by the federal government for over 100 years, it is within the states’ police powers, and therefore, within the traditional area of state regulation.²⁷ Accordingly, the presumption against preemption applies.²⁸ It is well accepted that federal agency action may have the force of federal law for preemption purposes, so regulations could preempt state law.²⁹

The FDCA prohibits misbranded food, and a food label is considered misbranded if it is false or misleading.³⁰ A food is also considered misbranded if “it bears or contains any artificial flavoring, artificial coloring, or chemical preservative unless it bears labeling stating that fact.”³¹ The presence of a color additive must also be disclosed.³² The FDCA does not provide a private right of action; rather the FDCA is enforced through FDA administrative proceedings.³³ The Nutrition Labeling and Education Act, (NLEA), of 1990 was added to ensure consistency with a national standard and to preclude states from adopting inconsistent requirements.³⁴ The NLEA contains an express preemption provision, 21 U.S.C. § 343-1, providing that states must not have food

²¹ See, e.g., *Holk*, 575 F.3d at 340-41 (finding the claim was not impliedly preempted because the FDA has not officially defined the term); See also, e.g., *Lockwood*, 597 F. Supp. 2d at 1031 (failing to find the claims expressly preempted because the claims did not allege artificial ingredients).

²² See U.S. CONST. art. VI, cl. 2.

²³ *Holk*, 575 F.3d at 334.

²⁴ *Smith v. Wells Fargo Bank*, 135 Cal. App. 4th 1463, 1476 (2005); *In re Farm Raised Salmon Cases*, 175 P.3d 1170, 1177 (Cal. 2008).

²⁵ *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (stating that “the purpose of Congress is the ultimate touch-stone” in preemption analysis (quoting *Retail Clerks Int’l Ass’n Local 1652 v. Schermerhorn*, 375 U.S. 96, 103 (1963))).

²⁶ *Bates v. Dow Agrosciences L.L.C.*, 544 U.S. 431, 449 (2005).

²⁷ *Holk*, 575 F.3d at 334-35.

²⁸ *Id.*

²⁹ *Von Koenig v. Snapple Beverage Corp.*, 713 F. Supp. 2d 1066, 1074 (C.D. Cal. 2010).

³⁰ 21 U.S.C. § 331(b) (2011); 21 U.S.C. § 343(a) (2011).

³¹ 21 U.S.C. § 343(k) (2011); 21 C.F.R. § 101.22(k) (2011).

³² *Id.*

³³ *Lockwood v. Conagra Foods, Inc.*, 597 F. Supp. 2d 1028, 1030 (C.D. Cal. 2009).

³⁴ *In re Farm Raised Salmon Cases*, 175 P.3d 1170, 1175 (Cal. 2008).

labeling requirements that are not “identical” to the FDCA.³⁵ “Not identical” has been applied to state requirements that “(1) are not imposed by or contained in the applicable provision [or regulation]; or (2) differ from those specifically imposed by or contained in the applicable provision [or regulation].”³⁶ The express preemption provision applies to specific provisions such as those for artificial flavoring, artificial coloring, or chemical preservatives, and also applies to health and nutrient content claims.³⁷

III. RECENT FOOD LABELING CASES REGARDING THE FEDERAL PREEMPTION DEFENSE

A. Express Preemption Under § 343-1(a) of the Nutrition Labeling and Education Act

Express preemption requires Congress to expressly state its intent to preempt state law.³⁸ Generally, when a manufacturer is in compliance with FDA regulations, courts are more willing to find the claims preempted. In *In re Ferrero Litigation*, the plaintiff alleged the defendant “deceptively omitted” the fact that Nutella contains artificial flavoring.³⁹ The court found § 343(k) expressly preempted this claim because the label complies with the disclosure requirement by listing the artificial flavor.⁴⁰ In *Lockwood v. Conagra Foods*, the court found § 343(k) did not expressly preempt the claims because they did not allege artificial ingredients.⁴¹ Instead, the plaintiffs alleged the defendant’s “Healthy Choice” pasta sauce was not “all natural” because it contained high fructose corn syrup rather than alleging that it contained artificial flavoring, coloring, or a chemical preservative.⁴² The court’s analysis suggests a claim based on the failure to disclose artificial flavoring or coloring may be preempted, but a claim simply alleging that a food product is not “all natural” because it contains artificial ingredients would not be preempted.

In *In re PepsiCo.*, the plaintiffs claimed that the defendants fraudulently misrepresented the source of Aquafina water by indicating the water came from mountain sources, when it in fact was public drinking water. The court ruled that these claims were expressly preempted by 21

³⁵ 21 U.S.C. § 343-1(a)(1) (2011).

³⁶ *In re Ferrero Litig.*, 794 F. Supp. 2d 1107, 1114 (C.D. Cal. 2011) (citing 21 C.F.R. § 100.1(c)(4) (2012)).

³⁷ See 21 U.S.C. § 343-1(a)(3)–(5) (2011) (citing 21 U.S.C. § 343(k), (q), (r) (2011)).

³⁸ *Smith v. Wells Fargo Bank*, 135 Cal. App. 4th 1463, 1476 (2005).

³⁹ *In re Ferrero Litig.*, 794 F. Supp. 2d at 1114.

⁴⁰ *Id.*

⁴¹ *Lockwood v. Conagra Foods, Inc.*, 597 F. Supp. 2d 1028, 1031 (C.D. Cal. 2009).

⁴² *Id.*

U.S.C. § 343(r).⁴³ Under 21 C.F.R. § 165.110(a)(3)(ii), manufacturers of purified water are not required to disclose the source of the water.⁴⁴ The court first analyzed the FDCA's labeling requirement and then compared the plaintiffs' state law cause of action to determine if the state claim imposed a requirement that was not "identical" to federal law.⁴⁵ The court noted that state law causes of action are preempted if they "impose a broader obligation."⁴⁶ The court found the plaintiffs' claims were not identical to federal law because there is a regulation concerning the municipal source of bottled water and Aquafina was in compliance with that regulation.⁴⁷ The court noted that subject matter lacking specific FDA regulations would not be preempted.⁴⁸

The court in *Mills v. Giant of Md. LLC* found the plaintiffs' claims, that defendants' milk did not contain adequate warnings on the labels, were expressly preempted under § 343-1(a)(1).⁴⁹ Under § 343-1(a)(1), no state may establish a requirement that is the "subject of a standard of identity" that is not identical to such standard or to the requirements in § 343(g).⁵⁰ When a food is misbranded, § 343(g) applies because the food does not contain all of the requirements in the "standard of identity," which is different from claims regarding additions to the food product's "standard of identity."⁵¹ The FDA has the power to create a "reasonable definition and standard of identity."⁵² Milk is subject to a "standard of identity" under 21 C.F.R. § 131, and the plaintiffs' sought to impose additional requirements through the added warning labels.⁵³ The court stated "a product subject to 'a standard of identity' has a carefully delineated list of information that must appear on its label."⁵⁴

In *Yumul v. Smart Balance*, the plaintiffs alleged the defendants' nutrient content claims such as "No Cholesterol" and "healthy" were false and misleading.⁵⁵ The court found the claims were expressly preempted by § 343(r) because they imposed a requirement that was not "identical" to federal law by forbidding a manufacturer from labeling its food products in

⁴³ *In re Pepsico, Inc., Bottled Water Mktg. & Sales Practices Litig.*, 588 F. Supp. 2d 527, 537 (S.D.N.Y. 2008).

⁴⁴ *Id.* at 536-37.

⁴⁵ *Id.* at 536.

⁴⁶ *Id.* at 534.

⁴⁷ *Id.* at 537.

⁴⁸ *Id.* at 538 n.10.

⁴⁹ *Mills v. Giant of Md., L.L.C.*, 441 F. Supp. 2d 104, 108 (D.C. 2006).

⁵⁰ *Id.* at 106.

⁵¹ *Id.* at 108 n.5.

⁵² *Id.* at 107 n.4.

⁵³ *Id.* at 106 n.4.

⁵⁴ *Id.* at 108.

⁵⁵ *Yumul v. Smart Balance, Inc.*, No. 10-00927 MMM, 2011 U.S. Dist. LEXIS 109952, at *7 (D. Cal. Mar. 14, 2011).

a way that complied with FDA regulations.⁵⁶ In *Turek v. General Mills*, the plaintiffs alleged that the defendants failed to disclose that their food products contained “non-natural” fibers.⁵⁷ The court found that the plaintiffs’ claims were expressly preempted by § 343(r) and § 343(q).⁵⁸ In *Astiana v. Ben & Jerry’s Homemade, Inc.*, the court found that the plaintiffs’ claims, that the label was false and misleading because the product was not “all natural,” were not expressly preempted by § 343(r) because there is no regulation defining the term “natural.”⁵⁹

B. Express Parallel Claim Exception

The court in *Thomas Mason v. Coca-Cola* acknowledged a parallel claim exception to express preemption when a plaintiff alleges a claim under state law based on the failure to follow federal labeling regulations.⁶⁰ The Supreme Court of California, in *In re Farm Raised Salmon Cases*, also stated that Congress did not expressly preempt private claims based on state laws with “identical” requirements to the FDCA.⁶¹ Therefore, it appears a plaintiff may make a claim under state law that is based on either federal law or an “identical” state law.

In *In re Farm Raised Salmon Cases*, the plaintiffs alleged that the defendants failed to disclose the presence of artificial coloring in their farmed salmon.⁶² Under California law, private parties may assert unfair competition law causes of action based on violations of the state’s Sherman Food, Drug, and Cosmetic Law.⁶³ The California Supreme Court found by negative implication that states may regulate color additives if the state’s regulations are “identical” to § 343(k).⁶⁴ The court found the state’s Sherman Law provision regarding the use of color additives was “identical” to § 343(k), thereby satisfying the parallel claim exception to express preemption.⁶⁵ The court noted that even if the wording had not been identical, the Sherman Law incorporates all of the FDA’s regulations.⁶⁶ Under *In re Farm Raised Salmon Cases’* analysis, state claims regarding foods labeled “natural,” that do not disclose the presence of artificial coloring, would be preempted only if the claims were not “identical” to a

⁵⁶ *Id.* at *34-37.

⁵⁷ *Turek v. Gen. Mills, Inc.*, 754 F. Supp. 2d 956, 957 (N.D. Ill. 2010).

⁵⁸ *Id.* at 960-62.

⁵⁹ *Astiana v. Ben & Jerry’s Homemade, Inc.*, No. C 10-4387, 2011 U.S. Dist. LEXIS 57348, at *26-27 (N.D. Cal. May 26, 2011).

⁶⁰ *Mason v. Coca-Cola Co.*, No. 09-0220-NLH-JS, 2010 U.S. Dist. LEXIS 65107, at *8 (D. N.J. June 30, 2010).

⁶¹ *In re Farm Raised Salmon Cases*, 175 P.3d 1170, 1177 (Cal. 2008).

⁶² *Id.* at 1173.

⁶³ *Id.* at 1174 n.5.

⁶⁴ *Id.* at 1175.

⁶⁵ *Id.* at 1178.

⁶⁶ *Id.*

specific FDA regulation. If the claims are based on state law that is not identical to federal requirements, then § 343-1 would expressly preempt those claims.

To ensure consistency in food labeling express preemption analysis, courts should follow the analysis applied to the FDCA by the U.S. Supreme Court in *Riegel v. Medtronic*. Some cases have followed U.S. Supreme Court preemption analysis that was not based on the FDCA. The court in *Turek* applied the “Bates test,” used by the U.S. Supreme Court to determine the preemptive effect of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), to determine the preemptive scope of the NLEA.⁶⁷ Other courts have followed the analysis from medical device and prescription drug cases that are not the most recent U.S. Supreme Court decisions in the area.⁶⁸

C. Implied Preemption Generally

Implied preemption is analyzed “in the absence of anything Congress said or even thought about.”⁶⁹ In *In re Ferrero litigation*, the court noted “the NLEA states that it ‘shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under [21 U.S.C. § 343-1(a)] of the [FDCA].”⁷⁰ Courts have analyzed this section in different ways. Some courts have found the statement to mean only express preemption is possible. The California Supreme Court stated the “preemptive scope” of § 343-1 was only intended to cover “the plain language of the statute itself.”⁷¹ The *In re PepsiCo* court found implied preemption is not excluded, but the NLEA’s rule of construction “refers to the express preemption provision of Section 403A solely for the purpose of exempting it.”⁷² In *Red v. Kraft Foods*, the court found the *In re PepsiCo* court’s interpretation “somewhat odd.”⁷³ The court in *Holk* found it is possible to find implied preemption based on “provisions of federal law other than the NLEA.”⁷⁴

⁶⁷ *Turek v. Gen. Mills Inc.*, 754 F. Supp. 2d 956, 957 (N.D. Ill. 2010).

⁶⁸ See *In re Farm Raised Salmon Cases*, 175 P.3d at 1175; see also *Turek*, 754 F. Supp. 2d at 958.

⁶⁹ *Living on the Point of the Spear*, DRUG & DEVICE L. (Sept. 25, 2008), <http://druganddevicelaw.blogspot.com/2008/09/living-on-point-of-spear.html>.

⁷⁰ *In re Ferrero Litig.*, 794 F. Supp. 2d 1107, 1113 (C.D. Cal. 2011).

⁷¹ *In re Farm Raised Salmon Cases*, 175 P.3d at 1178-79.

⁷² *In re PepsiCo, Inc.*, 588 F. Supp.2d 527, 533 n.4 (S.D.N.Y. 2008).

⁷³ *Red v. Kraft Foods, Inc.*, 754 F. Supp. 2d 1137, 1140 n.2 (C.D. Cal. 2010).

⁷⁴ *Holk v. Snapple Beverage Corp.*, 575 F. 3d 329, 336 (3d Cir. 2009).

D. Implied Field Preemption

Field preemption is found where the federal regulation is “so pervasive” that Congressional intent to “dominate the field” may be inferred.⁷⁵ The court in *Lockwood v. Conagra Foods, Inc.* stated the NLEA included a preemption provision allowing identical state regulations, indicating Congress considered state regulation and enforcement alongside federal regulation.⁷⁶ The *Lockwood* court noted the FDA has a policy defining the word “natural” rather than a legal requirement, which shows the FDA did not intend to occupy the field.⁷⁷ The FDA’s policy is an advisory opinion used to show acceptable standards, but it is not a legal requirement.⁷⁸ The *Lockwood* court found that *Holk*’s decision, which is discussed below, was “neither binding nor persuasive.”⁷⁹

E. Implied Conflict Preemption

1. Preemption with Undefined Terms: Natural Claims

Conflict preemption occurs when federal and state law conflict to make compliance with both impossible.⁸⁰ In *Holk*, plaintiffs alleged Snapple’s beverage products were not “all natural” because they contained high fructose corn syrup (HFCS).⁸¹ The court found the claims against Snapple were not impliedly preempted because the FDA has not officially defined the term.⁸² The FDA’s informal policy statements on the definition of “natural” and FDA warning letters were not sufficient to preempt state law.⁸³ The court in *Holk* did not reach the issue of whether the claims were expressly preempted because Snapple waived its express preemption argument.⁸⁴ The court noted §343(k), regarding artificial flavoring, would not expressly preempt state law because HFCS is a sweetener and not a flavoring.⁸⁵ Since the NLEA explicitly denies implied preemption based on the NLEA, the court looked at other federal laws to determine whether the claims were impliedly preempted.⁸⁶ The court’s reasoning in *Holk* is flawed

⁷⁵ *Smith v. Wells Fargo Bank*, 135 Cal. App. 4th 1463, 1476 (Cal. Ct. App. 2009).

⁷⁶ *Lockwood v. Conagra Foods, Inc.*, 597 F. Supp. 2d 1028, 1032 (C.D. Cal. 2009).

⁷⁷ *Id.* at 1033.

⁷⁸ *Id.*

⁷⁹ *Id.* at 1034.

⁸⁰ *Smith*, 135 Cal. App. 4th at 1476.

⁸¹ *Holk v. Snapple Beverage Corp.*, 575 F. 3d 329, 332 (3d Cir. 2009).

⁸² *Id.* at 340.

⁸³ *Id.* at 340-42.

⁸⁴ *Id.* at 336.

⁸⁵ *Id.* at 336 n.3.

⁸⁶ *Id.* at 336.

because the court only looked for the existence of an FDA regulation rather than the level of FDA control over the regulation as discussed below.

2. Preemption with Defined Terms: Vitamin and Mineral Claims Under §343(r)

Based on the *Holk* court's widely followed analysis, one would assume courts would universally find that FDA defined terms are preempted. However, *Thomas Mason v. Coca-Cola Co.* reached a different result. In *Thomas Mason v. Coca-Cola Co.*, the plaintiff claimed "Diet Coke Plus" violated FDA regulations and was misleading because "Plus" indicates an added amount of vitamins and minerals.⁸⁷ The term "Plus" has been precisely defined in FDA regulations.⁸⁸ The court found that in order to find implied conflict preemption, more than just a regulation defining the term is necessary.⁸⁹ The *Thomas Mason v. Coca-Cola Co.* decision shows that even if the FDA defined the term "natural," it is not guaranteed that state claims would be preempted. Therefore, predicting whether a state claim will be preempted based on whether the term at issue has been defined is still uncertain and should not be used as the method for resolving preemption issues.

Considering the controversy regarding the scope of implied preemption and the existence of the express preemption provision applicable to food labeling laws, this note will analyze express preemption under § 343-1. The express preemption analysis under the *In re Farm Raised Salmon Cases* is the most persuasive. *In re Farm Raised Salmon Cases* was decided by the California Supreme Court, and the denial of certification by the U.S. Supreme Court indicates that the *In re Farm Raised Salmon Cases* decision is the preferred method.⁹⁰ However, the analysis should also turn on the degree of FDA premarket approval and FDA regulations following the procedure the U.S. Supreme Court used in *Riegel*. Therefore, claims regarding food labels that are subject to "rigorous" premarket approval should be preempted if the state claims are based on the violation of a federal regulation or the state regulation is not "identical" to the federal requirement.

⁸⁷ *Mason v. Coca-Cola Co.*, No. 09-0220-NLH-JS, 2010 U.S. Dist. LEXIS 65107, at *1-2 (D.N.J. 2010).

⁸⁸ *Id.* at *5 (citing 21 C.F.R. §101.54(e)).

⁸⁹ *Id.* at *12-13.

⁹⁰ *In re Farm Raised Salmon Cases*, 175 P.3d 1170 (Cal. 2008), *cert. denied*, 555 U.S. 1097 (2009).

IV. FOOD LABELING COMPARED TO MEDICAL DEVICE PREEMPTION ANALYSIS

Preemption analysis regarding food labeling should be determined similarly to the recent preemption analysis used by the U.S. Supreme Court for medical devices and prescription drugs because all three are regulated by the FDCA. The California Supreme Court's decision in the *In re Farm Raised Salmon Cases* relied on the United States Supreme Court's plurality opinion in *Medtronic v. Lohr*, which involved medical devices.⁹¹ The Court in *Lohr* held none of the plaintiffs' claims were expressly preempted under § 360k(a), which states that no State may establish "any requirement that is different from or in addition to, any requirement applicable under 21 USC § 301."⁹² Medical devices are divided into three classes depending upon how dangerous they are to human life, with Class III being the most dangerous.⁹³ The different classes determine the different degrees of premarket approval and compliance regulations.⁹⁴ The Court in *Lohr* determined the claims were not preempted because the FDA's premarket "notification" process did not involve federal "requirements."⁹⁵ Under the premarket "notification" process in § 510(k) of the FDCA, medical devices are allowed to be marketed if they are "substantially equivalent" to medical devices in interstate commerce before May 28, 1976.⁹⁶ Under the § 510(k) premarket "notification" process, the review is completed in an average of 20 hours whereas medical devices requiring premarket approval undergo around 1,200 hours of review.⁹⁷ Despite the extensive approval process, the FDA does not guarantee the safety of devices that pass the premarket notification process.⁹⁸ In premarket notification, the FDA only allows the device to be marketed; it does not require the device to take any specific form.⁹⁹

In *Riegel v. Medtronic*, which involved medical devices, the U.S. Supreme Court again determined whether state claims were expressly preempted by the FDCA. In *Riegel*, the plaintiff was injured from a defect in a Class III medical device that received premarket approval from the FDA.¹⁰⁰ The analysis the Court used in *Riegel* first determines whether

⁹¹ *In re Farm Raised Salmon Cases*, 175 P.3d at 1180-81.

⁹² *Medtronic v. Lohr*, 518 U.S. 470, 480 (1996) (citing Medical Device Amendments of 1976 (MDA) to the Federal, Food, Drug, and Cosmetic Act (FDCA) 21 U.S.C. §360k(a)).

⁹³ *Id.* at 176-77.

⁹⁴ *Id.*

⁹⁵ *Id.* at 492-94.

⁹⁶ *Id.* at 478.

⁹⁷ *Id.* at 479.

⁹⁸ *Id.* at 479-80.

⁹⁹ *Id.* at 493-494.

¹⁰⁰ *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 320 (2008).

there is an applicable federal requirement.¹⁰¹ In reaching that decision, the U.S. Supreme Court found that the FDA's "rigorous" premarket approval process imposes "requirements" under the FDCA.¹⁰² Premarket approval is "focused on safety, not equivalence," and a device receiving premarket approval must be made without deviations from the terms in its approval application.¹⁰³ For a manufacturer to make changes affecting "safety or effectiveness," the manufacturer must submit an application for supplemental premarket approval, which is evaluated similarly to an initial application.¹⁰⁴ After devices receive premarket approval, they are subject to reporting requirements and the FDA can withdraw its approval.¹⁰⁵ The Court next determined that *Riegel's* state common-law claims had "requirements" that were "different from, or in addition to the federal ones" and, therefore, were preempted.¹⁰⁶ State tort law would require devices to be safer but less effective, and a jury would not weigh the cost of a more dangerous design versus the benefit to society.¹⁰⁷ The Court also noted that a state's "requirements" includes its common-law duties.¹⁰⁸

The U.S. Supreme Court reached different conclusions about the scope of federal preemption in *Lohr* and *Riegel* because of the different degrees of the devices' premarket review.¹⁰⁹ *Lohr* is still considered good law, but the decision has been described as "fractured in an all but irreconcilable manner," and the decision "did little to clear up the confusion" of how broadly to apply the scope of federal preemption.¹¹⁰ The *Riegel* Court stated, "Congress is entitled to know what meaning this Court will assign to terms regularly used in its enactments."¹¹¹ The Court in *Riegel* found Congress intended the term "requirements" referenced in the FDCA to include a state's common-law duties.¹¹² The dissent in *Riegel* assumed that state tort suits regarding drugs and food and color additives were not preempted, but the majority stated that this had not been established.¹¹³ The majority did mention that if Congress intended the regimes to be treated similarly, then they would have made a preemption clause applicable to the entire FDCA.¹¹⁴ These statements are extremely

¹⁰¹ *Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 767-68 (5th Cir. 2011).

¹⁰² *Riegel*, 552 U.S. at 322.

¹⁰³ *Id.* at 323.

¹⁰⁴ *Id.* at 319.

¹⁰⁵ *Id.* at 319-320.

¹⁰⁶ *Id.* at 328.

¹⁰⁷ *Id.* at 325.

¹⁰⁸ *Id.* at 324.

¹⁰⁹ *Id.* at 322-23.

¹¹⁰ *In re Medtronic*, 592 F. Supp. 2d 1147, 1151 (D.C. Minn. 2009) (quoting *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1371 (11th Cir. 1999)).

¹¹¹ *Riegel*, 552 U.S. at 324.

¹¹² *Id.*

¹¹³ *Id.* at 327.

¹¹⁴ *Id.* at 327.

important for two reasons. First, a majority of the Supreme Court did not automatically assume food-labeling laws were not preempted. Second, the food labeling express preemption provision's application is intended to be tailored specifically to the food-labeling regime because the analysis is limited to the text of the statute. It is still important to consider how the Supreme Court interpreted other preemption provisions under the FDCA. The *In re Farm Raised Salmon Cases* decision citing *Lohr* was decided before the U.S. Supreme Court decided *Riegel*. So the analysis from *In re Farm Raised Salmon Cases* should incorporate the U.S. Supreme Court's analysis in *Riegel* while maintaining the language and specific provisions in the food labeling preemption provision.

A. Parallel Claim Exception

In *Riegel*, the Court left room for a plaintiff to allege a parallel claim by allowing a state to provide "a damages remedy premised on a violation of FDA regulations."¹¹⁵ Most of the other Circuits have held a plaintiff must plead a "device-specific" violation of a federal requirement.¹¹⁶ In *Martin*, the Fifth Circuit stated state common-law duties that incorporate the premarket approval process were not preempted.¹¹⁷ The Sixth Circuit found that a claim based on a violation of the FDA's "Good Manufacturing Practices," that has been incorporated into the premarket approval process, was not preempted.¹¹⁸ Similarly, state claims based on a violation of a federal food labeling regulation would not be preempted. Since there is not a federal regulation concerning "natural" food products, but rather an informal policy, the parallel claim exception does not apply to false and misleading labeling claims regarding "Natural" food products.

V. FOOD LABELING COMPARED TO PRESCRIPTION DRUG LABELS IMPLIED PREEMPTION ANALYSIS

In prescription drug cases, the U.S. Supreme Court considered similar factors concerning the level of FDA approval and review of the label to those used in medical devices during its preemption analysis.

¹¹⁵ *Id.* at 330.

¹¹⁶ See *Ilaraza v. Medtronic*, 677 F. Supp. 2d 582, 589 (E.D.N.Y. 2009) (acknowledging a minority view in a different case, and electing to follow the majority of the other courts); See also *Covert v. Stryker Corp.*, No. 1:08CV447, 2009 WL 2424559, at *13 (M.D.N.C. Aug. 5, 2009) (noting that cases rejecting the minority view are "more persuasive with regard to the pleading standards of Twombly").

¹¹⁷ *Martin v. Medtronic*, 254 F.3d 573, 582 n.8 (5th Cir. 2001); But see *In re Medtronic*, 592 F. Supp. 2d 1147, 1157 (D. Minn. 2009) (finding that the plaintiff did not allege parallel claims because Good Manufacturing Practice (GMP) and Quality System Regulation (QSR) are "too generic, standing alone to serve as the basis for Plaintiff's manufacturing-defects claims").

¹¹⁸ *Howard v. Sulzer Orthopedics, Inc.*, 382 F. App'x 437, 442 (6th Cir. 2010).

Congress declined to adopt an express preemption provision for prescription devices when it adopted one for medical devices.¹¹⁹ The Court in *Wyeth v. Levine* used the lack of an express preemption provision as a justification for failing to find preemption whereas the Court in *PLIVA v. Mensing* found implied conflict preemption.¹²⁰ The Court in *Wyeth* held a state law cause of action for failure to warn of the dangers of Phenergan was not preempted by the FDA's approval of the label.¹²¹ Under the FDA prescription drug approval process, the manufacturer must prove to the FDA the drug is safe and effective.¹²² The Court found that simply requiring the manufacturer to comply with an FDA approved label was not enough to make compliance with both state and federal law impossible.¹²³ Manufacturers of prescription drugs have statutory authority from Congress to unilaterally change their label without FDA consent after the label receives initial approval.¹²⁴ However, manufacturers of medical devices must have changes approved by the FDA, and without this approval, manufacturers of medical devices may not deviate from the specifications in the approval.¹²⁵

In *PLIVA v. Mensing*, the U.S. Supreme Court again considered the issue of preemption concerning prescription drug labeling and found the plaintiffs' claims to be preempted.¹²⁶ The Court found preemption in *PLIVA* even though the generic prescription was approved under a lesser equivalency standard rather than being approved as a new drug.¹²⁷ The Court noted that *Riegel* and *Lohr's* analysis, which concluded that lower premarket notification of an equivalent device was not a federal requirement and premarket approval of a new device was a federal requirement, was not persuasive because there is not an express preemption provision for prescription drugs.¹²⁸ In *PLIVA*, the state claims were preempted because the manufacturers of the generic drug could not comply with the state's stronger label requirements because the FDA required the generic label to be the "same" as the brand-name drug label.¹²⁹ The Court distinguished *PLIVA* from *Wyeth* because the manufacturers in *PLIVA* could not independently act without the FDA's approval to comply with the

¹¹⁹ *Wyeth v. Levine*, 555 U.S. 555, 567-69 (2009).

¹²⁰ *See id.*; *see also* *PLIVA v. Mensing*, 131 S. Ct. 2567, 2581 (2011).

¹²¹ *Wyeth*, 129 S. Ct. at 1204.

¹²² *Id.* at 1195 (citing Federal Food, Drug, and Cosmetic Act, Pub. L. No. 87-781, 76 Stat. 781, 784 §§102(c) and 104(b) (1962)).

¹²³ *Id.* at 1199.

¹²⁴ *Id.*

¹²⁵ *Riegel v. Medtronic*, 552 U.S. 312, 319 (2008).

¹²⁶ *PLIVA v. Mensing*, 131 S. Ct. 2567, 2581 (2011).

¹²⁷ *Id.* at 2574.

¹²⁸ *See Wyeth* 129 S. Ct. at 1196; *See also Living on the Point of the Spear*, *supra* note 68 (discussing the differences between and implications of express and implied pre-emption).

¹²⁹ *PLIVA*, 131 S. Ct. at 2577.

state law duty.¹³⁰ The Court stated that when deciding whether compliance with both federal and state law is possible, if the private party cannot act without the Federal Government's "special permission and assistance, which is dependent on the exercise of judgment by a federal agency," the state claims are preempted because they are not the private parties' independent action.¹³¹ The Court in *Wyeth* and *PLIVA* employed the same analysis and asked what federal law permitted the manufacturer to do independently, and then determined that the claim is not preempted if the manufacturer could have complied with state law.¹³² While preemption analysis under prescription drug labels differs from medical device and food labeling preemption analysis, the level of FDA involvement and the level of the manufacturer's control are still important considerations and should be integrated into food labeling preemption analysis.

Implied preemption analysis is not limited to the words of the statute because it derives its power from the Supremacy Clause.¹³³ Therefore, implied preemption analysis from other areas of law is even more relevant because "it is not statute specific."¹³⁴ This note proposes, when considering food-labeling claims not covered by the express preemption provision, courts should follow the analysis used in *PLIVA* and *Wyeth* to determine implied preemption. The focus of implied preemption analysis from *PLIVA* and *Wyeth* is the level of the manufacturer's control and its ability to unilaterally make changes after premarket approval.

VI. EXPRESS PREEMPTION ANALYSIS: PREMARKET APPROVAL AND FDA REGULATIONS REGARDING FOOD LABELING

The NLEA contains an express preemption provision regarding food labeling, unlike prescription drugs.¹³⁵ The express preemption provision applies only to the specific sections listed under § 343-1, such as general nutrition information under § 343(q); artificial coloring, artificial flavoring, or chemical preservatives under § 343(k); and nutrition level and health related claims under § 343(r). To determine whether state claims are expressly preempted under § 343-1, courts should perform a two-step analysis similar to the one the Supreme Court used in *Riegel*. First, courts should determine whether a federal "requirement" exists based on the level of premarket approval and FDA regulations. Courts should determine whether the level of FDA review is more similar to premarket notification in *Lohr*, which does not guarantee safety, or whether it is more like the

¹³⁰ *Id.* at 2581.

¹³¹ *Id.*

¹³² See *Wyeth*, 129 S. Ct. at 1198; See also *PLIVA*, 131 S. Ct. at 2575.

¹³³ *Living on the Point of the Spear*, *supra* note 68.

¹³⁴ *Id.*

¹³⁵ *Turek v. Gen. Mills*, 754 F. Supp. 2d 956, 958 (E.D. Ill. 2010).

“rigorous” premarket approval in *Riegel*, which does not allow individuals to unilaterally change the specifications in the application without the FDA’s consent. In making this decision, courts should analyze different factors including the extent of FDA premarket approval, specific versus generic regulations, whether the FDA guarantees safety, and the manufacturer’s level of unilateral control over changes in labeling after premarket approval. Second, courts should analyze whether the state requirement is “identical” to the federal requirement.

A. Food Labeling Generally

The FDA does not approve manufacturers, but they are inspected and subjected to “Good Manufacturing Practices.”¹³⁶ Food labeling in general is not subject to premarket approval.¹³⁷ The FDA’s general food labeling requirements concerning the contents of a label, where its placed, the font, size, etc. are considered “nonbinding recommendations.”¹³⁸ There are FDA regulations that are enforced, such as one that requires that food product claims are not false or misleading.¹³⁹ Food labels for prepared foods including bread, cereal, canned and frozen food, snacks, deserts, drinks, and the like are required, whereas nutrition labeling for raw produce such as fruits, vegetables, and raw fish is voluntary.¹⁴⁰ FDA regulation 21 CFR § 101.9 requires nutrition information for all food products unless there is an exception. Nutrient and food components’ quantities must also be disclosed.¹⁴¹ Furthermore, nutrition information declared on the label must be either the mandatory or voluntary nutrients or food components listed under 21 CFR § 101.9.

General food labeling claims that are not subject to premarket approval, and are only required to comply with general regulations, would not be considered a federal “requirement” under *Lohr*. The Court in *Lohr* found manufacturing and labeling requirements that are “entirely generic,” and concern device regulation as a whole, did not preempt common-law claims, and differed from premarket approval because premarket approval is specific to individual devices.¹⁴² Food labeling is not generally subject to

¹³⁶ *Is it Really FDA Approved?*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm047470.htm> (last updated Feb. 20, 2009).

¹³⁷ *Id.*

¹³⁸ *General Food Labeling Requirements, Guidance for Industry: A Food Labeling Guide*, U.S. FOOD & DRUG ADMIN., (Oct. 2009) <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/FoodLabelingGuide/ucm064866.htm>.

¹³⁹ *Is it Really FDA Approved?*, *supra* note 135.

¹⁴⁰ *Labeling & Nutrition: Food Labeling and Nutrition Overview*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/food/labelingnutrition/default.htm> (last updated Sept. 5, 2012).

¹⁴¹ 21 C.F.R. § 101.9 (2012).

¹⁴² *Riegel v. Medtronic*, 552 U.S. 312, 323-24 (2008) (citing *Medtronic Inc. v. Lohr*, 518 U.S. 470, 503-5, 521 (1996)).

premarket approval, and the regulations requiring that the labels are not false or misleading and contain nutrient information are similar to the “generic” regulations in *Lohr*. The “generic” regulations in *Lohr* included a “listing of the devices, good manufacturing practices, labeling, and the misbranding and adulterations provisions of the Act.”¹⁴³ Also, the “substantial equivalence” letter, expressly stating that the FDA was not officially approving the device, was considered a “generic” regulation.¹⁴⁴

Without an FDA regulation defining the term “natural,” the current “natural” food label informal policy would probably be considered a “generic” regulation because it is not enforced and the FDA does not guarantee its safety.¹⁴⁵ Without an FDA regulation, the term “natural” is not required to be in a specific form similar to the device received premarket notification in *Lohr*. Products claiming to be “natural” do not receive as much premarket review as the medical device in *Lohr* because manufacturers do not even have to notify the FDA of the use of the term.¹⁴⁶ Therefore, claims based on general food labeling regulations, including the “natural” food label informal policy, are not federal “requirements.” Under the proposed analysis finding there is not a federal “requirement,” claims that food products are not “natural,” are not expressly preempted under current FDA regulations.

B. Health Claims

Health claims describe the relationship between a substance, including a food, food component, or dietary ingredient, and its effect on reducing the “risk of a disease or health-related condition.”¹⁴⁷ Health claims are subject to FDA review and approval through regulations contained in the NLEA including § 343(r)(1)(B).¹⁴⁸ The 1997 Food and Drug Administration Act allows health claims to be based on a statement from the U.S. Government or National Academy of Sciences, and the 2003 FDA Consumer Health Information for Better Nutrition Initiative mandates specific quality and strength standards for the scientific evidence in order to receive FDA approval.¹⁴⁹ An example of a health claim that is authorized by an FDA regulation under the NLEA is the claim that “diets high in calcium may reduce the risk of osteoporosis.”¹⁵⁰ Qualified health claims may be used if the scientific evidence is not established, but the qualified

¹⁴³ *Lohr*, 518 U. S. at 493.

¹⁴⁴ *Id.*

¹⁴⁵ *FOOD LABELING CHAOS*, *supra* note 1.

¹⁴⁶ *Is it Really FDA Approved?*, *supra* note 135.

¹⁴⁷ *Claims that Can be Made for Conventional Foods and Dietary Supplements*, U.S. FOOD & DRUG ADMIN. (Sept. 2003), <http://www.fda.gov/food/labelingnutrition/labelclaims/ucm111447.htm>.

¹⁴⁸ *Id.*

¹⁴⁹ *Id.*

¹⁵⁰ *Id.*

claim must contain limiting language.¹⁵¹ Health claims are regulated under § 343(r), to which the express preemption provision, § 343-1 specifically applies.¹⁵²

Approved health claims subjected to FDA review would be considered federal “requirements” under *Riegel*. The FDA performs an “extensive review of scientific literature” when authorizing the claims and there are specific FDA regulations under § 343(r).¹⁵³ Also, the express preemption provision applies specifically to § 343(r).¹⁵⁴

Qualified health claims generally undergo a process including an initial file review, opportunity for public comment, scientific review, and a regulatory decision.¹⁵⁵ Qualified claims may be used on any food product meeting the specifications in the approval letter, and therefore, are more similar to the “substantially equivalent” standard used in the premarket notification process in *Lohr*.¹⁵⁶ Since each individual qualified health claim may not be reviewed and approved by the FDA, qualified health claims would not be considered federal “requirements.” In summary, approved health claims are likely to be considered federal “requirements” and would preempt state claims, but qualified health claims would not be considered federal “requirements.”

C. Structure-Function Claims

A structure-function claim states the benefit that the food or food component will provide to the human body.¹⁵⁷ An example of a structure-function claim is “calcium builds strong bones.”¹⁵⁸ Structure-function claims on dietary supplement labels must notify the FDA within thirty days of marketing the dietary supplement and must state a disclaimer that the FDA has not reviewed the claim.¹⁵⁹ General food manufacturers do not have to notify the FDA of their structure-function claims.¹⁶⁰ Structure-function claims are not regulated by the FDA and are one of the “most deceptive” claims used today.¹⁶¹ Since structure-function claims are not

¹⁵¹ *Id.*

¹⁵² 21 U.S.C.A. § 343(r) (West 2012); 21 U.S.C.A. § 343-1 (West 2012).

¹⁵³ 21 U.S.C.A. § 343(r) (West 2012); *Is it Really FDA Approved?*, *supra* note 135.

¹⁵⁴ *See* 21 U.S.C.A. § 343-1 (West 2012).

¹⁵⁵ *Guidance for Industry: Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements*, U.S. FOOD & DRUG ADMIN. (Jul. 2003), <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm053832.htm>.

¹⁵⁶ *Medtronic Inc. v. Lohr*, 518 U.S. 470, 493 (1996); *Is it Really FDA Approved?*, *supra* note 135.

¹⁵⁷ *Is it Really FDA Approved?*, *supra* note 135.

¹⁵⁸ *Id.*

¹⁵⁹ *Id.*

¹⁶⁰ *Id.*

¹⁶¹ *See FOOD LABELING CHAOS*, *supra* note 1.

regulated, they would not be found to be a federal “requirement” under *Lohr* so state claims would not be preempted.

D. Nutrient Content Claims

Nutrient content claims “characterize the level of a nutrient in a food” using terms such as “free, high, or low,” or they compare the nutrient levels to other foods by saying “more, reduced, and light.”¹⁶² The term “healthy” is also considered a nutrient content claim and can only be made if it meets the definition in the regulation.¹⁶³ A claim stating “only 200 mg of sodium” is also considered a nutrient content claim because it characterizes the sodium level as being “low.”¹⁶⁴ Nutrient content claims are subject to a premarket approval process and extensive FDA regulations defining commonly used terms.¹⁶⁵ Under § 343(r), a food is misbranded if “a claim is made in the label or labeling of the food which expressly or by implication characterizes the level of any nutrient” unless “the characterization of the level made in the claim uses terms which are defined in regulations.” Nutrient content claims are regulated under § 343(r)(1)(A), to which the express preemption provision, § 343-1(a)(5), specifically applies.¹⁶⁶

Nutrient content claims would be considered federal “requirements” because of the premarket approval process and extensive FDA regulations. If the FDA made a regulation defining the term “natural,” it would likely be considered a voluntary nutrient content claim.¹⁶⁷ As a nutrient content claim, “natural” would be a federal “requirement” under *Riegel* and state requirements that are not identical would be preempted.

E. Food Additives Claims

Under 21 USC § 321(s) of the FDCA, a food additive is “any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food.” Food additive claims may be preempted if they are an artificial flavoring or chemical preservative under § 343-1(a)(3) and if state claims are not identical to § 343(k).¹⁶⁸ The FDA specifies the conditions for the approval of food additives in regulations

¹⁶² *Id.*

¹⁶³ *Id.*

¹⁶⁴ *Id.*

¹⁶⁵ *Id.*

¹⁶⁶ 21 U.S.C. § 343-1 (2010).

¹⁶⁷ See Farris, *supra* note 13, at 415.

¹⁶⁸ 21 U.S.C. § 343-1(a)(3) (2010).

published in the Federal Register.¹⁶⁹ New food additives are subject to premarket approval, and the manufacturers have the burden to prove that the additives are safe.¹⁷⁰ FDA experts review the safety results to ensure “the additive is safe for its intended use.”¹⁷¹ In addition to premarket approval, FDA field investigators inspect food companies and collect samples; laboratory scientists analyze the samples; and compliance officers follow through on enforcement of legal issues.¹⁷² Even substances not intended to be added to food, but “migrate” to food, are considered new food additives and are subject to safety review.¹⁷³ Existing food additives with a history of safety, referred to as Generally Recognized as Safe (GRAS) substances, are not subject to premarket approval.¹⁷⁴

Regulations concerning new food additives are subject to premarket approval and would therefore be considered a federal “requirement” under *Riegel*.¹⁷⁵ Similar to the “rigorous” premarket approval in *Riegel*, the premarket approval of food additives is reviewed by FDA examiners to ensure safety and compliance with the regulations and is enforced.¹⁷⁶ Premarket approval of food additives can require toxicology review, chemistry review, and environmental review, and toxicology review alone can take up to 4,500 hours.¹⁷⁷ The court considered premarket approval for medical devices a federal “requirement” when it required 1,200 hours of review.¹⁷⁸ Additionally, food additive labels must comply with the specifications in the approved application so the manufacturer does not have unilateral control over changes to the label.¹⁷⁹ Food additive regulations are a federal “requirement” because of the large extent of premarket approval ensuring the safety of the food product, and therefore, they preempt state law causes of action.

GRAS substances are not subject to premarket approval, but the application requires the same amount of information as new food additives.¹⁸⁰ The GRAS notification program is voluntary and the FDA

¹⁶⁹ Antonia Mattia & Robert Merker, *Regulation of Probiotic Substances as Ingredients in Foods: Premarket Approval or “Generally Recognized as Safe” Notification* (U.S. Food & Drug Admin., College Park, MD), 2008, available at <http://www.law.umaryland.edu/programs/health/events/probiotics/documents/mattiamerker.pdf>.

¹⁷⁰ *Is it Really FDA Approved?*, *supra* note 135.

¹⁷¹ *Id.*

¹⁷² *Id.*

¹⁷³ *Id.*

¹⁷⁴ *Id.*

¹⁷⁵ *Id.*

¹⁷⁶ Mattia & Merker, *supra* note 168.

¹⁷⁷ See RESEARCH TRIANGLE INST. CTR. FOR ECON. RESEARCH, RESOURCE EVALUATION OF THE FDA FOOD ADDITIVE PETITION PROCESS (Jul. 1998) [herein after RESOURCE EVALUATION], available at <http://aspe.hhs.gov/health/reports/food.pdf>.

¹⁷⁸ See *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 474 (1996).

¹⁷⁹ *Is it Really FDA Approved?*, *supra* note 135.

¹⁸⁰ RESOURCE EVALUATION, *supra* note 176.

does not make the safety decision.¹⁸¹ The manufacturer makes the safety decision instead of the FDA, causing it to be similar to the premarket notification in *Lohr*, which does not guarantee safety.¹⁸² Since the program is voluntary and not subject to premarket approval, GRAS substance regulations would not be considered a federal “requirement” and thus federal law preempts state law claims.¹⁸³

F. Color Additive Claims

Color additive claims could also be expressly preempted by § 343(k) if they claim that a food product contains artificial coloring. Color additives are subject to premarket approval, and “must be used in compliance with its approved uses, specifications, and restrictions.”¹⁸⁴ During the approval process, the FDA evaluates the safety of the food.¹⁸⁵

There are multiple FDA regulations concerning disclosure of color additives. Under the FDCA, a food is misbranded “if it bears or contains any...artificial coloring...unless it’s labeling states that fact.”¹⁸⁶ The use of a color additive must be disclosed through phrases such as “artificial color,” “artificial color added,” or “color added,” and the disclosure must be located on the food, its container, or on its wrapper.¹⁸⁷ Food ingredients are considered a color additive under 21 U.S.C. § 70.3(f) if the “customary or reasonably foreseeable” expected result is to transplant color, and the food ingredient was “deliberately used as a color.”¹⁸⁸ Color additives do not have a GRAS exception, and therefore, all color additives are subject to premarket approval unless they are “used solely for a purpose other than coloring.”¹⁸⁹ The improper use of a listed color additive or use of an unlisted color additive can cause a product to be considered adulterated, and the FDA can take enforcement action against adulterated products.¹⁹⁰

Color additive regulations concerning “artificial coloring” would be considered a federal “requirement” because they are subject to premarket approval and must comply with the specifications in the application.¹⁹¹ At least ten analyses are performed on a color additive sample submitted to the

¹⁸¹ *Id.*

¹⁸² See generally *Lohr*, 518 U.S. 470.

¹⁸³ 21 U.S.C. § 343(k) (2011).

¹⁸⁴ Julie N. Barrows et al., *Color Additives: FDA’s Regulatory Process and Historical Perspectives*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/ForIndustry/ColorAdditives/RegulatoryProcessHistoricalPerspectives/default.htm> (last updated Dec. 17, 2009).

¹⁸⁵ Mattia & Merker, *supra* note 168 at S116.

¹⁸⁶ *In re Farm Raised Salmon Cases*, 175 P.3d 1170, 1175 (Cal. 2008) (quoting 21 U.S.C. § 343(k) (2011)).

¹⁸⁷ *Id.* at 1174-75 (quoting 21 U.S.C. §§ 101.22(k)(2),(c) (2011)).

¹⁸⁸ 21 C.F.R. § 70.3(f) (2012).

¹⁸⁹ Barrows et al., *supra* note 183.

¹⁹⁰ *Id.*

¹⁹¹ *Is it Really FDA Approved?*, *supra* note 135.

FDA for premarket approval.¹⁹² The premarket approval process ensures the food product is safe, and there are also more specific FDA regulations.¹⁹³ Color additive claims that include artificial coloring would likely be considered a federal “requirement” under *Riegel* and would be expressly preempted.

VII. LIKELIHOOD OF CONSUMER CONFUSION OF FOOD PRODUCT LABELS

Whether consumers actually rely on claims made on the label influences the outcome of the lawsuits. A recent study by the FDA found, when purchasing a food product for the first time, 54% of consumers claim they read the food label, and 91% of consumers are cognizant of the connection between proper nutrition and the risk of diet-related disease.¹⁹⁴ However, consumers are more skeptical of Nutrient Content Claims with 56% believing that “some or none of them are accurate.”¹⁹⁵

Consumers’ skepticism is most likely caused by the current FDA regulations that are out of date and not enforced.¹⁹⁶ Despite the fact that premarket approval is required by the NLEA for Health Claims, the FDA “essentially adopted a policy of non-enforcement” during the Bush Administration.¹⁹⁷ Premarket approval for Nutrient Content Claims has not kept up with recent scientific developments, and the regulations need to be updated.¹⁹⁸ In 2009, even the FDA Commissioner stated the food labels are essential to aiding consumers’ healthy nutrition but regulations have not been “substantially addressed” since the NLEA was enacted.¹⁹⁹ The Center for Science in the Public Interest recommends the FDA implement regulations prohibiting structure-function claims, require general food labeling claims such as those stating “made with whole wheat” to also describe the percent of the claim, and define the term “natural” through regulation.²⁰⁰ If the FDA improves its regulations and premarket approval processes, more of the food labeling claims discussed above should be found to be preempted by federal law through the recommended two-step approach.

¹⁹² Barrows et al., *supra* note 183.

¹⁹³ *Is it Really FDA Approved?*, *supra* note 135.

¹⁹⁴ *Survey Shows Gains in Food-Label Use, Health/Diet Awareness*, U.S. FOOD & DRUG ADMIN. (Mar. 2, 2010), <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm202611.htm>.

¹⁹⁵ *Id.*

¹⁹⁶ *FOOD LABELING CHAOS*, *supra* note 1, at I-3, I-4.

¹⁹⁷ *Id.* at I-4.

¹⁹⁸ *Id.*

¹⁹⁹ *Id.* at I-2.

²⁰⁰ *Id.* at vii.

VIII. CONCLUSION

To determine express preemption, courts should apply the two-step approach similar to the U.S. Supreme Court analysis in *Riegel*. Courts should first determine whether a food labeling regulation is a federal “requirement,” and should then determine whether the state claim is identical to the federal “requirement.” In determining whether an FDA regulation is a federal “requirement,” courts should consider the level of premarket approval employed by the FDA. Without a clear definition of the term “natural” or an official policy by the FDA, it is likely that “natural” food labels will be considered a general food-labeling claim that does not impose a federal “requirement.” Therefore, claims alleging that a food product label is false and misleading because it is not “natural,” such as the claims alleged against Kellogg’s Kashi brand, would not be expressly preempted under the recommended two-step approach. Furthermore, federal law should not preempt state claims regarding general food labeling and structure-function. If the state law does not impose identical requirements to federal law, federal law should preempt health claims, nutrient content claims, color additive claims based on artificial color, and food additive claims based on artificial flavoring and chemical preservatives. This recommended approach will provide consistency for courts when analyzing whether state claims of a false and misleading food label are preempted by the FDCA.

