

PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 08-3060

STACY HOLK,
Appellant

v.

SNAPPLE BEVERAGE CORPORATION

On Appeal from the United States District Court
for the District of New Jersey
District Court No. 3-07-cv-03018
District Judge: The Honorable Mary L. Cooper

Argued June 24, 2009

Before: BARRY, SMITH, *Circuit Judges*
and RESTANI, *Judge**

*The Honorable Jane A. Restani, Chief Judge of the United States Court of International Trade, sitting by designation.

(Filed: August 12, 2009)

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OPINION

SMITH, *Circuit Judge*.

This appeal presents three issues related to the federal preemption of state causes of action. Plaintiff-appellant Stacy Holk brought several state law claims against defendant-appellee the Snapple Beverage Corporation in the Superior Court of New Jersey. After removing Holk’s lawsuit to the United States District Court for the District of New Jersey, Snapple sought to dismiss Holk’s complaint on, *inter alia*, the grounds of express preemption, implied field preemption, and implied conflict preemption. The District Court granted Snapple’s motion on the basis of implied preemption. For the reasons discussed below, we will reverse.

I.

A.

Congress has regulated food and beverage labeling for more than 100 years. In 1906, it passed legislation commonly known as the “Wiley Act” that established labeling standards. Pure Food and Drug Act of 1906, Pub. L. No. 59-384, 34 Stat. 768, *repealed by* Act of June 25, 1938, ch. 675, § 902(a), 52 Stat. 1059. At the time, the Wiley Act was considered a substantial reform because it prohibited the adulteration and misbranding of food sold and distributed in interstate commerce. Pub. L. No. 59-384, §§ 7–8. By today’s standards, however, the Wiley Act offered only modest reforms: it “enabled the

Government to go to court against illegal products but lacked affirmative requirements to guide compliance. Labels were not even required to state the weight or measure—only that a contents statement, if used, must be truthful.” U.S. Food and Drug Administration, *The Story of the Laws Behind the Labels, Part II* (1981).

Congress replaced the Wiley Act in 1938 with the Federal Food, Drug, and Cosmetic Act (“FDCA”). Pub. L. No. 75-717, 52 Stat. 1040 (1938). Mounting public concern over unsafe food and drug products and marketing prompted its passage. *United States v. Bhutani*, 266 F.3d 661, 665 (7th Cir. 2001). The FDCA authorized the Food and Drug Administration (“FDA”) to regulate food safety and labeling. *Fellner v. Tri-Union Seafoods, L.L.C.*, 539 F.3d 237, 251 (3d Cir. 2008). Specifically, under the FDCA, the FDA could “promulgate food definitions and standards of food quality;” “set tolerance levels for poisonous substances in food;” and take enforcement action on adulterated and misbranded foods. *Id.* The FDCA had its shortcomings, however. Neither the FDCA nor FDA regulations required detailed nutritional information on all food labels. Emily J. Schaffer, *Is the Fox Guarding the Henhouse? Who Makes the Rules in American Nutrition Policy?*, 57 Food & Drug L.J. 371, 404 (2002). In fact, nutrition labeling was required only if the manufacturer made a nutrition claim about the product such as “low-fat” or “high in fiber.” *Id.*

In response to growing concerns from consumer groups about unsubstantiated health claims on food and beverages, the FDA and Congress began considering a national labeling law. Claudia L. Andre, Note, *What's in that Guacamole? How Bates and the Power of Preemption Will Affect Litigation Against the Food Industry*, 15 Geo. Mason L. Rev. 227, 232 (2007). In 1990, Congress passed the Nutrition Labeling and Education Act ("NLEA"). Pub. L. No. 101-535, 104 Stat. 2353 (1990) (codified at 21 U.S.C. § 343 *et seq.*). NLEA introduced a number of substantial reforms: (1) it required nutrition labeling for nearly all food products under the authority of the FDA, with exemptions for small businesses, restaurants, and some other retail establishments; (2) it changed the requirements for ingredient labels on food packages; (3) it imposed and regulated health claims on packages; (4) it standardized all nutrient content claims; and (5) it standardized serving sizes. *The Impact of the Nutrition Labeling and Education Act of 1990 on the Food Industry*, 47 Admin. L. Rev. 605, 606 (1995).

B.

Snapple Beverage Corporation ("Snapple") manufactures a variety of beverages, including a number of juice and tea-based drinks. In its marketing and advertising materials, Snapple represents that these beverages are "All Natural." As the FDA has acknowledged, "[t]he word 'natural' is often used to convey that a food is composed only of substances that are not manmade and is, therefore, somehow more wholesome."

Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms, 56 Fed. Reg. 60,421, 60,466 (Nov. 27, 1991). Snapple products, however, contained high fructose corn syrup (“HFCS”), an ingredient manufactured from processed cornstarch.¹

Stacy Holk bought two bottles of Snapple on May 4, 2007. She paid \$1.09 for each bottle. She had purchased other Snapple products over the preceding six years. Holk contends that the labels on these products are deceptive. She argues that consumers “have been, and continue to be, easy prey for Snapple’s unlawful activities because of their willingness to pay a premium price for foods and beverages, including Snapple beverages, that are represented to be ‘All Natural.’”

C.

Holk filed a class action lawsuit against Snapple in the Superior Court of New Jersey, asserting claims on the basis of: (I) the New Jersey Consumer Fraud Act; (II) unjust enrichment and common law restitution; (III) breach of express warranty; and (IV) breach of the implied warranty of merchantability. Holk’s claims were predicated on her belief that a number of statements on Snapple’s labels were misleading. She argued

¹At the time of Holk’s suit, Snapple products contained HFCS. In late 2008, Snapple announced that it was reformulating its lineup of beverages and replacing HFCS with sugar in its beverages. *See, e.g., Betsy McKay, Snapple Introduces Snappier Look, New Formula—Beverage Brand to Emphasize Tea’s Health Benefits Amid Weaker U.S. Sales; Sugar Will Be Added to Improve Drinks’ Flavor*, Wall St. J., Nov. 14, 2008, at B4.

that (1) Snapple products were not “All Natural” because they contained HFCS; (2) Snapple products were not “Made from the Best Stuff on Earth,” as indicated on the label; and (3) Snapple falsely labeled some beverages, for example, calling one drink “Acai Blackberry Juice,” despite the fact that the drink contained neither acai berry juice nor blackberry juice.

Snapple removed the case to the United States District Court for the District of New Jersey pursuant to the Class Action Fairness Act, 28 U.S.C. 1453(b). It then filed a motion to dismiss. The parties subsequently agreed that Holk could amend her complaint, rather than respond to Snapple’s motion. In October 2007, Holk filed an Amended Complaint, which reasserted that Snapple’s labels were misleading because they claimed the products were “All Natural” and because Snapple advertised some products as containing juice that was not in the beverages. The Amended Complaint did not allege any claims based on Snapple’s use of the phrase “Made From the Best Stuff on Earth.” Snapple filed a second motion to dismiss, arguing that Holk’s claims were preempted, that the claims should be dismissed under the doctrine of primary jurisdiction, and that the allegations failed to state a claim. Holk responded by dropping the argument related to the juice components of Snapple beverages, leaving only the claim that Snapple products containing HFCS were deceptively labeled “All Natural.”

The District Court heard oral argument on Snapple’s motion to dismiss in June 2008. On June 12, 2008, the District

Court dismissed Holk’s complaint. It held that Snapple’s claims were preempted. In its opinion, the District Court correctly identified and discussed the three types of preemption. It also noted that Snapple argued that all three types of preemption were present in this case, as Snapple contended that (1) NLEA expressly preempted state labeling requirements that are not identical to federal requirements; (2) the comprehensive nature of the FDCA and its implementing regulations demonstrate that Congress intended the federal government to occupy the field; and (3) that state law stands as an obstacle to the purposes underlying the FDCA. Next, the District Court rejected Snapple’s express preemption argument, stating that there was not “specific preemptive language” in the FDCA that covered the claims. Nonetheless, the Court ruled that “Plaintiff’s claims in this case are impliedly preempted by the detailed and extensive regulatory scheme established by the [FDCA] and the FDA’s implementing regulations.”

The District Court stated that the FDA has used the broad authority granted to it under the FDCA to issue comprehensive regulations governing the labeling and naming of juice drinks. The Court declared that the comprehensive nature of these regulations demonstrate that “the FDA has carefully balanced beverage industry and consumer interests and created a complex regulatory framework to govern beverage labeling.” Though it acknowledged that the FDA has not defined “natural,” it found that the “FDA has in fact contemplated the appropriate use of the term,” as indicated by the FDA’s definition of “natural

flavor” and its informal policy regarding use of the term “natural.” The Court also noted that the FDA has the authority to enforce the FDCA and regulations issued pursuant to it. In the Court’s view, these factors counseled in favor of its conclusion “that the [FDCA] and FDA regulations so thoroughly occupy the field of beverage labeling at issue in this case that it would be unreasonable to infer that Congress intended states to supplement this area.”

Finally, the District Court deferred to the agency’s expertise in the regulation of food and beverages. It asserted that it would be inappropriate for the Court to set rules, which the FDA “with all of its scientific expertise” has not yet done. Thus, the District Court concluded that the claims were “impliedly preempted” because “permitting states through statutes or common law causes of action to impose additional limitations and requirements on beverage labels such as described here would create obstacles to the accomplishment of Congress’s objectives”²

Holk filed this timely appeal.

²Because the District Court found that Holk’s claims were preempted, it did not address Snapple’s primary jurisdiction argument or whether Holk’s complaint stated a claim for relief under New Jersey law.

II.

The District Court had jurisdiction under 28 U.S.C. § 1332(d), the Class Action Fairness Act. This Court has jurisdiction pursuant to 28 U.S.C. § 1291. Our review of a district court’s ruling on a motion to dismiss is plenary. *Evancho v. Fisher*, 423 F.3d 347, 350 (3d Cir. 2005). When reviewing the District Court’s decision, we must “accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief.” *Phillips v. County of Allegheny*, 515 F.3d 224, 231 (3d Cir. 2008) (quoting *Pinker v. Roche Holdings Ltd.*, 292 F.3d 361, 374 n.7 (3d Cir. 2002)).

III.

Snapple argues that the District Court’s dismissal must be upheld “whether analyzed under the doctrine of express preemption, implied ‘field’ preemption, or implied ‘obstacle’ preemption.” The preemption doctrine is rooted in Article VI of the United States Constitution, which states that the laws of the United States “shall be the supreme Law of the Land; . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.” U.S. Const. art. VI, cl. 2. Under the Supremacy Clause, federal law may be held to preempt state law where any of the three forms of preemption doctrine may be properly applied: express preemption, field preemption, and

implied conflict preemption. *Hillsborough County, Fla., v. Automated Med. Labs., Inc.*, 471 U.S. 707, 713 (1985). We are guided in our preemption analysis “by the rule that ‘[t]he purpose of Congress is the ultimate touchstone in every preemption case.’” *Altria Group, Inc. v. Good*, 129 S. Ct. 538, 543 (2008) (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)).

Additionally, we must begin our analysis by applying a presumption against preemption. *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992). “In areas of traditional state regulation, we assume that a federal statute has not supplanted state law unless Congress has made such an intention clear and manifest.” *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005) (internal quotation marks omitted). This requires that, if confronted with two plausible interpretations of a statute, we “have a duty to accept the reading that disfavors pre-emption.” *Id.*; see also *Wyeth v. Levine*, 129 S. Ct. 1187, 1195 (2009); *Cipollone*, 505 U.S. at 518.

Health and safety issues have traditionally fallen within the province of state regulation. This is true of the regulation of food and beverage labeling and branding. *Plumley v. Massachusetts*, 155 U.S. 461, 472 (1894) (“If there be any subject over which it would seem the states ought to have plenary control . . . it is the protection of the people against fraud and deception in the sale of food products.”). The federal government did not begin to regulate the labeling of food

products until 1906, when Congress passed the Wiley Act. Nonetheless, Snapple argues that the presumption against preemption should not be applied “because of the century-long tradition of federal regulation over food and beverage misbranding, and the expansive scheme of juice-beverage labeling regulation in particular.” The Supreme Court, however, rejected a similar argument in *Levine* and applied the presumption. 129 S. Ct. at 1195 & n.3. Accordingly, all of Snapple’s preemption arguments must overcome the presumption against preemption, as food labeling has been an area historically governed by state law.

A.

Snapple argues that Holk’s state law claims are expressly preempted by NLEA, specifically 21 U.S.C. § 343-1(a)(3). As a threshold matter, however, we must consider whether this issue is properly before us. As stated above, Holk initially argued that Snapple’s labels were misleading on several grounds, namely because Snapple claimed the products were “All Natural” despite containing HFCS and because Snapple advertised some products as containing juice that was not in the beverages. Holk subsequently dropped the argument related to the juice contents of certain Snapple beverages. This prompted Snapple to concede, during oral argument before the District Court, that it was no longer arguing express preemption: “[T]here’s only one preemption argument left because of the dropping of the juice claims. . . . There was expressed [sic]

preemption, there was implied field preemption, and now there's implied obstacle preemption. And it's implied obstacle preemption that applies to the high fructose corn syrup natural claims." Yet, on appeal, Snapple again raises express preemption.

Holk argues that because Snapple did not raise express preemption before the District Court in relation to her HFCS argument, Snapple has waived its express preemption argument. Snapple counters that "[w]here a new ground would support affirmance, this Court may invoke it so long as it is supported by the record."

First, we note that the District Court did not rule in Snapple's favor on express preemption. The Court stated that it "agrees with Plaintiff that Congress has not explicitly preempted Plaintiff's claims by inserting any specific preemptive language into the [FDCA]" It also noted that "Snapple's express preemption arguments were directed at Plaintiff's claims concerning the fruit juices contained in Snapple beverages, which Plaintiff has withdrawn." Because the District Court did not rule in Snapple's favor on its express preemption argument, we do not have an express preemption claim to affirm.

Second, Snapple is correct that this Court has held that "we may affirm a correct decision of the district court on grounds other than those relied upon by the district court."

Cent. Pa. Teamsters Pension Fund v. McCormick Dray Line Inc., 85 F.3d 1098, 1107 (3d Cir. 1996); *see also Helvering v. Gowran*, 302 U.S. 238, 245 (1937) (“In the review of judicial proceedings the rule is settled that, if the decision below is correct, it must be affirmed, although the lower court relied upon a wrong ground or gave a wrong reason.”) However, this rule does not apply to cases in which the party has waived the issue in the district court. This Court has stated: “We may affirm the lower court’s ruling on different grounds, provided the issue which forms the basis of our decision was before the lower court.” *Morse v. Lower Merion Sch. Dist.*, 132 F.3d 902, 904 n. 1 (3d Cir. 1997) (citing *Mark v. Borough of Hatboro*, 51 F.3d 1137, 1139 n.1 (3d Cir. 1995)); *see also Exxon Shipping Co. v. Baker*, 128 S. Ct. 2605, 2616–18 (2008) (stating that an appellate court’s “reasons for reaching” an untimely express preemption argument “do not hold up” and that appellate courts usually will not and should not hear untimely preemption arguments); *Bailey v. Dart Container Corp. of Mich.*, 292 F.3d 1360, 1362 (Fed. Cir. 2002) (“[A]n appellee can present in this court all arguments supported by the record *and advanced in the trial court* in support of the judgment as an appellee, even if those particular arguments were rejected or ignored by the trial court.” (emphasis added)).

We conclude that Snapple has waived its express preemption argument with regard to Holk’s HFCS claims. Though Snapple contended in its two motions to dismiss that Holk’s juice content claims were expressly preempted by 21

U.S.C. § 343-1(a)(3), it did not raise this provision with regard to Holk’s HFCS claim. In fact, it did not raise *any* express preemption argument in response to the HFCS claim and explicitly disclaimed the applicability of express preemption to this claim. This clearly demonstrates that the issue was not before the District Court. For this reason, we conclude that the issue is waived.³

B.

Field preemption occurs when state law occupies a “field reserved for federal regulation,” leaving no room for state regulation. *United States v. Locke*, 529 U.S. 89, 111 (2000). It may also be inferred when “an Act of Congress ‘touch[es] a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on

³Because we find that Snapple has waived its express preemption argument, we will not reach the merits of this issue. However, we note that the FDA appears to consider HFCS a sweetener and not a flavoring, and thus the allegedly troublesome federal statute, § 343(k), would be inapplicable. *See, e.g.*, 21 C.F.R. § 184.1866; Committee on Food Chemicals Codex, Institute of Medicine, *Food Chemical Codex* 191–92 (4th ed. 1996). Additionally, § 343(k) is a disclosure requirement—*i.e.*, it regulates only what companies must place on a label. Holk’s claims go to what a company cannot put on a label for the purposes of commercial marketing, an important distinction.

the same subject.” *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). Nonetheless, for field preemption to be applicable, “congressional intent to supersede state laws must be ‘clear and manifest.’” *Id.* (citation omitted). Snapple asserts that Holk’s claims are preempted because federal law occupies both the field of beverage regulation and the field of juice drinks regulation.

First, we note that NLEA declares that courts may not find implied preemption based on any provision of NLEA. It states that the Act “shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under [21 U.S.C. § 343-1] of the Federal Food, Drug, and Cosmetic Act.” Pub. L. No. 101-535, § 6(c)(1). Accordingly, if we are to find that Holk’s claims are impliedly preempted, we must do so based on provisions of federal law other than NLEA.⁴

⁴NLEA expressly preserves implied preemption claims based on other provisions of federal law. It states that the provision prohibiting implied preemption based on NLEA:

shall not be construed to affect preemption, express or implied, of any such requirement of a State or political subdivision, which may arise under the Constitution, any provision of the Federal Food, Drug, and Cosmetic Act not amended by [NLEA’s preemption provision

Given this limitation, Snapple argues that the FDCA, pre-NLEA, broadly addressed labeling and the misbranding of food and beverage products.⁵ Snapple has also argued, both in its brief and during oral argument, that the FDA has promulgated, pursuant to its authority under the FDCA, “exhaustive” regulations regarding juice products in particular. Finally,

subsection], any other Federal law, or any Federal regulation, order, or other final agency action . . .

Pub. L. No. 101-535, § 6(c)(3).

⁵Though Snapple raised field preemption in its memorandum in support of its motion to dismiss the plaintiff’s amended complaint, and this argument was not particularized to Holk’s juice claims, Snapple disavowed the application of field preemption to Holk’s HFCS claim during oral argument before the District Court. Nevertheless, Holk has not put Snapple’s oral argument waiver before us.

We have held that “[a]n issue is waived unless a party raises it in its opening brief, and for those purposes a passing reference to an issue . . . will not suffice to bring that issue before this court.” *Laborers’ Int’l Union v. Foster Wheeler Corp.*, 26 F.3d 375, 398 (3d Cir. 1994) (internal quotation marks omitted). Holk did not argue in any of her briefs that Snapple waived its field preemption argument. She did not list the field preemption issue in her statement of issues, nor did she make any mention of this issue in the argument section of her opening or reply briefs. This failure is particularly noteworthy given that Holk directly challenged the District Court’s conclusions regarding field preemption. Furthermore, during oral argument before us, Holk’s counsel conceded that Holk was not arguing waiver with regard to Snapple’s field preemption claims. Accordingly, we will consider the merits of Snapple’s field preemption arguments.

Snapple asserts that the FDA has addressed HFCS and declared it to be “natural.” Snapple submits that “[f]ederal law thus comprehensively regulates misbranding of food in general, juice beverages in particular, the distinction between natural and artificial, and even the specific question of whether HFCS can be ‘natural.’” For this reason, Snapple maintains that the District Court’s analysis was correct.

Holk argues that the field in this case is not juice regulation, but rather food and beverage labeling. She contends that NLEA forecloses the implied preemption of state law in the food and beverage field. She reasons that the limited nature of the express preemption provision in NLEA, which applies only to those federal laws specifically enumerated, “would serve no purpose and would simply be surplus if Congress had intended to occupy the entire field of food and beverage labeling.” She also cites NLEA’s legislative history to demonstrate that Congress intended to preserve state authority in the food and beverage labeling field.

As discussed briefly above, field preemption requires a demonstration that “Congress . . . left no room for state regulation of these matters.” *Locke*, 529 U.S. at 111; *see also Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 541 (2001). It does not appear that Congress has regulated so comprehensively in either the food and beverage or juice fields that there is no role for the states. First, there was no express preemption provision in the FDCA prior to enactment of the NLEA. *See*

Levine, 129 S. Ct. at 1200 (recognizing the absence of an express preemption provision in the FDCA); *see also* Lars Noah, *The Imperative to Warn: Disentangling the “Right to Know” from the “Need to Know” about Consumer Product Hazards*, 11 Yale J. on Reg. 293, 351 (1994) (“The [FDCA] contains no general preemption provision.”). Thus, we are lacking a “clear and manifest” expression of Congressional intent to occupy either field.

Second, as Holk argues, NLEA’s express preemption provision demonstrated that Congress recognized the existence of state laws relating to beverages generally and juice products specifically. *See, e.g.*, 21 U.S.C. § 343-1(a)(2) (preempting state laws that conflict, *inter alia*, with federal law requiring foods to indicate: (1) the name and location of the manufacturer, as well as the weight or quantity of food contained in a package; and (2) the percentage of fruit or vegetable juice contained in a beverage). NLEA plainly states that the Act “shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under [21 U.S.C. § 343-1] of the Federal Food, Drug, and Cosmetic Act.” Pub. L. No. 101-535, § 6(c)(1). Furthermore, NLEA declares that its express preemption provision “shall not be construed to apply to any requirement respecting a statement in the labeling of food that provides for a warning concerning the safety of the food or component of the food,” thereby preserving state warning laws. Pub. L. No. 101-535, § 6(c)(2). These provisions demonstrate that Congress was cognizant of the operation of state law and

state regulation in the food and beverage field, and it therefore enacted limited exceptions in NLEA. As the Supreme Court instructed in *Levine*, “[t]he case for federal pre-emption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to stand by both concepts and to tolerate whatever tension there [is] between them.” 129 S. Ct. at 1200 (quoting *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 166–67 (1989)).

Furthermore, we note that the FDA has stated that it does not intend to occupy the field of food and beverage labeling, even with regard to regulations affecting juice products. *See Levine*, 129 S. Ct. at 1201 (recognizing that the Supreme Court has “attended to an agency’s explanation of how state law affects the regulatory scheme”). In a final rule published in 1986 concerning sulfiting agents, a substance present in some juice drinks, the FDA responded to a comment that it should adopt a policy that would result in the preemption of state law with regard to the labeling of food products containing sulfites. Food Labeling; Declaration of Sulfiting Agents, 51 Fed. Reg. 25,012, 25,016 (July 9, 1986). There, the FDA stated: “The agency does not use its authority to preempt State requirements unless there is a genuine need to stop the proliferation of inconsistent requirements between the FDA and the States. FDA is not persuaded that such a need now exists with regard to sulfite labeling.” *Id.* Similarly, in two proposed rules regarding nutrition labeling on food and beverage products, the FDA

acknowledged the receipt of numerous comments that urged the FDA to explicitly preempt contrary state labeling regulations. Food Labeling; Mandatory Status of Nutrition Labeling and Nutrient Content Revision, 55 Fed. Reg. 29,487, 29,509 (July 19, 1990) (seeking to amend the nutrition label as it pertains to the listing of nutrients); Food Labeling; Serving Sizes, 55 Fed. Reg. 29,517, 29,528 (July 19, 1990) (seeking to amend the nutrition label as it pertains to serving size). In both cases, the FDA responded:

The preemption issue is complex and divisive: whether a uniform, national label is necessary for consumers and manufacturers to function in the marketplace versus whether States should be permitted to require additional information for their residents. The input of States, as well as consumers, businesses, and other concerned parties is essential in evaluating this matter. FDA therefore requests comment on the issue of whether preemption is appropriate.

Food Labeling; Mandatory Status of Nutrition Labeling and Nutrient Content Revision, 55 Fed. Reg. at 29,509; Food Labeling; Serving Sizes, 55 Fed. Reg. at 29,528.

Finally, we are reluctant to find field preemption predicated solely on the comprehensiveness of federal regulations. The Supreme Court has repeatedly stated that “the

mere existence of a federal regulatory scheme,” even a particularly detailed one, “does not by itself imply pre-emption of state remedies.” *English*, 496 U.S. at 87; *see also Hillsborough County, Fla.*, 471 U.S. at 717. To conclude otherwise would be “virtually tantamount to saying that whenever a federal agency decides to step into a field, its regulations will be exclusive.” *Hillsborough County, Fla.*, 471 U.S. at 717.

In the instant case, not only do we lack a “clear and manifest” statement from Congress of its intent to preempt, but we also note that the claims in this case are governed by the presumption against preemption. These factors, along with the Supreme Court’s direction that we should not infer field preemption from the comprehensiveness of a regulatory scheme alone, lead us to conclude that neither Congress nor the FDA intended to occupy the fields of food and beverage labeling and juice products.

C.

Implied conflict preemption is present when it is “impossible for a private party to comply with both state and federal requirements.” *English*, 496 U.S. at 78–79. Alternatively, conflict preemption results when state law “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.” *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941). With regard to the latter,

“[i]f the purpose of the act cannot otherwise be accomplished—if its operation within its chosen field else must be frustrated and its provisions be refused their natural effect—the state law must yield to the regulation of Congress within the sphere of its delegated power.” *Id.* at 67 n.20 (quoting *Savage v. Jones*, 225 U.S. 501, 533 (1912)). Both federal statutes and regulations have the force of law and can preempt contrary state law. *See, e.g., Levine*, 129 S. Ct. at 1200 (“This Court has recognized that an agency regulation with the force of law can pre-empt conflicting state requirements.”); *Fellner v. Tri-Union Seafoods, L.L.C.*, 539 F.3d 237, 243 (3d Cir. 2008) (“Where Congress has delegated the authority to regulate a particular field to an administrative agency, the agency’s regulations issued pursuant to that authority have no less preemptive effect than federal statutes . . .”).

Snapple submits that Holk’s claims are preempted because they stand as an obstacle to federal law. It contends that the FDA has adopted a policy regarding the use of the term “natural” and that this policy would be undermined by Holk’s suit. Specifically, it alleges that liability in Holk’s suit would result in the imposition of “additional conditions not contemplated by the federal regime.” Additionally, Snapple argues that state law must yield if it undermines federal efforts to create uniform standards.

Holk counters that her state causes of action do not serve as an obstacle to federal objectives because there “are no federal

requirements in place regarding the term ‘natural.’” She also asserts that her claims do not conflict with federal law because, even if she obtained a favorable verdict, Snapple would not be required to undertake a specific corrective action.

To determine whether Holk’s claims present an obstacle to federal law, we must as an initial matter consider whether the FDA has regulations or has otherwise taken actions that are capable of having preemptive effect. In *Fellner v. Tri-Union Seafoods, L.L.C.*, we declared “that it is federal law which preempts contrary state law; nothing short of federal law can have that effect.” 539 F.3d at 243. We recognized that “there is no doubt that federal regulations as well as statutes can establish federal law having preemptive force.” *Id.* at 244. Beyond this, however, we noted that “in appropriate circumstances, federal agency action taken pursuant to statutorily granted authority short of formal, notice and comment rulemaking may also have preemptive effect over state law.” *Id.* For example, agency adjudications could have the force of law because agencies have the choice to address issues via rulemaking or adjudication. *Id.* That said, we declared that not every agency action or statement would have preemptive effect. *Id.* at 245.

In determining whether an agency action is entitled to deference, we will be guided by the Supreme Court’s pronouncement that “[i]t is fair to assume generally that Congress contemplates administrative action with the effect of

law when it provides for a relatively formal administrative procedure tending to foster the fairness and deliberation that should underlie a pronouncement of such force.” *Id.* (quoting *United States v. Mead Corp.*, 533 U.S. 218, 230 (2001)). Accordingly, we declined in *Fellner* to “afford preemptive effect to less formal measures lacking the ‘fairness and deliberation’ which would suggest that Congress intended the agency’s action to be a binding and exclusive application of federal law.” *Id.* Finally, with respect to agency letters, we noted that “we have found no case in which a letter that was not the product of some form of agency proceeding and did not purport to impose new legal obligations on anyone was held to create federal law capable of preemption.” *Id.*

In this case, we must determine whether the FDA’s policy statement on the use of the word “natural” has preemptive effect. In 1991, the FDA announced that it was considering defining the term “natural” for the purpose of future rulemaking. Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms, 56 Fed. Reg. 60,421, 60,466 (Nov. 27, 1991). At that time, the FDA recounted its existing “informal policy” on the use of the term:

[T]he agency *has considered* “natural” to mean that 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. For example,

the addition of beet juice to lemonade to make it pink would preclude the product being called “natural.”

Id. (emphasis added).

We conclude that the FDA’s policy statement regarding use of the term “natural” is not entitled to preemptive effect. First, the FDA declined to adopt a formal definition of the term “natural.” After soliciting comments on the use of the term “natural,” the FDA recognized that the use of the term “is of considerable interest to consumers and industry.” 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 (Jan. 6, 1993). It also stated that it believed “that if the term ‘natural’ is adequately defined, the ambiguity surrounding use of this term that results in misleading claims could be abated.” *Id.* Nevertheless, the FDA declined to do so: “Because of resource limitations and other agency priorities, FDA is not undertaking rulemaking to establish a definition for ‘natural’ at this time.” *Id.* This hardly supports preemption. *See Sprietsma v. Mercury Marine*, 537 U.S. 51, 65 (2002) (“Indeed, history teaches us that a Coast Guard decision not to regulate a particular aspect of boating safety is fully consistent with an intent to preserve state regulatory authority pending the adoption of specific federal standards.”).

Though the FDA declined to adopt a formal definition of “natural,” it declared that it would continue to adhere to the informal policy previously announced. 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. at 2,397. This too, however, lacks preemptive weight. The FDA’s request for comments on use of the term “natural” makes clear that the FDA’s informal policy predated the request for notice and comment. Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms, 56 Fed. Reg. at 60,466. Because a search of the *Federal Register* results in neither earlier references to this policy nor other requests for comments on the use of the term “natural,” the record demonstrates that the FDA arrived at its policy without the benefit of public input. Additionally, after requesting comments on the use of the term “natural,” the FDA did not appear to consider all the comments received. For instance, the FDA noted that one comment questioned whether restrictions on the use of “natural” could raise First Amendment concerns. 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. at 2,397. The FDA did not respond to this comment, as it declared it moot in light of its decision not to proceed with a definition. *Id.* In fact, despite numerous public comments, the FDA announced that it would adhere to its pre-existing policy on the use of the term “natural” and make no

changes. *Id.* at 2,407. Finally, the FDA stated that it was declining to define “natural,” in part, because there were still “many facets of the issue that the agency will have to carefully consider if it undertakes a rulemaking to define the term ‘natural.’” *Id.* This statement alone demonstrates a lack of the kind of “fairness and deliberation” contemplated by *Fellner*.

Despite these shortcomings, Snapple argues that the FDA’s policy is entitled to preemptive effect because the FDA has enforced the informal policy. In its briefs to this Court, Snapple directed our attention to several letters in which the FDA told a food or beverage manufacturer to remove the term “natural” from one of its labels for violating the FDA policy on the use of the term “natural.” We do not think these letters are sufficient to accord the policy the weight of federal law. In *Fellner*, we recognized that Congress likely intended to give administrative action the effect of law when the agency adhered to “a relatively formal administrative procedure tending to foster the fairness and deliberation that should underlie a pronouncement of such force.” 539 F.3d at 245 (quoting *Mead Corp.*, 533 U.S. at 230). Thus, we were predominately focused on the process by which the agency arrived at its decision, rather than on what happened after that decision was made. In this case, the deficiencies inherent in the process by which the FDA arrived at its policy on the use of the term “natural” are simply too substantial to be overcome by isolated instances of

enforcement.⁶

We believe that neither the FDA policy statement regarding the use of the term “natural” nor the FDA’s letter indicating that some forms of HFCS may be classified as “natural” have the force of law required to preempt conflicting state law. Both lack the formal, deliberative process contemplated in *Fellner*. As a result, there is no conflict in this case because there is no FDA policy with which state law could conflict.

⁶We also reject Snapple’s arguments that a letter from a FDA official from July 2008 is entitled to weight. The letter was not issued as part of any formal rulemaking or adjudication and was not subject to notice and comment. Additionally, the FDA issued the letter in response to a question from interested parties, rather than doing so in an enforcement action. Under *Fellner*, this letter does not have the force of law—it lacks the relatively formal procedure and “fairness and deliberation” to suggest that Congress intended this agency action “to be a binding and exclusive application of federal law.” *Fellner*, 539 F.3d at 245.

Furthermore, despite Snapple’s assertions, the letter is not entitled to deference as an agency’s interpretations of its regulations. Though the FDA letter regarding HFCS referenced the regulation pertaining to flavoring, the FDA letter did not state that it either interpreted or applied this regulation when it considered whether HFCS was “natural.”

IV.

For the reasons discussed above, we conclude that Holk's claims are not preempted. We will reverse the judgment of the District Court, and remand to the District Court for further proceedings consistent with the foregoing opinion.