

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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SARA MARENTETTE, MATTHEW O'NEIL
NIGHSWANDER, and ELLEN STEINLIEN,
on behalf of themselves and all others similarly
situated,

Plaintiffs,

- against -

ABBOTT LABORATORIES, INC.,

Defendant.

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PAMELA K. CHEN, United States District Judge:

Sara Marentette, Matthew O'Neil Nighswander, and Ellen Steinlein (collectively, "Plaintiffs"), on behalf of themselves and all others similarly situated, bring this putative class action against Abbott Laboratories Inc. and Abbott Nutrition (collectively, "Abbott" or "Defendant"), alleging that Abbott misled consumers about the ingredients of its Similac® Advance® Organic Infant Formulas (the "Products").¹ Specifically, Plaintiffs allege that the packaging for these products contains the representation "Organic" when in fact the Products contain many ingredients prohibited by the United States Department of Agriculture ("USDA") in organic products. Abbott moves to dismiss this entire action on the basis that: (1) Plaintiffs' claims are preempted by the Organic Foods Production Act of 1990, U.S.C. §§ 6501-6523 (the "OFPA"); (2) Plaintiffs failed to exhaust administrative remedies; (3) the Court should defer to the primary jurisdiction of the USDA; and (4) all claims lack merit for claim-specific reasons. Finding that

¹ Plaintiffs allege that "Abbott Laboratories, Inc. conducts business as Abbott Nutrition." (Dkt. 15, First Amended Complaint ("FAC"), ¶ 13.)

Plaintiffs' claims are preempted, the Court GRANTS Defendant's motion to dismiss the First Amended Complaint in its entirety.²

BACKGROUND

I. FACTUAL BACKGROUND³

The facts underlying Plaintiffs' claims are straightforward. Plaintiff Steinlein alleges that from August 2012 through February 2013, she purchased Similac® Advance® Organic Infant Formula approximately once per month at stores in California. (FAC ¶ 16.) Likewise, Plaintiffs Marentette and Nighswander claim that they purchased Similac® Advance® Organic Infant formula in both liquid and powder form in New York and New Hampshire. (*Id.* ¶ 17.)⁴ In addition

² Given that the Court's finding of preemption results in the dismissal of all of Plaintiffs' claims, the Court does not address Defendant's other arguments.

³ The facts in this section are drawn from the allegations contained in the First Amended Complaint and the materials that the Court has judicially noticed, and they are deemed to be true for the purposes of this motion. *See Nielsen v. Rabin*, 746 F.3d 58, 62 (2d Cir. 2014) (a district court must accept the factual allegations set forth in the complaint as true, and draw all reasonable inferences in favor of the plaintiff). Additionally, neither party appears to object to the other party's requests for judicial notice. To the extent the Court has relied on documents in this Order that must be judicially noticed to be considered at this stage, the Court observes that courts regularly take judicial notice of these types of documents. *See, e.g., In re Frito-Lay N. Am., Inc. All Nat. Litig.*, 12-MD-2413, 2013 WL 4647512, at *4 (E.D.N.Y. Aug. 29, 2013) (judicial notice of: "contents of the Federal Register and Code of Federal Regulations," "agency letters, policy and guidance documents, websites, and other agency data made available to the public," and "state laws and regulations"); *Reese v. McGraw-Hill Companies, Inc.*, 08 CIV. 7202, 2012 WL 9119573, at *1 (S.D.N.Y. Mar. 30, 2012), *aff'd sub nom. Boca Raton Firefighters & Police Pension Fund v. Bahash*, 506 F. App'x 32 (2d Cir. 2012) (judicial notice of Senate staff report). No other extrinsic documents have been relied upon in reaching the Court's decision.

⁴ According to the First Amended Complaint, Marentette and Nighswander have children together. (*See* FAC ¶ 17 ("Plaintiffs Sara Marentette and Matthew O'Neil Nighswander are parents to four young children [and] reside in Brooklyn, New York.").)

to containing the word “Organic,” the Products also display the following seal:⁵



Plaintiffs assert that they purchased the Products after seeing, and in reliance on, the “Organic” representation on the Products’ label, and because of this representation, were led to believe that the Products were organic and did not contain preservatives. (*Id.* ¶¶ 16-17.) Plaintiffs contend that the Products are not actually organic as defined under federal law because they contain certain ingredients that are prohibited in organic products. (*Id.* ¶¶ 18, 26.)⁶ Plaintiffs further claim that had they known that the Products were not organic, they would not have purchased the Products; however, they “would consider” purchasing the Products in the future if the Products were reformulated so as to make the “Organic” representation truthful. (*Id.* ¶¶ 19, 20.)

Plaintiffs allege that Defendant is liable under N.Y. Gen. Bus. Law § 349, the California Unfair Competition Law, Cal. Bus. & Prof. Code. § 17200 *et seq.*, the California False Advertising Law, Cal. Bus. & Prof. Code. § 17500, *et seq.*, the California Consumer Legal Remedies Act, Cal. Civ. Code § 1750 *et seq.*, the California Organic Products Act, Cal. Health & Safety Code §§ 110810-110959, and the common law of New York and California for breach of express

⁵ Available at <https://www.ams.usda.gov/rules-regulations/organic/organic-seal>. The Court has reproduced this image from the USDA website for clarity purposes, but it is identical to the image appearing on the Products as shown in Exhibit 1 to Plaintiffs’ First Amended Complaint.

⁶ These ingredients include sodium selenite, taurine, cholecalciferol, l-carnitine, choline bitartrate, adenosine-5’-monophosphate, cytidine-5’-monophosphate, disodium guanosine-5’-monophosphate, disodium uridine-5’-monophosphate, calcium pantothenate, cyanocobalamin, ascorbyl palmitate, choline chloride, m-inositol, docosahexaenoic acid single cell oil, arachidonic acid single cell oil, biotin, lutein, and beta-carotene. (FAC ¶ 18.)

warranty and unjust enrichment. (*Id.* ¶¶ 68-138.) All of these claims are based on the alleged false labeling of the Products as “Organic.” Defendant moves to dismiss Plaintiffs’ claims in their entirety.

DISCUSSION

I. LEGAL STANDARD

To withstand a motion to dismiss pursuant to Rule 12(b)(6), a complaint must plead facts sufficient “to state a claim to relief that is plausible on its face.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). In evaluating a 12(b)(6) motion, a district court must accept the factual allegations set forth in the complaint as true, and draw all reasonable inferences in favor of the plaintiff. *See Nielsen*, 746 F.3d at 62; *Cleveland v. Caplaw Enter.*, 448 F.3d 518, 521 (2d Cir. 2006). A complaint that “tenders ‘naked assertion[s]’ devoid of ‘further factual enhancement’” will not suffice. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 555 U.S. at 557). Rather, “[f]actual allegations must be enough to raise a right to relief above the speculative level[.]” *Twombly*, 550 U.S. at 555. A complaint should be dismissed where a plaintiff has not “nudged [its] claims across the line from conceivable to plausible[.]” *Id.* at 570. Of particular relevance here, “[a] district court may grant a motion to dismiss based on federal preemption, if the defense can easily be determined from the pleadings.” *Aaronson v. Am. Med. Sys., Inc.*, 09-CV-2487, 2010 WL 3603618, at *1 (E.D.N.Y. Sept. 7, 2010); *see also Farash v. Cont'l Airlines, Inc.*, 574 F. Supp. 2d 356, 362–63 (S.D.N.Y. 2008), *aff'd*, 337 F. App'x 7 (2d Cir. 2009) (preemption is a question of law).

II. ORGANIC FOODS PRODUCTION ACT OF 1990

Defendant attacks the adequacy of Plaintiffs’ State law claims by arguing that they are preempted by the OFPA. Specifically, Defendant contends:

Plaintiffs' state law claims are premised on the idea that Similac Organic is falsely labeled as organic as a matter of federal law. But USDA has already determined that Similac Organic is properly labeled as organic as a matter of federal law, and Plaintiffs cannot use state law causes of action to reverse USDA's federal determination.

(Dkt. 19-4 ("Def.'s Mem.") at ECF 12.)⁷

Enacted in 1990, the OFPA empowers the Secretary of Agriculture (the "Secretary") to "establish an organic certification program for producers and handlers of agricultural products that have been produced using organic methods." 7 U.S.C. § 6503(a). In passing the statute, Congress articulated three main purposes:

- (1) to establish national standards governing the marketing of certain agricultural products as organically produced products;
- (2) to assure consumers that organically produced products meet a consistent standard; and
- (3) to facilitate interstate commerce in fresh and processed food that is organically produced.

Id. § 6501. The USDA also adopted the National Organic Program (the "NOP"), an extensive set of implementing regulations. *See* 7 C.F.R. §§ 205.1–205.699. Under the OFPA and NOP, a product can only be sold or labeled as "Organic" if it has previously been certified as "Organic" by an accredited certifying agent.⁸ 7 U.S.C. §§ 6504–6505, 6514(a), 6515, 6519; *see also, e.g.*, 7 C.F.R. §§ 205.300(a), 205.302(c). Here, the parties do not dispute that the Products were certified

⁷ Citations to "ECF" refer to the pagination generated by the Court's electronic docketing system and not the documents internal pagination.

⁸ "Certifying agent" is defined as "the chief executive officer of a State or, in the case of a State that provides for the statewide election of an official to be responsible solely for the administration of the agricultural operations of the state, such official, and any person (including private entities) who is accredited by the Secretary as a certifying agent for the purpose of certifying a farm or handling operation as a certified organic farm or handling operation in accordance with [the OFPA]." 7 U.S.C. § 6502(3). The NOP creates a process for accrediting certifying agents. *See* 7 C.F.R. §§ 205.500–205.510.

as “Organic” by Quality Assurance International (“QAI”), a USDA-accredited certifying agent. (See Def.’s Mem. at ECF 9 (“USDA, through an agent, has *certified* that Similiac Organic is properly labeled as organic as a matter of federal law.”) (emphasis in original); Dkt. 20 (“Pls.’ Opp.”) at ECF 26 (“Abbott *hired a third party*—Quality Assurance International (“QAI”)—to certify its product.”) (emphasis in original).) See also <http://apps.ams.usda.gov/integrity/> (listing Abbott’s infant formula as being certified “Organic” by QAI). Nor do the parties dispute that the Products were labeled as “Organic” by Defendant.⁹

III. FEDERAL PREEMPTION OF STATE LAW CLAIMS

1. Preemption Background

“Federalism, central to the constitutional design, adopts the principle that both the National and State Governments have elements of sovereignty the other is bound to respect.” *Arizona v. United States*, 132 S. Ct. 2492, 2500 (2012) (citations omitted). Under the Supremacy Clause of the United States Constitution, “state laws that conflict with federal law are without effect” and are preempted. *Altria Grp., Inc. v. Good*, 555 U.S. 70, 76 (2008) (citation and quotation omitted); U.S. Const., art. VI, cl. 2. In addressing preemption questions, “the purpose of Congress is the ultimate touchstone.” *Wyeth v. Levine*, 555 U.S. 555, 564 (2009) (citation and quotation omitted). “Congress may indicate pre-emptive intent through a statute’s express language or through its structure and purpose.” *Altria*, 555 U.S. at 76 (citation omitted).

Defendant argues that “[t]here is plainly a conflict between a federal law authorizing a producer to label its formula as organic and state law causes of action that would impose liability for that very label.” (Def.’s Br. at ECF 14.) The type of preemption referenced by Defendant—

⁹ As discussed further below, Plaintiffs dispute what it means to be certified by a USDA-accredited certifying agent.

conflict preemption—applies in “cases where compliance with both federal and state regulations is a physical impossibility . . . and those instances where the challenged state law stands as an obstacle to the accomplishment and execution of the full purposes and objections of Congress.”¹⁰ *Arizona*, 132 S.Ct. at 2501 (quotations and citations omitted) (emphasis added). Defendant confines its argument to the latter, which is one form of conflict preemption known as “obstacle preemption.” (See Def.’s Mem. at ECF 14 (citing conflict preemption standard as whether State law poses an obstacle to establishing a national standard for organic products).) Accordingly, the question before the Court is whether Plaintiffs’ State law claims, which seek to impose liability on Defendant for an allegedly misleading representation that is permitted by a USDA-accredited agent, are preempted by the OFPA.

2. Applicable Case Law

Because so few courts have confronted the exact issue presented here, a brief survey of the cases addressing the OFPA’s preemptive scope is useful to frame the Court’s analysis. To begin, the Eighth Circuit remains the only circuit court to address the issue. See *In re Aurora Dairy Corp. Organic Milk Mktg. & Sales Practices Litig.*, 621 F.3d 781 (8th Cir. 2010). In *Aurora*, consumers asserted State law claims against organic-certified dairy producers and retailers, alleging, *inter*

¹⁰ There are “three typical settings in which courts will find that Congress intended to preempt state law.” *In re Methyl Tertiary Butyl Ether (MTBE) Products Liab. Litig.*, 725 F.3d 65, 96 (2d Cir. 2013). Aside from conflict preemption, which Defendant limits argument to here, the other two circumstances where preemption might apply are: (1) where Congress “enact[s] a statute containing an express preemption provision” (express preemption) or (2) where Congress regulates conduct in a field that it “has determined must be regulated by its exclusive governance” (field preemption). *Arizona*, 132 S. Ct. at 2500-01.

The Court notes that Defendant independently argues that because the USDA did not approve Plaintiffs’ State tort and statutory claims, they are expressly preempted. (Def.’s Mem. at ECF 17.) Because the Court concludes that Plaintiffs’ State law claims stand as an obstacle to the execution of the purposes of the OFPA, and that therefore, Plaintiffs’ State law claims are preempted on conflict preemption grounds, the Court need not address this argument.

alia, that their labeling of a milk product as “Organic” was misleading because the producer’s processes did not comply with the OFPA’s requirements for “Organic” products. *Id.* at 787-90. The Eighth Circuit, in finding these claims impliedly preempted, reached two holdings relevant here. First, it held that the consumers’ claims “that [the producer] and the retailers sold milk as organic when in fact it was not organic [were] preempted because they conflict[ed] with the OFPA.” *Id.* at 796. The court reasoned, in part, that “any attempt to hold [the producer] or retailers liable under state law based upon its products supposedly not being organic directly conflicts with the role of the certifying agent as set forth in [7 U.S.C.] § 6503(d).” *Id.* at 796-97.¹¹ Second, “state law challenges to the certification determination itself,” which would be preempted, are different than “state law challenges to the facts underlying certification,” which would not be preempted. *Id.* To explain the distinction, the Eighth Circuit provided the following hypothetical:

We believe, in enacting the OFPA, Congress did not intend for requirements such as [those governing livestock practices] to preclude a State from prosecuting a certified organic producer for violating the State’s animal cruelty statute by abusing its livestock. Certification relies upon inspection and observation of only a portion of a producer’s operations, and thus, the evidence which supported certification could, and very likely would, be different from the evidence which supports a state cause of action [for engaging in animal cruelty].

Id. at 798.

The only other appellate court to address the preemptive scope of the OFPA—the California Supreme Court—declined to agree or disagree with the Eighth Circuit’s holding that “claims making a frontal assault on the validity of the organic producer’s government certification” and those “against the federally sanctioned agent alleging that it erred either in initially granting

¹¹ The Court further emphasized that “[t]o the extent the class plaintiffs, relying on state consumer protection or tort law, seek to set aside [the defendant’s] certification, or seek damages from any party for [the defendant’s] milk being labeled as organic in accordance with the certification . . . state law conflicts with federal law and should be preempted.” *Id.* at 797.

certification or in not thereafter revoking certification” are preempted by the OFPA. *Quesada v. Herb Thyme Farms, Inc.*, 361 P.3d 868, 881-82 (Cal. 2015). Because “the complaint [in *Quesada*] accept[ed] as valid [the defendant’s] certification and compliance with federal regulations on its certified organic farm,” the California Supreme Court concluded that the claims at issue did not fall within the category of preempted claims recognized by the Eighth Circuit in *Aurora*. *Id.* at 882. This is because unlike the allegations in *Aurora*, the plaintiff in *Quesada* alleged that the defendant sold both organic and non-organic herbs and that on many occasions “knowingly and intentionally” either mixed the two together or sold its non-organic herbs in a container exhibiting the USDA-certified “Organic” seal. *Id.* at 882-83. Based on these facts, but finding the Eighth Circuit’s decision in *Aurora* to be “instructive,” the *Quesada* court concluded that “claims of intentional commingling and fraudulent substitution of conventional for organic produce” were not preempted. *Id.* at 883.¹²

Lastly, the Court is aware of four district court decisions that explore the preemptive scope of the OFPA, and reach contrary results. *See, e.g., Segedie v. Hain Celestial Grp., Inc.*, 14-CV-5029, 2015 WL 2168374, at *1 (S.D.N.Y. May 7, 2015) (rejecting *Aurora* and concluding that plaintiff’s State law claims alleging violations of New York and California consumer protection statutes, and breach of express and implied warranties, fraud, negligence, negligent

¹² The Court flatly rejects Plaintiffs’ arguments that the California Supreme Court’s decision in *Quesada* “directly contradicts Abbott’s preemption arguments” and did not hinge “upon the substitution of non-organic herbs for herbs that were certified organic.” (Dkt. 28, Plaintiffs’ Response to Defendant’s Notice of Supplemental Authority, at ECF 1-2.) Indeed, the California Supreme Court made clear that because the “gravamen” of the claims in *Quesada* were “different,” it had “no occasion to determine” whether claims like those presented in *Aurora* would be preempted “nor whether [the Court agreed] with the Eighth Circuit concerning the area of implied preemption it identifie[d].” *Quesada*, 361 P.3d at 882; *see also id.* at 883 (“Whether or not the improper certification claims preempted in *Aurora Dairy* would pose an obstacle to congressional purposes and objectives, the claims just recited do not.”).

misrepresentation, and unjust enrichment, were not an obstacle to the purpose of the OFPA); *Gedalia v. Whole Foods Mkt. Servs., Inc.*, 53 F. Supp. 3d 943 (S.D. Tex. 2014) (finding plaintiff’s State law claims for violations of California consumer protection statutes, breach of express and implied warranties, fraud, unjust enrichment, negligence, and negligent misrepresentation, not in conflict with the OFPA); *Brown v. Hain Celestial Grp., Inc.*, C-11-03082, 2012 WL 3138013, at *1 (N.D. Cal. Aug. 1, 2012) (citing *Aurora* with approval, but finding that the OFPA “does not expressly bar state law claims that do not conflict with OFPA’s provisions,” and finding that plaintiff’s State law claims for violations of California consumer protection and organic statutes in the context of cosmetics were not preempted); *Jones v. ConAgra Foods, Inc.*, 912 F. Supp. 2d 889, 895 (N.D. Cal. 2012) (holding that claims alleging violations of California consumer protection statutes were not preempted by the OFPA). As further explained below, to the extent these cases are not factually distinguishable from the present case, the Court disagrees with their reasoning.¹³ Aside from these decisions, the Court is not aware of—and the parties fail to reference—any additional precedent directly addressing this issue.

3. Plaintiffs’ Claims Are Preempted

As discussed further below, considering the relevant precedent, statutory text, and legislative history, the Court finds the Eighth Circuit’s decision in *Aurora* to be persuasive and applicable to this case. Here, QAI certified the Products as “Organic” under federal law and only then was Defendant permitted to use the word “Organic” and the USDA seal on the Products’ labels. Plaintiffs’ challenge to this labeling cannot be described in any way other than a direct challenge to the USDA-accredited certifying agent’s decision itself. The Court finds that such a challenge is preempted because “[t]o the extent state law permits outside parties, including

¹³ These decisions, while instructive, of course, are not binding on the Court.

consumers, to interfere with or second guess the certification process, the state law is an obstacle to the accomplishment of congressional objectives of the OFPA.” *Aurora*, 621 F.3d at 795 (citations and quotations omitted).¹⁴

The starting point for the Court’s analysis is the OFPA’s regulatory scheme, which was designed to nationalize the standards of “Organic” labeling. As previously discussed, a product must be certified by a USDA-accredited certifying agent in order to be sold or labeled as “Organic.” 7 U.S.C. §§ 6504–6505, 6514(a), 6515, 6519; *see also, e.g.*, 7 C.F.R. §§ 205.300(a), 205.302(c). In order to be “Organic” under the OFPA, a product must:

- (1) have been produced and handled without the use of synthetic chemicals, except as otherwise provided in [the OFPA];
- (2) except as otherwise provided in [the OFPA] and excluding livestock, not be produced on land to which any prohibited substances, including synthetic chemicals, have been applied during the 3 years immediately preceding the harvest of the agricultural products; and
- (3) be produced and handled in compliance with an organic plan agreed to by the producer and handler of such product and the certifying agent.

7 U.S.C. § 6504.

Of particular relevance here, the OFPA also empowers the Secretary to “establish a National List of approved and prohibited substances that shall be included in the standards for organic production and handling established under [the OFPA] in order for such products to be sold or labeled as organically produced under [the statute].” *Id.* at § 6517(a). This National List

¹⁴ Contrary to Plaintiffs’ assertion, QAI’s status as a “third party” does not compel a different conclusion. In *Aurora*, the Eighth Circuit found that the plaintiffs’ claims challenging the product’s “Organic” certification were preempted notwithstanding the fact that the products considered in *Aurora* were also certified by QAI. *Aurora*, 621 F.3d at 795-97. Indeed, as previously discussed, certification by an “accredited certifying agent,” such as QAI, is specifically contemplated and authorized by the OFPA’s implementing regulations. *See* 7 U.S.C. §§ 6504-6505, 6514(a), 6515, 6519.

contains “an itemization, by specific use or application, of each synthetic substance permitted . . . or each natural substance prohibited.” *Id.* § 6517(b).¹⁵ The OFPA prohibits producers and manufacturers from labeling a product as “Organic” if it contains ingredients not specified on the National List. *Id.* §§ 6504, 6510. The NOP also specifies that for a product to be labeled as “Organic,” it “must contain . . . not less than 95 percent organically produced raw or processed agricultural products.” 7 C.F.R. § 205.301(b).¹⁶ This thorough-going regulatory scheme, in and of itself, suggests that Congress did not intend for it to be disrupted by State law consumer claims.

The OFPA’s broad statements of purpose also weigh in favor of finding that Plaintiffs’ State law claims would be an obstacle to the implementation of the statute. As discussed above, Congress laid out these purposes in the statute itself:

- (1) to establish *national standards* governing the marketing of certain agricultural products as organically produced products;
- (2) to assure consumers that organically produced products *meet a consistent standard*; and
- (3) to facilitate interstate commerce in fresh and processed food that is organically produced.

7 U.S.C. § 6501 (emphasis added). These purposes would “be deeply undermined” by Plaintiffs’ State law claims, which would render the USDA’s “Organic” certification meaningless. *Aurora*,

¹⁵ The OFPA also defines who may decide what ingredients are allowed on the National List and how those decisions must be made. *See* 7 U.S.C. § 6517-18.

¹⁶ Plaintiffs contend that these regulations do not require certifying agents to actually review the Products’ ingredients and conclude that they are “Organic.” (Pls.’ Opp. at ECF 27.) They assert that “[t]he third-party certification process is like a financial audit[, and that] [j]ust as a financial audit is not a guarantee that the financial statements are true, organic certification is not a guarantee that the product is organic.” (*Id.*) Plaintiffs’ argument requires the illogical conclusion that Congress intended for the “Organic” label to not have any actual meaning, aside from informing consumers that a product may or may not be organic. This makes little sense and is inconsistent with the OFPA’s stated purposes and its legislative history.

621 F.3d at 796. Plaintiffs’ argument, that the statute’s second articulated purpose disfavors a finding of preemption,¹⁷ is plainly wrong. Indeed, the opposite is true. Permitting Plaintiffs’ claims would lead to a “divergence in applicable state laws as numerous court systems adopt possibly conflicting interpretations of the same provisions of the OFPA and the NOP.” *Aurora*, 621 F.3d at 796.¹⁸ It would also lead to the possibility of conflicting definitions of “Organic,” completely untethered from any definition articulated by Congress or the Secretary under the OFPA. These inconsistent results would lead to a loss of meaning of the word “Organic,” which would naturally confuse and potentially mislead consumers—not assure or inform them.

The Senate Report’s emphasis on *national* uniformity further confirms the Court’s perspective that Congress could not have intended to create a regulatory scheme in which courts, or even juries, would determine whether a certain product’s labeling as “Organic” was misleading to a reasonable consumer because of its ingredients. The Senate report reflects concern expressed during pre-enactment debates over the OFPA that “no two State laws [were] alike” and that “the differing State laws have also led to consumer confusion and troubled interstate commerce.” S. Rep. No. 101-357, 1990 U.S.C.C.A.N. 4656, 4943. Congress noted its worry that “[e]ven the most sophisticated organic consumer finds it difficult to know, with certainty, what the term ‘organic’ really means.” *Id.* The Senate Report concludes that the only solution guaranteeing “that

¹⁷ (*See* Pls.’ Opp. at ECF 29 (“In fact, allowing Plaintiffs’ claims directly advances the second purpose of the OFPA: to assure consumers that organically produced products meet a consistent standard.”) (quotations omitted).)

¹⁸ The Court acknowledges that the OFPA permits appeals of final Secretary decisions regarding, *inter alia*, a certification decision, to a United States District Court, which would appear to allow for divergent interpretations of OFPA provisions and certification decisions. 7 U.S.C. § 6520(b). But any review of a Secretary’s decision would be “through the lens of arbitrary-and-capricious review,” thus giving deference to the USDA’s interpretation. *Segedie*, 2015 WL 2168374, at *6 (citing 7 U.S.C. § 6520(b); *Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 844 (1984)).

consumers are sure to get what they pay for” are “national standards.” *Id.* These national standards can only be enforced by prohibiting claims, like Plaintiffs’ here, which challenge this nationally applicable certification of food products as “Organic.”

Another reason preemption is warranted is the OFPA’s enforcement and remedial scheme. *See Aurora*, 621 F.3d at 797 (“The structure of the OFPA, and particularly its remedial scheme, also support our conclusion that to the extent state laws challenge Aurora’s certification they are preempted.”) Under the OFPA, the Secretary and NOP’s Program Manager can investigate the accuracy of information provided by producers and certification agents by administering oaths, subpoenaing witnesses, compelling witness testimony, gathering evidence, and requiring the production of records. *See* 7 U.S.C. § 6519; 7 C.F.R. § 205.660. If the NOP’s Program Manager “has reason to believe that a certified operation has violated or is not in compliance with the [OFPA]” or a “certifying agent or a State organic program’s governing State official fails to take appropriate action to enforce the [OFPA] or regulations,” then “[t]he Program Manager may initiate suspension or revocation proceedings against a certified operation.” 7 C.F.R. § 205.660(b). Moreover, if an operation “knowingly sells or labels a product as organic, except in accordance with the [OFPA],” it is subject to a civil penalty of up to \$10,000 per violation and the possibility of a five-year prohibition from re-certification. *See* 7 U.S.C. § 6519(c).¹⁹ In addition, any action by the Secretary, applicable governing State official, or certifying agent that “adversely affects” a person or “is inconsistent with the organic certification program” is appealable to the Administrator for the Agricultural Marketing Service, and final agency decisions are then appealable to the district court. 7 C.F.R. § 205.680(a), (c); *see also* 7 U.S.C. § 6520. The OFPA’s

¹⁹ If there is evidence that an operation made a false statement to the Secretary, a governing State official, or a certifying agent, then criminal charges, which could result in imprisonment, could be brought under 18 U.S.C. § 1001. *Id.*

comprehensive and robust enforcement review system is further evidence of Congress's intent to create a uniform national standard for certifying and labeling "Organic" products, one that would be significantly disrupted, if not thwarted, by a hodgepodge of potentially inconsistent State and federal court decisions on what constitutes "Organic."²⁰

Against this backdrop of congressional intent and purpose, Plaintiffs argue that the Eighth Circuit's decision in *Aurora* is inconsistent with the Supreme Court's holding in *Wyeth v. Levine*, 555 U.S. 555 (2009), in which the Court held that State law failure-to-warn claims were not preempted by the Food Drug and Cosmetic Act's (the "FDCA") regulation of drug labeling. *Id.* at 581. The Court disagrees; the differences between the FDCA and OFPA warrant the different outcomes reached in *Wyeth* and *Aurora*.

In enacting the FDCA, Congress created a regulatory scheme in which manufacturers "bear[] responsibility for the content of [their] label at all times" and are "charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market." *Id.* at 571. "[I]t cast[s] federal labeling standards as a floor upon which States could build" and "establish[es] 'minimal standards' for drug labels," such that failure to meet the FDA's minimal standards is *prima facie* evidence of a failure to warn, but compliance with them does not insulate a manufacturer from liability due to an inadequate warning. *See id.* at 577. Thus, even after the FDA approves a drug label, a State tort suit might still "uncover known drug

²⁰ The Court acknowledges that there is "no private right of action to enforce the OFPA or the NOP regulations," *All One God Faith, Inc. v. Hain Celestial Grp., Inc.*, No. C 09-3517, 2012 WL 3257660, at *10 (N.D. Cal. Aug. 8, 2012), which means that Plaintiffs do not appear to have the option of suing Defendant for violating the OFPA. Although a consideration for the Court, this fact alone is not dispositive. While it is possible that the OFPA preempts claims in other similar factual scenarios, the Court only decides that it preempts claims such as those alleged by Plaintiffs here.

hazards” and serve as an “additional . . . layer of consumer protection that complements FDA regulation.” *Id.* at 579.

By contrast, the OFPA defines the precise term “Organic” and does not simply set minimum standards for that label, such that any product that meets all of the criteria set by the USDA for that term cannot be challenged as mislabeled or as violating any State law regarding truth in labeling with respect to that term. Under the OFPA, the word “Organic” is under the federal government’s control and is only permitted on a product after approval by a USDA-accredited certification agent. *See* 7 C.F.R §§ 205.300(a), 205.303. And although “[t]he governing State official may prepare and submit a plan for the establishment of a State organic certification program to the Secretary for approval,” a State program must still “meet the requirements” of the OFPA and “be approved by the Secretary.” 7 U.S.C. § 6507(a). In other words, the federal government has chosen to define an “Organic” product as one that has met a certain standard, and the only way the State can alter that standard is with the federal government’s approval. Once the federal government, through a USDA-accredited certifying agent, permits a manufacturer to label a product as “Organic” because it has met that standard, any allegation that the product is not truthfully labeled as such is a challenge to the certifying agent’s decision, *not* the manufacturer’s representation (as with a claim under the FDCA).

Relying on the district court’s decision in *Segedie*,²¹ Plaintiffs contend that because they are challenging the “facts underlying certification,” *i.e.*, that the Products contain chemicals prohibited in products certified as organic under the OFPA, their claims are not preempted. In *Segedie*, as here, the plaintiffs alleged that they were misled by products labeled as “Organic”

²¹ *Segedie* appears to be the only lower court decision within this Circuit to address the preemptive scope of the OFPA.

where those products contained ingredients that federal law prohibited in organic products. 2015 WL 2168374, at *1. In finding that the plaintiffs' claims were not preempted by the OFPA, the district court expressly disagreed with the Eighth Circuit's decision in *Aurora*, which the *Segdie* court concluded was inconsistent with *Wyeth*. *Id.* at *7. However, as previously discussed, the Court finds that the unique regulatory scheme of the OFPA warrants a different conclusion than that reached by the Supreme Court in *Wyeth* regarding the FDCA, and one consistent with *Aurora*.²² The Court, therefore, respectfully disagrees with the holding in *Segdie*, and finds that Plaintiffs' claim that the "Organic"-certified Products are falsely labeled because they allegedly contain ingredients not permitted by the OFPA amounts to a challenge to the USDA certification itself, and is therefore preempted.

CONCLUSION

For the reasons set forth above and because all of Plaintiffs' State law claims depend on the alleged falsity of the Products' "Organic" label, the Court finds that all of Plaintiffs' claims are preempted, and grants Defendant's motion to dismiss the First Amended Complaint in its entirety. In their opposition, Plaintiffs request leave to amend their First Amended Complaint in the event the Court dismissed their claims. (Pls.' Opp. at ECF 42 n.29.) Should Plaintiffs seek to amend their complaint, they shall file a letter no longer than three (3) pages by September 23, 2016, setting forth the bases for their request and attaching a proposed Second Amended Complaint. If Plaintiffs

²² As Plaintiffs correctly note, obstacle preemption is a rare remedy that is commonly not a successful defense. But the facts here, combined with the OFPA and NOP's extensive regulatory scheme, appears to be exactly the situation where obstacle preemption would apply. The Court, however, emphasizes the narrowness of its ruling. Preemption is warranted here because Plaintiffs' claims solely and directly attack the federal certification of Defendant's "Organic" label. The Court's ruling does not address, in any way, the applicability of the preemption doctrine to any other consumer-related causes of action, such as a failure to warn, or design or manufacturing defect claim, which could well not be preempted under the OFPA.

fail to renew their request to amend their complaint by this date, the Court will direct the Clerk of Court to enter judgment and terminate this case.

SO ORDERED.

/s/ Pamela K. Chen

Pamela K. Chen

United States District Judge

Dated: August 23, 2016
Brooklyn, New York