UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

LAURA BEDSON, individually and on behalf of all others similarly situated,

Plaintiff,

-against-

BIOSTEEL SPORTS NUTRITION INC.,

Defendant.

Index No.: 1:23-cv-00620-HG

**MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT BIOSTEEL SPORTS NUTRITION INC.'S MOTION TO DISMISS PLAINTIFF'S FIRST AMENDED COMPLAINT**

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## PRELIMINARY STATEMENT

Based solely on the results of her own "independent" testing—devoid of any details regarding the methodology or sample used—Plaintiff alleges Defendant BioSteel Sports Nutrition Inc. ("BioSteel") improperly marketed several flavors of its Sports Drink (the "Product") by failing to disclose the purported presence of certain per- and polyfluoroalkyl substances, commonly known as "PFAS." In doing so, this lawsuit is just one of a growing number of class actions around the country seeking to expand certain concepts of liability whereby a product label's omission of any incidental presence of a substance (here, PFAS) would be tantamount to consumer deception. Plaintiff's theories are fundamentally flawed and this matter should be dismissed pursuant to Fed. R. Civ. P. Rules 12(b)(6) and 12(b)(1), and join the growing list of cases holding that such vague and speculative allegations fail to support PFAS claims.[1]

The First Amended Complaint ("FAC") fails to cure the pleading deficiencies of the original Complaint and provides several independent bases for dismissal.[2] First, Plaintiff's vague and conclusory testing allegations do not sufficiently establish the presence of PFAS in the

[1] *See Brown v. Coty, Inc.,* Case No. 22 Civ. 2696, 2023 U.S. Dist. LEXIS 54316 (S.D.N.Y. Mar. 29, 2023); *Onaka v. Shiseido Ams. Corp.*, 21-cv-10665, 2023 U.S. Dist. LEXIS 53220 (S.D.N.Y. Mar. 28, 2023); *Richburg v. ConAgra Brands, Inc.,* Case No. 22 CV 2420, 2023 U.S. Dist. LEXIS 21137 (N.D. Ill. Feb. 8, 2023); *Ruiz v. ConAgra Brands, Inc.,* Case No. 22 CV 2421, 2023 U.S. Dist. LEXIS 21137 (N.D. Ill. Feb. 8, 2023); *Solis v. Coty, Inc.*, Case No. 22-cv-0400, 2023 U.S. Dist. LEXIS 38278 (S.D. Cal. Mar. 7, 2023); *GMO Free USA v. Cover Girl Cosmetics, et al.* No. 2021 CA 004786 B (D.C. Super. Ct., June 1, 2022) (unpublished opinion annexed as **Exhibit A**).

[2] Plaintiff's FAC alleges causes of action for: violations of NYGBL §§ 349, 350, NY Agric. & Mkts. Law § 199-a, Negligence *Per Se*, and Unjust Enrichment. In response to Defendant's first pre-answer motion to dismiss, Plaintiff now abandons her previous fraud and constructive fraud claims. However, the FAC still contains a now superfluous section entitled "FEDERAL RULE OF CIVIL POROCEDURE [sic] 9(b) ALLEGATIONS." FAC ¶¶ 146 -153. The FAC also lists "breach of warranty" (as did the initial Complaint) despite there being no such cause of action in either the Complaint or FAC. FAC ¶ 12. Accordingly, Defendant also moves to dismiss any purported ancillary fraud, constructive fraud or breach of warranty claims to the extent that pleading is even recognized by this Court.

Products, which is fatal to all claims. Plaintiff does not specifically allege Defendant used PFAS intentionally, that it knowingly added PFAS as an ingredient, or that PFAS was even present in the Products she allegedly purchased. There are no specifically pled facts regarding Defendant's alleged knowledge of the purported PFAS presence, constructive or otherwise. Instead, Plaintiff bases her entire case solely on the conclusory allegation of PFAS detection in the Products via undisclosed testing. Despite tethering four causes of action to this slender reed, the FAC is silent on this testing's date, time, place, methodology, and sample size.

Second, even if, *arguendo*, a PFAS presence were in *some* BioSteel Products, Plaintiff still lacks Article III standing to seek damages because the FAC fails to contain any plausible basis to allege the specific Product(s) she purchased contained PFAS. Plaintiff's PFAS allegations are based on irrelevant comparisons to distinguishable EPA-proposed guidelines regarding *lifetime exposure* in *drinking water*, inapplicable to this FDA-regulated food. Without a plausible causal connection between the alleged presence of PFAS in the Products at issue and Plaintiff's claimed economic injury, this matter should be dismissed with prejudice for lack of subject matter jurisdiction as other similar New York cases have held.

Third, the FAC also fails to state a cause of action under any of its theories of recovery. The FAC identifies no deceptive statement capable of misleading a reasonable consumer as required by New York General Business Law ("NYGBL") §§ 349, 350 as well as Plaintiff's related unjust enrichment claims. It is uncontested that Defendant's Product labeling[3] contains no "PFAS-free" representations and the listed ingredients show PFAS are not intentionally added. Plaintiff lists a myriad of nutritional and environmental representations on the Products' labeling (e.g., Zero

[3] An exemplar of the labeling of BioSteel's Sports Drink (Blue Raspberry-flavored) is reproduced in FAC at ¶¶ 5, 24, 25, 26, and 32.

Sugar, Vegan, Gluten-free), none of which are disputed as inaccurate. Instead, Plaintiff claims these representations are objectively misleading because of the alleged undisclosed presence of PFAS. Plaintiff pleads not a single fact to support the conclusory allegations that Defendant possessed such material information or that it "knew or should have known" about the alleged presence of PFAS. This failure to allege any deceptive act is fatal to Plaintiff's claims because they are all premised on the implausible assertion that Defendant's Product labeling is materially misleading despite having no relation to PFAS.

Furthermore, Plaintiff's new claims regarding purported violations of public health misbranding and adulteration statutes such as N.Y. Agric & Markets Law ("NY Agric. & Mkts. Law") and the Food, Drug and Cosmetic Act ("FDCA"), under either private right of action or negligence *per se* theories, fail as a matter of law. At the outset, neither the FDCA nor New York's Agriculture and Markets Law offers a private right of action. Likely recognizing the same, Plaintiff also inventively reframes alleged violations of these statutes as negligence *per se*, but this would effectively afford a private right of action where none exists. Moreover, seeking recovery for a mere economic injury (as Plaintiff does here) rather than a physical one under a negligence *per se* theory ignores the well settled New York law that a negligence action seeking recovery for economic loss will not lie.

Lastly, Plaintiff essentially seeks to impose a PFAS-disclosure requirement for product labels entirely different from the requirements of the federal regulatory scheme set forth by the U.S. Food and Drug Administration ("FDA") which therefore subjects all claims to preemption. The FDA has already signaled an intent to regulate PFAS in food and beverages, which falls squarely within the FDA's primary jurisdiction and should be left to the special competence of

that administrative agency. For all these reasons, Defendant respectfully requests the Court dismiss this lawsuit in its entirety, with prejudice.

## FACTUAL BACKGROUND

### I. PLAINTIFF'S FIRST AMENDED COMPLAINT CONFIRMS THE PERVASIVE NATURE OF PFAS IN THE ENVIRONMENT

Presumably due to the nascent stage of PFAS litigation, Plaintiff has provided a host of footnoted and varied references in her FAC from sources as diverse as non-peer reviewed websites to EPA publications, explaining the nature and purported dangers of PFAS in the environment. As Plaintiff is pleading an economic (and not medical) injury, these materials are irrelevant to adjudicating the present motion to dismiss. Nevertheless, it is significant to note that even Plaintiff's own cited sources undermine her claims of deception and alleged significant contamination as they admit PFAS to be ubiquitous in the environment and unavoidable at trace levels. Despite the prevalence of PFAS, Plaintiff attempts to take the untenable position that their alleged presence in the Products *at any level* constitutes consumer deception, adulteration, and misbranding resulting in economic injury.

### II. THE FIRST AMENDED COMPLAINT FAILS TO OFFER SPECIFIC FACTS TO SUPPORT ALLEGATIONS OF ECONOMIC HARM

The FAC fails to provide this Court with the necessary factual allegations regarding Plaintiff's Product purchase and testing to support her allegations. Specifically, Plaintiff alleges she purchased the Blue Raspberry Product "numerous times online from amazon.com." FAC ¶ 126. No specific allegation is made regarding the manufacturing batch or lot numbers of the Product(s) Plaintiff allegedly bought. According to Plaintiff, unspecified "independent third-party testing" detected "significant" and "material" levels of several PFAS chemicals in the Products. FAC ¶¶ 63, 65, 75, 111, 122. Aside from Plaintiff's conclusory statement that the testing was purportedly "conducted in accordance with accepted industry standards for detecting the presence

of PFAS" (FAC ¶ 64), she provides no details regarding such testing, including who conducted it, how many batches or flavors were tested, whether Plaintiff purchased or used Products from any tested batch(es), or what methodology was used for the testing.

Special attention must be paid to the factual deficiencies of Plaintiff's testing allegations as these purported results are relevant to all of Plaintiff's causes of actions. Even the sources cited within the FAC do not support Plaintiff's assertions. Initially, despite claiming independent testing detected several forms of PFAS analytes aside from Perfluorooctanoic acid ("PFOA"), the FAC provides results for none of these other claimed detections (6:2FTS, PFDA, PFHpA, PFNA, PFUdA, PFDoA, PFHxA, PFPeA, PFTeDA, PFOS, and PFBS). FAC ¶ 65. Furthermore, while Plaintiff concedes that even the EPA (let alone FDA) has not established a guidance for any of those itemized PFAS analytes, she claims the EPA "recently confirmed that the levels at which negative health effects could occur from exposure to certain PFAS chemicals is much lower than previously understood - including near zero in some cases," and cites to an article by the American Cancer Society. FAC ¶ 67, fn. 39. Review of that article, however, indicates absolutely no reference to any of these other PFAS analytes allegedly detected by Plaintiff at undisclosed levels. The article does however express the pervasive nature of PFAS in the environment: "There doesn't seem to be a way to avoid exposure to PFAS completely, as they can be detected in just about everyone's blood" and that in addition to food, PFAS chemicals "can be found at low levels in … drinking water, and in household dust."[4]

Regarding PFOA, the FAC provides results only in relation to a distinguishable EPA interim "lifetime health advisory" of exposure at "0.004 part per trillion (ppt)." FAC ¶ 71. To that

[4] *See* FAC, fn. 39 & 40. https://www.cancer.org/cancer/risk-prevention/chemicals/teflon-and-perfluorooctanoic-acid-pfoa.html

end, Plaintiff claims PFOA was found "in amounts more than 200 times the EPA's current recommend levels of exposure." FAC ¶ 73. Significantly, an EPA interim advisory is not a relevant or binding guidance for an FDA-regulated product, especially when referring to "lifetime exposure" to drinking water rather than occasional consumption of a 16.7 oz. sports drink like Defendant's, as generally noted by the EPA reference presumably relied upon by Plaintiff.[5]

Based on the alleged presence of PFAS in the Product at trace levels Plaintiff challenges Defendant's general representations such as "designed with sustainability in mind" and "good for you and the environment" as tantamount to deceptively marketing the Product as PFAS-free. FAC ¶¶ 4-10, 21-3. Incredibly, the FAC points to the Defendant's website, listing a host of product qualities—unrelated to PFAS—in support of Plaintiff's deceptive advertising claim, including:

- Zero Sugar
- Essential Electrolytes

[5] *See* FAC, fn. 41-43. The EPA's "interim" "lifetime health advisory levels" are set to "protect all people, including sensitive populations and life stages, from adverse health effects resulting from exposure throughout their lives to [PFAS] in drinking water." *See* https://www.epa.gov/sdwa/questions-and-answers-drinking-water-health-advisories-pfoa-pfos-genx-chemicals-and-pfbs#q3; *see also* https://www.epa.gov/sites/default/files/2016-11/documents/clarification_memo_pfoapfos_dw_has.pdf. (EPA stating that its PFAS drinking water health advisories "only apply to exposure scenarios involving drinking water" and that "**[c]alculation of specific risk levels for foods would require development of entirely different exposure assumptions**"**).** (emphasis added).

Furthermore, even if this Court were to acknowledge the distinguishable EPA advisories, these advisories also indicate Plaintiff's purported detection of PFAS is implausible given the current state of PFAS testing technology. Specifically, the EPA concedes that "[b]ased on current methods, the 2022 interim health advisory levels for PFOA and PFOS [cited by Plaintiff] are below the level of both detection (determining whether or not a substance is present) and quantitation (the ability to reliably determine how much of a substance is present)." *See* FAC, fn. 41-43, https://www.epa.gov/sdwa/questions-and-answers-drinking-water-health-advisories-pfoa-pfos-genx-chemicals-and-pfbs#q7. The EPA further explains that for PFOA, the minimum level that can be reliably detected and quantified is 4 parts per trillion – or 1000 times the PFOA health advisory level of 0.004 ppt. Accordingly, although Plaintiff claims to have found deleterious amounts of PFAS at "200 times" the level recommended by the EPA for lifetime exposure to drinking water (or 0.8 ppt), even EPA-certified labs cannot reliably detect PFAS analytes at that level.

- Vegan
- Non-GMO
- Gluten Free
- Recyclable
- Plant-Based Cap
- BPA/PET Free
- Packaging Made from renewable Sources
- 12 x 16.7 fl oz Tetra Pak Bottles

(FAC ¶ 27).

Rather than identifying deceptive statements, the FAC merely itemizes all of Defendant's Product representations (that objectively have nothing to do with PFAS, *e.g.*, "Zero Sugar") in support of her claims. As expressed further below, based on these deficient allegations, Plaintiff cannot meet the requirements for Article III standing or any of her causes of action, all of which must be dismissed accordingly.

## ARGUMENT

### I. PLAINTIFF'S FAILURE TO SUFFICIENTLY ALLEGE THE PRESENCE OF PFAS IN THE PRODUCT IS FATAL TO ALL CLAIMS

Plaintiff fails to allege sufficient facts regarding any PFAS contamination of the Products to state a plausible claim as a matter of law. *See Bell Atl. Corp v. Twombly,* 550 U.S. 544 (2007); *Ashcroft v. Iqbal,* 556 U.S. 662 (2009). Despite the allegations of some (unpled) amount of PFAS in the Products based solely on Plaintiff's testing, the FAC is silent as to this testing's specific date, time, place, sample size, laboratory, or methodology. Under Fed. R. Civ. P. Rule 12(b)(6), a complaint must contain facts that sufficiently "state a claim to relief that is plausible on its face." *Iqbal,* 556 U.S. at 678. Specifically, "a plaintiff's obligation to provide the 'grounds' of his 'entitlement to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly,* 550 U.S. at 555 (quotation marks omitted). Without this requisite specificity, plaintiffs cannot "raise a right to relief above the speculative

level." *Id.* While "a court must accept as true all of the allegations contained in a complaint," Second Circuit decisions adjudicating Rule 12(b)(6) motions rely on "judicial experience and common sense" in rejecting "mere conclusory statements." *Wright v. Publrs. Clearing House, Inc.,* 439 F. Supp. 3d 102, 109 (E.D.N.Y. 2020) citing *Harris v. Mills,* 572 F.3d 66, 72 (2d Cir. 2009).

Indeed, there is no information pled or cited to support that the PFOA levels allegedly detected are "material" and "significant" unless this Court were to accept counsel's unsupported and conclusory assertion that "Ingestion of Any Amount of PFOA and PFOS Creates Significant Health Risks." *See* FAC ¶ 65. Further, Plaintiff does not even distinguish whether the results of the tests conducted were to the Product's exterior packaging or the liquid beverage inside. Even more problematic, this vague pronouncement is pled only in a misguided comparison to the EPA's *proposed* "lifetime health advisory levels for PFOA exposure in drinking water," which is inapplicable to FDA-regulated food, like the Product at issue. FAC ¶¶ 65-69.[6] In the absence of any quantification within her Complaint, Plaintiff essentially asks this Court to step into the shoes of the FDA and establish a "near zero" level of PFAS as a threshold for food, alleging there is "no 'safe' level of exposure" and that "even 'trace' levels of PFAS can pose a risk to humans." FAC ¶ 69, 70.

This is not a matter of fact-finding, but goes to the heart of the plausibility of Plaintiff's allegations and the sufficiency of her pleading. Even in a motion to dismiss, courts are "not required to accept Plaintiff's conclusory statements without more." *Turnipseed v. Simply Orange Juice Co.*, No. 20 Civ. 8677, 2022 U.S. Dist. LEXIS 38823, *14 (S.D.N.Y. Mar. 4, 2022). In *Turnipseed,* 2022 U.S. Dist. LEXIS 38823, at *15, the Southern District dismissed a complaint

[6] Even Plaintiff's improper citations to distinguishable EPA advisories (FAC, fn. 41-43) reveal that EPA has said PFOA cannot be reliably detected by testing at levels below 4ppt – let alone the approximate 0.8 ppt level (FAC, ¶ 71 – 73) Plaintiff claims to have detected.

because plaintiff's conclusory allegations regarding the subject product's vanilla flavoring were too speculative given the limited testing information provided in the Complaint:

> Plaintiff claims that the Product was allegedly subjected to a laboratory test, but she fails to provide any details whatsoever about what this laboratory test entailed. She does not, for instance, describe the testing methodology followed, the specific date, time, or place of the testing, who conducted the testing, the qualifications of the testers, etc.

*Id.*

Accordingly, the Court dismissed that complaint because in the absence of testing details, as "Plaintiff's conclusory allegations alone [prevented] the Court [from] draw[ing] a reasonable inference" of the claims alleged. *Turnipseed,* 2022 U.S. Dist. LEXIS 38823, at *15; *see also Santiful v. Wegmans Food Mkts. Inc.*, No. 20-CV-2933, 2022 U.S. Dist. LEXIS 15994, *8, *15 (S.D.N.Y. Jan. 28, 2022) (dismissing complaint because of plaintiff's failure to "plausibly allege" artificial flavors "[w]ithout any information about the alleged lab analysis."); *Myers v. Wakefern Food Corp.,* No. 20 Civ. 8470, 2022 U.S. Dist. LEXIS 35981, *20 (S.D.N.Y. Mar. 1, 2022) (dismissing Complaint alleging presence of artificial flavors because Complaint failed to describe any details about the lab testing method, date, time, place, and who conducted the testing).

Similar to the *Turnipseed*, *Santiful* and *Myers* courts, this Court should dismiss Plaintiff's FAC due to the absence of testing details. It is beyond cavil that there can be no claims of deceptive practices or misbranding regarding the sale of an allegedly PFAS-containing product when this Court has been provided no plausible basis to believe Defendant's Products even contain PFAS. As a matter of law, Plaintiff's failure to allege plausibly the presence of PFAS in the Product defeats each of her claims.

## II. PLAINTIFF LACKS ARTICLE III STANDING TO SUSTAIN HER CLAIMS

While Plaintiff fails to provide any plausible basis to believe any BioSteel Product contains PFAS, the FAC's deficiencies are even more stark regarding the claim that Plaintiff actually

purchased an allegedly PFAS-containing Product. Without a plausible causal connection between the alleged presence of PFAS in the Product at issue and Plaintiff's claimed economic injury, this matter should be dismissed for lack of subject matter jurisdiction. Fed. R. Civ. P. Rule 12(b)(1).

Article III standing requires a plaintiff to "demonstrate (1) 'injury in fact' (2) a 'causal connection' between that injury and the complained of conduct, and (3) a likelihood that the injury will be redressed by a favorable decision." *Strubel v. Comenity Bank,* 842 F.3d 181, 187-88 (2d Cir. 2016) *quoting Lujan v. Defs of Wildlife,* 504 U.S. 555 (1992); s*ee also Gaminde v. Lang Pharma Nutrition, Inc.,* No. 1:18-cv-300, 2019 U.S. Dist. LEXIS 48595 (N.D.N.Y. Mar. 25, 2019) (standing requires that plaintiff prove by a preponderance of evidence that he suffered an injury in fact which is concrete and particularized, such that the injury affects the plaintiff in a personal and individual way). Even under the lenient standard of review for "standing at the pleading stage . . . a plaintiff cannot rely solely on conclusory allegations of injury or ask the court to draw unwarranted inferences in order to find standing." *Baur v. Veneman,* 352 F.3d 625, 636-37 (2d Cir. 2003). Plaintiff still "must plead enough facts to make it plausible that they did indeed suffer the sort of injury that would entitle them to relief." *Maddox v. Bank of New York Mellon Tr. Co., N.A.,* 19 F.4th 58, 65-66 (2d Cir. 2021).

**A. Plaintiff's Conclusory Allegations of Injury Fail to Confer Standing**

Only conjecture supports Plaintiff's attempt to allege an injury under a "price premium" theory that "Plaintiff and putative Class Members would not have purchased Defendant's Product or they would have paid less for them" if advised of the Product's alleged PFAS content. FAC ¶ 92. Specifically, the FAC contains no plausible allegations "to demonstrate that [plaintiff] actually purchased adulterated products . . . ." *Onaka v. Shiseido Ams. Corp.*, 21-cv-10665, 2023 U.S. Dist. LEXIS 53220, at *12 (S.D.N.Y. Mar. 28, 2023). Instead, Plaintiff alleges only that she purchased the Product "numerous times online from amazon.com." FAC ¶ 126. No additional

information is provided for this Court to tie these purchases to the testing that allegedly detected PFAS. Plaintiff does not provide the dates or number of transactions that purportedly constitute "numerous" purchases. Furthermore, Plaintiff not only fails to plead the Product(s) she actually purchased were tested, but she does not even claim that Products from the same batch she purchased were tested. Thus, she fails to plead a "particularized" injury.

Further, even after acknowledging "the composition of the Product may change over time," FAC ¶ 129, Plaintiff asks this Court to accept that trace amounts of PFAS, allegedly detected in an unknown number of products from an unknown sample size somehow sufficiently pleads that Plaintiff purchased a PFAS-containing Product. However, facts indicating the "mere possibility of misconduct" are insufficient under Rule 12(b)(6). *Iqbal*, 556 U.S. at 679. As such, Plaintiff's FAC has none of the markers of reliability to raise its conclusory allegations to the requisite level of plausibility. Without such plausibility, Federal courts routinely hold such deficient allegations of third-party testing or studies indicating contamination of only certain batches as insufficient to support claims a plaintiff purchased a contaminated product. *See, e.g., Gaminde,* 2019 U.S. Dist. LEXIS 48495, at *6 ("[I]t is speculation to allege that because two CVS Krill Oil bottles in a USDA study were found to have less than the stated amount of Omega-3 Krill Oil, the bottle that Gaminde purchased must as well."); *Doss v. Gen. Mills, Inc.,* No. 18-619240-Civ, 2019 U.S. Dist. LEXIS 100791, at *6 (S.D. Fla. June 14, 2019), *aff'd*, 816 F. App'x 312 (11th Cir. 2020) (finding that plaintiff lacked standing where she did not "allege that the Cheerios she herself bought actually contain[ed] any glyphosate—just that some Cheerios that have been tested do").[7]

[7] *See also, e.g., Bodle v. Johnson & Johnson Consumer,* No. 3:21-cv-07742-EMC, 2022 WL 18495043 (N.D. Cal. Feb. 24, 2022) (dismissing for lack of standing and holding that even testing which revealed 23 contaminated batches were not enough for the complaint to claim systemically contaminated batches or the purchase of a contaminated product.); *Bowen v. Energizer Holdings, Inc.*, No. CV 21-4356-MWF, 2023 U.S. Dist. LEXIS 21654 at *28 (C.D. Cal. Jan. 5, 2023)

**B. New York Court Recently Held Lack of Standing in Similar Purported PFAS Class Action**

In a recent and remarkably analogous matter, the Southern District of New York dismissed a case for lack of standing when plaintiffs' complaint, containing the same omission claims as here, was too vague to plausibly allege a connection between the claimed injury and the plaintiffs – specifically that plaintiffs had purchased any PFAS-containing products. *See Onaka,* 2023 U.S. Dist. LEXIS 53220, at *12. There, plaintiffs alleged an economic injury by purchasing FDA-regulated products labeled "clean" and "natural" that allegedly contained PFAS and attempted to claim a connection between plaintiffs and the injury based only upon their own testing and reports of PFAS in the industry. *Id.* In dismissing the case based on lack of standing, the *Onaka* court held that plaintiffs' "Complaint [did] not allege Plaintiffs tested any of their own purchases for PFAS." *Id.* Accordingly, plaintiff's "claims [were] too speculative to confer standing." *Onaka*, 2023 U.S. Dist. LEXIS 53220, at *16.

Lastly, having failed to allege any specific facts connecting Plaintiff's alleged purchase to claimed economic injury, the FAC also provides no plausible basis for this Court to believe PFAS contamination, if present at all, is so widespread in the Product's production that standing should be assumed. While the FAC references a few irrelevant studies and environmental findings regarding the presence and dangers of PFAS in the environment, it also contains no relevant studies, publications, or investigations of any kind regarding the detection of PFAS in sports drink products, let alone Defendant's specific Product. FAC ¶¶ 38-74. As such, there are "no facts from

(holding plaintiff's lack of allegations to have purchased product from tested batch was fatal to standing analysis because "economic harm premised on speculative risks cannot establish Article III standing"); *Schloegel v. Edgewell Pers. Care Co.,* No. 4:21-cv-00631, 2022 U.S. Dist. LEXIS 46393, at * 6 (W.D. Mo. Mar. 16, 2022) (finding plaintiff lacked standing where she alleged that samples of defendant's sunscreen products contained benzene but "failed to allege that she actually purchased Banana Boat Sunscreen products which were adulterated with benzene").

which [this] Court could extrapolate that [plaintiff's] isolated testing should apply broadly to Defendant's Products, regardless of when they were purchased." *Id.* at *13. Accordingly, like the complaint in *Onaka*, the First Amended Complaint here should be dismissed for lack of standing under Rule 12(b)(1).

## III. PLAINTIFF FAILS TO STATE A CLAIM UNDER RULE 12(b)(6)

Even if this Court were to find Plaintiff's threadbare testing allegations sufficient to assert a claim that Plaintiff's Product contained trace amounts of PFAS, the FAC would still require dismissal for Plaintiff's failure to identify any deceptive or fraudulent marketing of the Products to consumers. *See Axon v. Citrus World, Inc.,* 354 F. Supp. 3d 170, 183 (E.D.N.Y. 2018). Furthermore, Plaintiff's deficient consumer deception claims cannot be salvaged by rebranding them as alleged violations of public health statutes such as N.Y. Agric & Markets Law or the FDCA under either private right of action or negligence *per se* theories. As expressed below, under the plain language and interpretive case law of the N.Y. Agric. & Markets Law, no private right of action exists. Lastly, aside from failing to allege plausible claims of adulteration, Plaintiffs negligence *per se* claims run afoul of New York's economic loss doctrine prohibiting negligence claims for mere economic injuries. *Colangelo v. Champion Petfoods USA, Inc*., 6:18-CV-1228, 2020 U.S. Dist. LEXIS 26919, *41 (N.D.N.Y. Feb. 18, 2020).

### A. Plaintiff's NYGBL §§ 349 and 350 Claims Fail to Allege Any Requisite Deceptive Statement Capable of Plausibly Misleading a Reasonable Consumer

Plaintiff fails to identify any deceptive statement by Defendant required to assert claims under NYGBL §§ 349 and 350 Such general allegations fail to state a valid claim under NYGBL §§ 349 and 350, where a plaintiff must allege "(1) that the defendant's deceptive acts were directed at consumers, (2) the acts are misleading in a material way, and (3) the plaintiff has been injured as a result." *Chufen Chen v. Dunkin' Brands, Inc.,* 954 F.3d 492, 500 (2d Cir. 2020). Specifically,

"plaintiff must plausibly allege that a significant portion of the general consuming public or targeted consumers, acting reasonably in the circumstances could be misled." *Campbell v. Whole Foods, Mkt. Grp, Inc.*, 516 F. Supp. 3d 370, 381 (S.D.N.Y. 2021); *see also Fink v. Time Warner Cable*, 714 F.3d 739, 741 (2d Cir. 2013); *Axon v. Citrus World, Inc.*, 354 F. Supp. 3d 170, 183 (E.D.N.Y. 2018); *Bowring v. Sapporo U.S.A., Inc.*, 234 F. Supp. 3d 386, 390 (E.D.N.Y. 2017).[8]

Significantly, it is uncontested that Defendant's Product labeling contains no "PFAS-free" representations and the listed ingredients show PFAS are not intentionally added. FAC at ¶¶ 5, 24, 25, 26, and 32. Accordingly, even by Plaintiff's own admissions, any alleged PFAS presence would be incidental. *Id.* Given these facts, Plaintiff resorts to claiming that Defendant's general representations regarding the product's qualities such as "designed with sustainability in mind" and "good for you and the environment" deceptively market the Product as a "safe and healthy sports drink." FAC ¶¶ 4-10, 23-36. Incredibly, the FAC points to the Defendant's website, listing a host of undisputed Product qualities—none of which have anything to do with PFAS—in support of Plaintiff's faulty deceptive advertising claim, including but not limited to "Zero Sugar," "Non-GMO," and "Plant-Based Cap."[9] Accordingly, rather than identifying a ***deceptive*** statement, Plaintiff asks this Court to hold that the totality of Defendant's general Product representations, objectively having nothing to do with PFAS, violate NYGBL because they do not address the PFAS contamination alleged only by her counsel and based upon testing with unpled methodology.

[8] "It is well-settled that a court may determine as a matter of law that an allegedly deceptive advertisement would not have misled a reasonable consumer." *Fink,* 714 F.3d at 741; *see also Cohen v. JP Morgan Chase & Co.*, 498 F.3d 111, 126 (2d Cir. 2007) (holding "the New York Court of Appeals has adopted an objective definition of 'misleading'. . . .").

[9] A full list of product representations that are undisputed as accurate can be found in the Background section of this brief at pages 6-7.

Plaintiff cannot sustain her flawed theory that accurate Product representations would reasonably be taken as a representations about the presence or absence of PFAS.

In a case directly on point, *Axon v. Citrus World, Inc.,* 354 F. Supp. 3d 170, 183 (E.D.N.Y. 2018), this Court dismissed plaintiffs' NYGBL §§ 349 and 350 claims, holding that the trace amounts of glyphosate (a pesticide) allegedly detected in defendant's "Florida Natural" orange juice could not support plausible allegations of consumer deception. Significantly, there, as here, the offending substance was "not an 'ingredient' added to defendant's products." *Id.* The Court held as a matter of law it was "not plausible to allege that a reasonable consumer would interpret the brand label "Florida's Natural" as meaning that the product contains no traces of glyphosate…." *Id.* at 183; *see also Parks v. Ainsworth Pet Nutrition*, 377 F. Supp. 3d 241, 247 (S.D.N.Y. 2019) (holding as a matter of law that "a reasonable consumer would not be so absolutist as to require that 'natural' means there is no glyphosate, even an accidental and innocuous amount, in the Products"). Similarly, here, the Court should find reasonable consumers would not interpret the statements on the Product packaging or advertising referenced in Plaintiff's FAC to mean there are no traces of PFAS.

Contrary to the case law above, Plaintiff seeks to stretch the legitimate purposes of NYGBL by claiming even more ambiguous terms like "good" are objectively misleading to a reasonable consumer due to the Product's alleged PFAS content in conjunction with irrelevant product quality representations. Such a vague theory is routinely rejected by Courts who ***require allegations of specific misrepresentations, not a plaintiff's subjective inference***, to sustain a NYGBL claim. *See*, *e.g.*, *Harris v. Pfizer, Inc.*, 586 F. Supp. 3d 231, 243 (S.D.N.Y. 2022). In *Harris,* the Southern District granted defendant's Rule 12(b)(6) motion, regarding economic harm suffered by the purchase of a product allegedly containing nitrosamine due, in part, to plaintiff's failure to

"identify any misleading statement." *Id*. Notably, the Court held a "plaintiff does not have a claim under the NYGBL just because she comes away from an advertisement with an incorrect impression. That impression must be reasonably traceable to a misleading statement from the defendant." *Id.* at 243-244; s*ee also Solis v. Coty, Inc.*, Case No. 22-cv-0400, 2023 U.S. Dist. LEXIS 38278, at *20-21 (S.D. Cal. Mar. 7, 2023) (dismissing because plaintiff "cannot identify a misrepresentation in defendant's marketing materials" and holding that general safety and environmental advertising is "far too generalized to reasonably be construed as representations about [a] product's PFAS content."*).*

Lastly, while the New York Court of Appeals has held NYGBL § 349 prohibits "representations or omissions . . . likely to mislead a reasonable consumer" the cause of action also cannot survive under any claim Defendant "omitted" an alleged PFAS presence in the Product. *See Oswego Laborers' Local 214 Pension Fund v. Marine Midland Bank, N.A*., 85 N.Y.2d 20, 26 (1995). Specifically, the New York Court of Appeals in *Oswego* held that in order to avoid a tidal wave of litigation against businesses that was not intended by enacting NYGBL § 349, courts must apply an objective definition of deceptive acts and practices, whether they are representations or omissions, limited to those likely to mislead a reasonable consumer acting reasonably under the circumstances. *Id*. In the case of omission claims in particular, the question becomes whether "the business alone possesses material information that is relevant to the consumer and fails to provide this information." *Id.* Accordingly, in *Harris,* 586 F. Supp. 3d at 244, the Southern District dismissed NYGBL claims against defendant Pfizer for an alleged omission that its product, the stop-smoking drug Chantix, had nitrosamine contamination finding that the plaintiff failed to identify a statement that was "rendered false or misleading by any omission." *Id*. at 241. Unlike here, *Harris* contained no factual dispute regarding that contamination, as Pfizer issued a recall a

year after the plaintiff's purchase of the product. Nonetheless, the Court still dismissed the NYGBL claims, holding "plaintiff's conclusory assertions [were not] sufficient to plausibly establish that Pfizer knew about any nitrosamine contamination in the medication that the plaintiffs purchased at the time they purchased it." *Id*. at 244.

Here, Plaintiff's conclusory allegation that "[a]t all times relevant to this action, Defendant knew, or at minimum should have known, that its Product contains PFAS" (FAC ¶ 76) fails to state a claim for a violation of NY GBL §§ 349-50. *See Womack v. EVOL Nutrition Assocs.,* No. 21-332, 2021 U.S. LEXIS 238347, at *29 (N.D.N.Y. Dec. 14, 2021) (dismissing NYGBL omissions claims where "the sole allegation regarding Defendant's knowledge [was] vague and conclusory [as it alleged] that 'Defendant knew or should have known [of the potential serious dangers]'"). At the outset, this type of alleged constructive knowledge, claiming a defendant "should have known" is defective on its face, as the New York Court of Appeals requires a showing that defendant is engaging in an act or practice that is deceptive or misleading in a material way. *See Oswego Laborers' Local 214 Pension Fund,* 85 N.Y.2d at 25. Furthermore, there is absolutely no support given for Defendant's alleged actual knowledge anywhere in the entirety of the FAC.[10] The requisite knowledge pled is not just deficient—but is nonexistent—justifying dismissal of Plaintiff's NYGBL claims.

**B. Failure to Plead a Deceptive Act is Also Fatal to Plaintiff's Unjust Enrichment Claim**

Without any showing of a deceptive act, Plaintiff's unjust enrichment claim also fails because, other pleading requirements aside, plausibly pled deception is a threshold requirement for this claim. In the highly analogous *Twohig v. Shop-Rite Supermarkets, Inc*., 519 F. Supp. 3d 154, 165 (S.D.N.Y. 2021), the Southern District dismissed all claims, including unjust enrichment,

[10] Defendant's lack of any actual knowledge is further supported by Plaintiff's decision to withdraw her previous fraud claim from the FAC.

regarding allegedly deceptively labeled Soy Milk after holding the product label was not misleading under NYGBL:

> Plaintiffs also bring claims for fraud, negligent misrepresentation, breaches of express and implied warranty, and unjust enrichment. These claims are all premised on the assertion that Defendant's labeling is materially misleading. Because [the court has] already determined that Plaintiffs failed to allege that the Product's labeling would be likely to deceive or mislead a reasonable consumer, these causes of action are also dismissed . . . .

*Id.*

An unjust enrichment claim is not available "where it simply duplicates, or replaces, a conventional contract or tort claim." *Corsello v. Verizon N.Y., Inc.,* 18 N.Y.3d 777, 790 (2012). Here, Plaintiff's unjust enrichment claim is based on the same alleged deceptive conduct and suffers the same pleading deficiencies, mandating dismissal.

**C. N.Y. Agriculture and Markets Law § 199-a Has No Private Right of Action**

Having abandoned her fraud and constructive fraud causes of action from the original Complaint, Plaintiff now seeks to replace those claims with a purported violation of New York's Agriculture and Markets Law § 199-a ("NY Agric. & Mkts. Law"). To be clear, the FAC's Third Cause of Action is not referencing this statute as some proof of negligence, but claiming the alleged violation itself is actionable. Such a claim, however, cannot stand as a matter of law because this statute, like the misbranding provisions of the FDCA it was modeled upon, has no private right of action. *See* N.Y. Agric. & Mkts. Law 202-c ("***The commissioner*** may institute such action at law or in equity as may appear necessary to enforce compliance with sections one hundred ninety-nine-a, two hundred and two hundred one of this article… and, in addition to any other remedy under this chapter or otherwise, may apply for relief by injunction.") (emphasis added). *See also* 21 U.S.C. § 337(a) ("[A]ll such proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States.")

The plain meaning of this statutory language has been confirmed by New York Federal Courts, including the Eastern District, who have held that the NYGBL is the proper statute for a private party to seek relief:

> While New York's Agriculture and Marketing law incorporates the FDCA's labeling provisions forbidding the misbranding of food, plaintiffs receive their private rights of action for the misbranding of food ***under consumer protection laws such as NYGBL*** §§ 349 and 350.

*Axon v. Citrus World,* 354 F. Supp. 3d 170,185 n. 9 (E.D.N.Y. 2018) (emphasis added).

Likewise, in *Koenig v Boulder Brands, Inc.,* 995 F Supp. 2d 274, 280-81 (S.D.N.Y. 2014) the Court held:

> New York's Agriculture and Marketing law incorporates the FDCA's labeling provisions and, likewise, provides that food shall be deemed misbranded '[i]f its labeling is false or misleading in any particular.' New York law also provides remedies, including private rights of action, for misbranding food under consumer protection laws, such as GBL § 349, which broadly prohibits use of "deceptive acts or practices" in business dealings in New York.

*Id. quoting,* in part, *Ackerman v. Coca-Cola Co.,* CV-09-0395, 2010 U.S. Dist. LEXIS 73156, *4 (E.D.N.Y. Jul. 21, 2010). *See also Wurtzburger v. Kentucky Fried Chicken*, No. 16-CV-08186 (NSR), 2017 U.S. Dist. LEXIS 205881, at *10 (S.D.N.Y. Dec. 13, 2017) (holding "[a]lthough there is no private right of action under the FDCA . . . New York law provides remedies and a private right of action for misbranding food ***under GBL § 349*** . . .') (emphasis added).

Notably, the FAC does not even attempt to claim Plaintiff is entitled to a private right of action under the FDCA, likely recognizing the well-settled Supreme Court precedent of *Buckman Co. v. Plaintiffs' Legal Comm*., 531 U.S. 341 (2001), holding that claims seeking to enforce FDCA regulations, or claims where the violation of FDCA regulations were a "critical element" of the case, are impliedly preempted and, as such, no private right of action exists. *Id.* at 352-52.

Nevertheless, Plaintiff attempts to achieve this same incongruous result by asserting a private right of action claim under the remarkably similar New York statute which "incorporates the FDCA's labeling provisions." Indeed, in *Axon*, the Eastern District Court clarified that the class action plaintiffs avoided such conflict preemption because they received their private right of action, not from N.Y. Agric. & Markets Law, but "under consumer protection laws such as NYGBL §§ 349 and 350." *Axon*, 354 F. Supp. 3d at 185 n. 9.[11] Accordingly, Plaintiff's NY Agric. & Mkts. Law count should be dismissed as a matter of law as it confers no private right of action to a consumer such as Plaintiff and Plaintiff's allegations are merely duplicative of those made under her fatally flawed General Business Law claims.

**D. Plaintiff's Negligence *Per Se* Cause of Action Fails Under New York Economic Loss Doctrine and For Other Reasons**

Perhaps recognizing N.Y. Agric. & Market Law contains no private right of action, Plaintiff's FAC attempts to backdoor implausible violations of both the N.Y. Agric. & Mkts. Law and the FDCA upon which it was based as constituting negligence *per se*. Nevertheless, this claim must fail because if the mere allegation of a statutory "violation were to establish negligence *per se*, plaintiff would effectively be afforded a private right of action that the statute does not recognize." *Cohen v. Northeast Radiology, P.C.*, 20 cv 1202, 2021 U.S. Dist. LEXIS 16497, at *20, 20 cv 1202 (S.D.N.Y. Jan. 28, 2021) *citing Smahaj v. Retrieval-Masters Creditors Bureau Inc.*, 69 Misc. 3d 597, 608 (Sup. Ct. Westchester Cty 2020). Such a workaround would impermissibly violate the statutes' plain wording affording government the sole authority to

[11] While Plaintiff counsel's July 3, 2023 letter to this Court in opposition to Defendant's request for this motion claims that the Second Circuit has recognized a private right of action under N.Y. Agric. & Mkts. Law, citing *Porrazzo v. Bumble Bee Foods, LLC,* 822 F. Supp. 2d 406, 424 (S.D.N.Y. 2011), this assertion is not supported by the case law. [Dkt. 24]. Indeed, the Eastern District class action case of *Axon v. Citrus World* was decided post-*Porazzo.* Furthermore, review of the *Porazzo* personal injury case indicates that the argument of N.Y. Agric. & Market's lack of a private right of action was never raised by Defendants or adjudicated by the Court.

enforce these regulations. *See Riley v. Cordis Corp*., 625 F. Supp. 2d 769, 777 (D. Minn. 2009) (holding "a private litigant may not bring a state law claim against a defendant when the state law claim is in substance (even if not in form) a claim for violating the FDCA").

Plaintiff attempts to liken N.Y. Agric. & Mkts. Law and the FDCA to New York's General Business Law by alleging that they "are designed to protect consumers like Plaintiff" ignoring that these public health statutes are not based in or intended to apply to a consumer's alleged economic harm. FAC, ¶ 206. This distinction is critical as it is "well settled that New York law holds that a negligence action seeking recovery for economic loss will not lie." *Colangelo v. Champion Petfoods USA, Inc*., 6:18-CV-1228, 2020 U.S. Dist. LEXIS 26919, *41 (N.D.N.Y. Feb. 18, 2020) (dismissing negligence *per se* claim based on dog food manufacturer's alleged violation of N.Y. Agric. & Mkts. Law) *quoting Black Radio Network, Inc. v. NYNEX Corp*., No. 96-CV-4138, 2000 U.S. Dist. LEXIS 594, *10 (S.D.N.Y. Jan. 25, 2000) *quoting Suffolk Cty. v. Long Island Lighting Co.,* 728 F.2d 52, 62 (2d Cir. 1984).[12]

Lastly, the FAC fails to plausibly allege any violation because unintentionally added substances do not constitute adulteration if the quantity of the "deleterious substance . . . in such food does not ordinarily render it injurious to health." 21 U.S.C § 342(a)(1); § 200 of N.Y. Agric & Mkts. Law; FAC ¶ 203. Here, despite citing internet sources on potential health risks Plaintiff neither alleges personal injury nor raises any reasonable probability of injury by inventing a "zero" tolerance standard for PFAS based only on the contortion of an EPA health advisory, which is

[12] Indeed, in Plaintiff's counsel's July 3, 2023 letter in opposition to Defendant's request for this motion, counsel claimed "the Second Circuit has expressly recognized that a private right of action for per se negligence claims arises under New York State law upon violation of the FDCA citing to *Henson v. Wright Med. Tech, Inc*., No. 5:12-CV-805, 2013 U.S. Dist. LEXIS 44295, *16 (N.D.N.Y. Mar. 28, 2013), but neglecting to advise that *Henson* and the cases it cites are inapposite as they are personal injury cases where violations of the FDCA's failure to warn regulations resulted in a plaintiff's physical injury. [Dkt No. 24]

inapplicable to FDA-regulated food, pertaining only to the lifetime exposure of PFAS in drinking water, and not occasional Sports drink consumption.

## IV. PLAINTIFF'S CLAIMS ARE PREEMPTED AND SUBJECT TO FDA'S PRIMARY JURISDICTION

Plaintiff ignores that FDA regulations already control and speak to disclosure of "incidental additives" in food, and the FDA is studying and has signaled, specifically, an intent to regulate PFAS in numerous products, including foods. As such, labeling, safety and regulating the acceptable levels of PFAS in food products is squarely within the FDA's primary jurisdiction and should be left to the "special competence" of that "administrative agency." *See Reiter v. Cooper,* 507 U.S. 258, 268 (1993). If Plaintiff's claims are not barred by preemption (or otherwise dismissed), they should be dismissed pending FDA review of the broader issue of PFAS in food. Any decision other than dismissing these claims under the consumer protection laws cited by Plaintiff would pose an obstacle to federal policy.

### A. Plaintiff's "Failure to Disclose" Claims Are Preempted.

Plaintiff's claims of omission are preempted by the Nutrition Labeling & Education Act ("NLEA"), which includes a broad express preemption provision directing that "no State or political subdivision of a State may directly or indirectly establish . . . any requirement for . . . labeling of food . . . that is not identical to the requirement[s]" imposed by federal law. 21 U.S.C. § 343-1(a)(2). The phrase "'[n]ot identical to' does not refer to the specific words in the requirement but instead means that the State requirement directly or indirectly imposes obligations or contains provisions" that are "not imposed by or contained in" or that "[d]iffer from those specifically imposed by or contained in" the statute or the FDA's implementing regulations. 21 C.F.R. § 100.1(c)(4). Accordingly, states can impose requirements that are identical to those imposed by the FDCA, but not different from or more burdensome than those requirements. *See*

*In re PepsiCo, Inc., Bottled Water Mktg. & Sales Practices Litig.*, 588 F. Supp. 2d 527, 532 (S.D.N.Y. 2008).

Plaintiff does not identify any FDA regulation requiring the disclosure of PFAS on food labeling, because none exists. To the contrary, the NLEA, 21 U.S.C. § 343-1(a)(2), a 1990 amendment to the FDCA, expressly preempts manufacturers from having to disclose the presence of "[i]ncidental additives that are present in a food at insignificant levels and do not have any technical or functional effect in that food," including "[s]ubstances migrating to food from equipment or packaging or otherwise affecting food that are not food additives as defined in section 201(s) of the act." 21 C.F.R. § 101.100(a)(3)(iii). Any PFAS allegedly found in the Product would constitute incidental additives that need not be disclosed under FDA's regulations as Plaintiff does not plead that PFAS have any technical or functional effect on the Products. Other courts have preempted claims under the same regulation where plaintiffs sought to require disclosure of other incidental additives. *See In re Bisphenol-A (BPA) Polycarbonate Plastic Prod. Liab. Litig.*, No. 08-1967, 2009 WL 3762965, at *5 (W.D. Mo. Nov. 9, 2009) (finding that 21 C.F.R. § 101.100(a)(3)(iii) exempted defendants "from disclosing the presence of BPA in their products" and preempted plaintiff's claims because "they would impose disclosure requirements concerning BPA, the exact opposite of the exemption § 343(i)(2) permits").

Furthermore, because Plaintiff fails to allege any actual levels of PFAS in the Products (aside from vague and misguided comparison to the EPA's interim lifetime health advisory for drinking water that does not even apply to FDA-regulated foods), she cannot argue that PFAS are found in anything more than "insignificant levels." Plaintiff essentially seeks to impose a PFAS-disclosure requirement for product labels entirely different from the requirements set forth in the federal regulatory scheme set forth by the FDA. Therefore, imposing liability on Defendant would

run afoul of well-settled law that state common law duties "cannot impose obligations beyond, or different from, what federal law requires." *In re PepsiCo, Inc., Bottled Water Mktg. & Sales Practices Litig.,* 588 F. Supp. at 532. Finally, Defendant's compliance with controlling FDA regulations also serves as a "complete defense" to plaintiff's NYGBL claims. *See* NYGBL §§ 349(d), 350-d(b). [13]

**B. The Primary Jurisdiction Doctrine Mandates Dismissal of Plaintiff's Claims.**

While Plaintiff's claims are subject to dismissal for the reasons set forth above, each of the claims should also be dismissed, or in the alternative, stayed, pursuant to the primary jurisdiction doctrine, which "applies where a claim is originally cognizable in the courts, but enforcement of the claim requires, or is materially aided by, the resolution of threshold issues, usually of a factual nature, which are placed within the special competence of the administrative body." *Palmer v. Amazon.com, Inc.*, 51 F.4th 491, 505 (2d Cir. 2022) (citing *Golden Hill Paugussett Tribe of Indians v. Weicker*, 39 F.3d 51, 58-59 (2d Cir. 1994)). A court invokes the primary jurisdiction doctrine when it determines that the agency, not the courts, should have the "initial decision making responsibility." *Id.* (citing *Ellis v. Tribune Television Co.*, 443 F.3d 71, 81 (2d Cir. 2006)). The Second Circuit has determined that four factors—referred to as the "*Ellis* factors"—guide the analysis as to whether the primary jurisdiction doctrine applies:

> (1) whether the question at issue is within the conventional experience of judges or whether it involves technical or policy considerations within the agency's particular field of expertise; (2) whether the question at issue is particularly within the agency's discretion; (3) whether there exists a substantial danger of inconsistent rulings; and (4) whether a prior application to the agency has been made.

*Palmer*, 51 F.4th at 506.

[13] *Duchimaza v. Niagara Bottling, LLC*, 619 F. Supp. 3d 395, 411-412 (S.D.N.Y. 2022) ("It is a 'complete defense' to liability under GBL §§ 349 and 350 that an 'act or practice is . . . subject to and complies with the rules and regulations of, and the states administered by, the federal trade commission or any official department, division, commission or agency of the United States.")

Each of the *Ellis* factors weigh in favor of finding that the FDA has primary jurisdiction. First, resolution of Plaintiffs' claims requires consideration of how to test for PFAS, what level of PFAS is harmful, and what levels of PFAS are acceptable in foods, and the Product. Whether the Product contains impermissible levels of PFAS—or enough PFAS that the Product's labeling should have been changed—is a technical issue that requires policy considerations within the FDA's expertise. And, given its ubiquity, PFAS is a popular subject in the plaintiffs' bar, so there is a likelihood of inconsistent rulings on the issue. *See In re Gerber Prods. Co. Heavy Metals Baby Food Litig.,* No. 1:21-cv-269, 2022 U.S. Dist. LEXIS 189822, at *55 (E.D. Va. Oct. 17, 2022) (multiple courts considering similar issues will "likely result in a patchwork of decisions that vary by location, court, manufacturer, and product, resulting in different labeling standards for substantially similar . . . products produced by different manufacturers"). There is little doubt that PFAS pose novel and complex scientific and regulatory issues that the FDA is grappling with, and PFAS currently present issues outside the scope of the conventional experience of judges, requiring technical considerations within FDA's field of expertise. Moreover, as Plaintiff alleges injuries non-specific to herself and that PFAS endanger the health of a considerable number of persons, the FDA's determination on these issues will materially aid the Court in resolving those issues. Thus, this case should be dismissed under the primary jurisdiction doctrine, if not otherwise dismissed.

## CONCLUSION

Wherefore Defendant respectfully requests that this Court issue an Order in favor of Defendant, dismissing Plaintiff's claims in their entirety, with prejudice.

Dated: New York, New York
August 4, 2023

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