UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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CHRISTINE BISCHOFF, *on behalf of herself and on all others similarly situated*,

Plaintiff,

- against -

ALBERTSONS COMPANIES, INC.; ACME MARKETS, INC.; SAFEWAY, INC.; BETTER LIVING BRANDS, LLC; and LNK INTERNATIONAL, INC.,

Defendants.

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OPINION & ORDER

No. 22-CV-4961 (CS)

Appearances:

Neal J. Deckant
Julia K. Venditti
Bursor & Fisher, P.A.
Walnut Creek, California
Counsel for Plaintiff

Christopher A. DeGennaro
Foley & Lardner LLP
New York, New York
Counsel for Defendants

Seibel, J.

Before the Court is Defendants' Motion to Dismiss Plaintiff's First Amended Complaint. (ECF No. 39.) For the following reasons, the motion is GRANTED.

I. BACKGROUND

For purposes of this motion, I accept as true the facts, but not the conclusions, set forth in the Amended Complaint. (ECF No. 35 ("AC").) [1] Defendants advertise, market, and sell generic versions of certain over-the-counter ("OTC") drugs, including acetaminophen, under the brand name "Signature Care." (*Id.* ¶¶ 1, 20-25.) As relevant here, Defendants have introduced two lines of OTC gelcaps containing acetaminophen with a label containing the phrase "Rapid

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[1] When deciding a motion to dismiss, a court is entitled to consider:

> (1) facts alleged in the complaint and documents attached to it or incorporated in it by reference, (2) documents integral to the complaint and relied upon in it, even if not attached or incorporated by reference, (3) documents or information contained in defendant's motion papers if plaintiff has knowledge or possession of the material and relied on it in framing the complaint . . . , and (5) facts of which judicial notice may properly be taken under Rule 201 of the Federal Rules of Evidence.

Weiss v. Inc. Village of Sag Harbor, 762 F. Supp. 2d 560, 567 (E.D.N.Y. 2011) (Unless otherwise indicated, case quotations omit all internal citations, quotation marks, footnotes, and alterations.). In addition, "material that is a matter of public record may be considered in a motion to dismiss." *Byrd v. City of N.Y.*, No. 04-CV-1396, 2005 WL 1349876, at *1 (2d Cir. June 8, 2005) (summary order).

In support of their motion, Defendants submit the Declaration of Christopher A. DeGennaro, which attaches several publicly available documents drafted by the United States Pharmacopeia ("USP") and the U.S. Food and Drug Administration ("FDA"). (ECF No. 41.) Because these documents are publicly available and Plaintiff does not object to their consideration, I take judicial notice of these exhibits. *See, e.g.*, *Apotex Inc. v. Acorda Therapeutics, Inc.*, 823 F.3d 51, 60 (2d Cir. 2016) ("[W]e may properly take judicial notice of this document (without converting [defendant's] motion to dismiss into a motion for summary judgment) because the [FDA] Guidance is publicly available and its accuracy cannot reasonably be questioned."); *Morgan v. Albertsons Cos., Inc.*, No. 22-CV-2948, 2023 WL 3607275, at *1 n.1 (N.D. Cal. Mar. 13, 2023) ("[Defendant] requests that the Court take judicial notice of FDA warning letters and FDA guidance, as well as testing materials to which the complaint refers. Plaintiffs rely on some of the materials contained [in the] request for judicial notice in their opposition to the motion to dismiss and do not state they oppose it. The Court grants judicial notice of the existence of these materials, but not for the truth or accuracy of the statements therein.").

Release": Signature Care Rapid Release Gelcaps and Signature Care PM Rapid Release Gelcaps, (together, the "Products"). (*Id.* ¶¶ 5-6.)

Plaintiff Christine Bischoff, a New York resident, purchased the Products in reliance on the representation on the packaging that the gelcaps are "Rapid Release." (*Id.* ¶ 19.) Plaintiff alleges that despite the "Rapid Release" label, the Products do not work faster than the lower-priced Signature Care acetaminophen products that do not include the "Rapid Release" label on their packaging. (*Id.* ¶¶ 43-53; *see id.* Ex. A, at 44-46.) To support her allegations, Plaintiff commissioned an independent study to test the dissolution rates of the Products as compared to Signature Care non-"Rapid Release" acetaminophen products, (the "Study"). (*Id.* ¶ 54.) The Study revealed that the non-"Rapid Release" products dissolved slightly faster than the Products. (*Id.* ¶¶ 54-55.) Specifically, while both sets of products were 100% dissolved by 30 minutes, non-"Rapid Release" products dissolved 80% in 9.7 minutes and 85% in 10.7 minutes, while the Products dissolved 80% in 10.9 minutes and 85% in 12.0 minutes. (*Id.* ¶ 54.)

Plaintiff filed her original complaint on June 13, 2022, bringing claims for (1) violation of New York General Business Law ("GBL") § 349; (2) violation of New York GBL § 350; (3) breach of express warranty; (4) breach of the implied warranty of merchantability; (5) unjust enrichment; (6) negligent misrepresentation; and (7) fraud. (ECF No. 1 ¶¶ 69-132.) Plaintiff seeks to represent a nationwide class of individuals who purchased the Products within the statute of limitations and a New York subclass of individuals who purchased the Products in New York within the statute of limitations. (*Id.* ¶ 58.)

On August 5, 2022, Defendants filed a pre-motion letter in anticipation of their motion to dismiss, (ECF No. 26), and Plaintiff responded on September 8, 2022, (ECF No. 33). On September 15, 2022, at a pre-motion conference, I granted Plaintiff leave to amend her

Complaint. (*See* Minute Entry dated Sept. 15, 2022.) Plaintiff filed the AC on September 30, 2022, and the instant motion followed. (*See* ECF No. 39.)

II. LEGAL STANDARD

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* "While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, 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. While Federal Rule of Civil Procedure 8 "marks a notable and generous departure from the hypertechnical, code-pleading regime of a prior era, . . . it does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions." *Iqbal*, 556 U.S. at 678-79.

In considering whether a complaint states a claim upon which relief can be granted, the court "begin[s] by identifying pleadings that, because they are no more than conclusions, are not entitled to the assumption of truth," and then determines whether the remaining well-pleaded factual allegations, accepted as true, "plausibly give rise to an entitlement to relief." *Id.* at 679. Deciding whether a complaint states a plausible claim for relief is "a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Id.* "[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of

misconduct, the complaint has alleged – but it has not 'shown' – 'that the pleader is entitled to relief.'" *Id.* (quoting Fed. R. Civ. P. 8(a)(2)).

III. DISCUSSON

Defendants move to dismiss the AC on several grounds, including that: (1) Plaintiff's claims are expressly preempted by the Federal Food, Drug, and Cosmetic Act ("FDCA"); (2) the claims should be dismissed under the doctrine of primary jurisdiction; and (3) Plaintiff fails to state a claim under state consumer protection statutes. (*See* ECF No. 40 ("Ds' Mem.").) For the reasons stated below, the Court concludes that Plaintiff's claims are preempted under the FDCA and thus it need not reach the applicability of the primary jurisdiction doctrine or the sufficiency of Plaintiff's pleading.

A. Regulatory Framework

Under the Supremacy Clause of Article VI of the Constitution, "state law that conflicts with federal law is without effect." *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516 (1992). "The key to the preemption inquiry is the intent of Congress. Congress may manifest its intent to preempt state or local law explicitly, through the express language of a federal statute, or implicitly, through the scope, structure, and purpose of the federal law." *New York SMSA Ltd. P'ship v. Town of Clarkstown*, 612 F.3d 97, 104 (2d Cir. 2010). "In determining whether federal preemption applies, courts must start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act." *Truss v. Bayer Healthcare Pharms. Inc.*, No. 21-CV-9845, 2022 WL 16951538, at *2 (S.D.N.Y. Nov. 15, 2022). But "where . . . Congress has expressly manifested its intent to preempt state law, no presumption against preemption arises." *Canale v. Colgate-Palmolive Co.*, 258 F. Supp. 3d 312, 319 (S.D.N.Y.

2017). "Rather, courts focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' preemptive intent." *Id.*

Congress passed the FDCA "in 1938 as part of a comprehensive federal regulatory scheme to protect consumers from fraud or misrepresentation in the sale of food, drugs, and cosmetics." *Critcher v. L'Oreal USA, Inc.*, No. 18-CV-5639, 2019 WL 3066394, at *2 (S.D.N.Y. July 11, 2019), *aff'd*, 959 F.3d 31 (2d Cir. 2020). "In doing so, Congress intended to create a national and uniform regulatory scheme, which up until the FDCA's passage, had been subject to the disparate laws of the states." *Truss*, 2022 WL 16951538, at *3. The FDCA authorizes the FDA to regulate the labeling of OTC drugs. *See* 21 U.S.C. § 301 *et seq.*; 21 C.F.R. § 201.66.

The FDCA contains an express preemption clause for OTC drugs that preempts "any requirement" that is "different from or in addition to" or "otherwise not identical with" the FDCA:

> [N]o State or political subdivision of a State may establish or continue in effect any requirement – (1) that relates to the regulation of a drug that is not subject to the requirements of section 353(b)(1) or 353(f)(1)(A) of this title [including OTC drugs]; and (2) is different from or in addition to, or that is otherwise not identical with, a requirement under this chapter.

21 U.S.C. § 379r(a). "[T]he term 'requirements' . . . reaches beyond positive enactments, such as statutes and regulations, to embrace common-law duties." *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 443 (2005). A common law rule that "requires that manufacturers label or package their products in [a] particular way" qualifies as a requirement with respect to labeling. *Id.* at 444.

> A state law that applies to drugs . . . is preempted if it imposes a requirement that is not identical to the requirements of the FDCA and the FDA's regulations. But this comes with a caveat: preemption does not preclude a state-law claim if the state requirement is outside the scope of the relevant federal requirements.

Bimont v. Unilever U.S., Inc., No. 14-CV-7749, 2015 WL 5256988, at *2 (S.D.N.Y. Sept. 9, 2015).

In 1988, the FDA published a tentative final monograph governing the use of acetaminophen and other OTC drugs. *See* Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use; Tentative Final Monograph ("1988 TFM"), 53 Fed. Reg. 46204-01, 46251, 46260 (Nov. 16, 1988).[2] The 1988 TFM establishes the "conditions under which a category of OTC drugs or specific OTC drugs [including acetaminophen] are generally recognized as safe and effective and not misbranded." 21 C.F.R. § 330.10(a)(7)(i). As relevant here, the 1988 TFM incorporates the dissolution standards for acetaminophen tablets promulgated in the USP, *see* 1988 TFM, 53 Fed. Reg. at 46251, 46260 – standards which identify acetaminophen tablets as "immediate release" when a product dissolves by at least 80% after 30 minutes, *see* Fourth Interim Revision Announcement <7/11> Dissolution, U.S. Pharmacopeia (last revised Nov. 21, 2016), http://www.usp.org/sites/default/files/usp/document/harmonization/gen-method/q01_pf_ira_33_4_2007.pdf. The 1988 TFM became a final order effective March 27, 2020 under the CARES Act. *See In re Acetaminophen - ASD-ADHD Prods. Liab. Litig.*, No. 22-CV-9011, 2022 WL 17348351, at *5 (S.D.N.Y. Nov. 14, 2022), *reconsideration denied*, No. 22-CV-9011, 2023 WL 3126574 (S.D.N.Y. Apr. 27, 2023).

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[2] From 1972 to 2020, the monograph system involved four regulatory steps: (1) an advisory review panel was established to evaluate the safety and effectiveness of the OTC drug; (2) the advisory review panel submitted its report to the FDA Commissioner; (3) the FDA published a tentative final monograph ("TFM"); and (4) after receiving comments on the TFM, the FDA published a final monograph.

In re Acetaminophen - ASD-ADHD Prods. Liab. Litig., No. 22-CV-8830, 2023 WL 3026412, at *4 (S.D.N.Y. Apr. 20, 2023).

The FDA has also published two FDA guidance documents relevant to the claims at issue: Dissolution Testing and Acceptance Criteria for Immediate-Release Solid Oral Dosage Form Drug Products Containing High Solubility Drug Substances: Guidance for Industry, U.S. Department of Health and Human Services et al. (2018) (the "Dissolution Testing Guidance"), (ECF No. 41-5), and the Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate-Release Solid Oral Dosage Forms Based on a Biopharmaceutics Classification System: Guidance for Industry, U.S. Department of Health and Human Services et al. (2017) (the "Immediate-Release Guidance"), (ECF No. 41-6). (*See* Ds' Mem. at 12-13.) The Dissolution Testing Guidance provides, "For immediate release solid oral drug products containing a high solubility drug substance (as defined herein), the dissolution criterion is Q=80% in 30 minutes." (ECF No. 41-5 at 5); *see Bailey v. Rite Aid Corp*., No. 18-CV-6926, 2019 WL 4260394, at *5 (N.D. Cal. Sept. 9, 2019) ("[T]he FDA Guidance provides that in order for oral drug products with a high solubility to be considered 'immediate release,' the dissolution rate must be 80% in 30 minutes."). The Immediate-Release Guidance provides that an immediate release drug product is "considered *rapidly dissolving* when a mean of 85 percent or more of the labeled amount of the drug substance dissolves within 30 minutes" and "considered *very rapidly dissolving* when a mean of 85 percent or more of the labeled amount of the drug substance dissolves within 15 minutes." (ECF No. 41-6 at 3 (emphasis in original)); *see Sapienza v. Albertson's Cos., Inc.*, No. 22-CV-10968, 2022 WL 17404919, at *2 (D. Mass. Dec. 2, 2022) ("Further FDA guidance identifies acetaminophen tablets dissolving 85% or more within 30 minutes as 'rapidly dissolving' and those that dissolve within 15 minutes as 'very rapidly dissolving.'").

B. Application

Defendants argue that Plaintiff's state law claims are preempted because the FDA regulates the labeling of OTC acetaminophen products and Plaintiff's claims seek to impose additional and different labeling requirements for the Products. (Ds' Mem. at 8-12.) Specifically, Defendants argue that because the Products satisfy USP standards for immediate release acetaminophen tablets incorporated in the 1988 TFM, in that they dissolve by at least 80% in thirty minutes, Plaintiff's requested relief – which presumably would require that the Products not say "Rapid Release" or that they contain a caveat that other products release faster, *see Harris v. Topco Assocs., LLC*, 538 F. Supp. 3d 826, 831 (N.D. Ill. 2021) ("[T]he crux of [plaintiff's] claims would require Topco to label its products in a particular way . . . .") – would create different and additional obligations for Defendants. (*Id.* at 9.)

In opposition, Plaintiff argues that neither the 1988 TFM nor the USP provisions have any bearing on her claims because the 1988 TFM includes a dissolution standard only for acetaminophen tablets, not gelcaps, and the USP provisions merely discuss "immediate release," "extended release," and "delayed-release" dosage forms, not "rapid release." (ECF No. 42 ("P's Opp.") at 7.) Plaintiff further argues that because the two FDA guidance documents lack the force of law, her claims cannot be preempted by them. (*Id.* at 9-10.)

Before delving into the parties' arguments, it would be useful to summarize the case law addressing the exact question before the Court: whether Plaintiff's state law claims are preempted by the FDCA in that they create additional requirements for labeling acetaminophen gelcaps as "rapid release." The parties brought to the Court's attention three relevant district court cases: *Bailey v. Rite Aid Corp.*, No. 18-CV-6926, 2019 WL 4260394 (N.D. Cal. Sept. 9, 2019), *Sapienza v. Albertson's Cos., Inc.*, No. 22-CV-10968, 2022 WL 17404919 (D. Mass. Dec.

2, 2022), and *Morgan v. Albertsons Cos., Inc.*, 22-CV-2948, 2023 WL 3607275 (N.D. Cal. Mar. 13, 2023). (*See* Ds' Mem. at 15-16; P's Opp. at 8-10; ECF No. 45; ECF No. 50.) *Sapienza* and *Morgan* involve the same Products at issue here, while the claims in *Bailey* arose from the labeling of similar acetaminophen gelcaps, manufactured by Rite Aid, as "rapid release."

In *Bailey*, the court rejected the defendant's argument that the plaintiff's state law claims were preempted by the FDCA. *See* 2019 WL 4260394, at *3-5. Instead, the court found that the 1988 TFM did not preempt the plaintiff's state law claims because it did not address dissolution standards for "rapid release" acetaminophen and because other FDA publications suggested that "immediate" and "rapid" were not synonymous. *Id.* at *5. Specifically, the *Bailey* court held that the defendant failed to meet its "burden to establish the relationship between the 1998 TFM [*sic*] and the testing procedures and standards in the USP document." *Id.* The court further found that neither the Dissolution Testing Guidance nor the Immediate-Release Guidance are binding and thus could not preempt the state law claims. *Id.*

In contrast, the *Sapienza* court held that the plaintiff's claims were preempted by the FDCA. *See* 2022 WL 17404919, at *3-4. The court found that the study cited in the complaint showed that the gelcaps met the USP and Immediate-Release Guidance dissolution standards, rendering the plaintiff's claims "preempted insofar that they attempt to augment the existing approved labeling requirement." *Id.* at *3. The court observed that "the phrase at issue, 'rapid release,' closely resembles the FDA's standards 'immediate release' and 'rapidly dissolving' – both of which the Signature Care gelcaps meet. These terms are significantly similar, refer to acetaminophen dissolution rates, and are covered under existing FDA guidance." *Id.* at *4. In support of the conclusion that "FDA preemption regulates dissolution standards generally - the subject matter of [the plaintiff's] state-law claims - even if the wordings slightly differ," the court

cited *Colella v. Atkins Nutritionals, Inc.*, 348 F. Supp. 3d 120, 137 (E.D.N.Y. 2018) (finding claims preempted because "while the FDA may not have considered the exact language addressed, it had clearly addressed the substance of the claims at issue"); *Canale v. Colgate-Palmolive, Co.*, 258 F. Supp. 3d 312, 322-23 (S.D.N.Y. 2017) (finding claims not preempted because unlike in *Bowling v. Johnson & Johnson*, 65 F. Supp. 3d 371, 375 (S.D.N.Y. 2014), where the FDA did not consider the exact language but had addressed the substance of the claims at issue, the claims involved "a subject the FDA did not consider in its rulemaking"); and *Bimont v. Unilever U.S., Inc.*, No. 14-CV-7749, 2015 WL 5256988, at *3 (S.D.N.Y. Sept. 9, 2015) (finding claims preempted on ground that "[i]f the FDA regulates a given subject matter, it preempts all non-identical state laws within that subject matter"). *Id.* "To find otherwise," the court concluded, "would require the FDA to list phrases in every possible permutation of similar words to have preemptive effect" and "would undermine the latitude Congress gives agencies to have authority over matters in which they have subject matter expertise – here the FDA's responsibility to evaluate and regulate drugs." *Id.*

Finally, in *Morgan*, the court found that the "1988 TFM's designation of the gelcaps as 'immediate release' encompasses a representation of those gelcaps as 'rapid release'" because, "[a]s a matter of logic, 'immediate release' necessarily includes 'rapid release.'" 2023 WL 3607275, at *6. The Northern District of California declined to follow *Bailey* after concluding that the court in that case "did not address the self-evident relationship between the terms 'immediate' and 'rapid,'" and incorrectly "relied on . . . non-binding FDA guidance" to determine that the terms were not synonymous. *Id.*

Plaintiff urges the Court to disregard *Sapienza* and follow the court's logic in *Bailey* for three reasons.[3] (*See* ECF No. 47.) First, Plaintiff notes that the *Sapienza* court acknowledges that the term "rapid release" does not appear in the cited FDA regulations but "nevertheless treated the challenged phrase as synonymous with the terms 'immediate release' and 'rapidly dissolving.'" (*Id.* at 2.) And while that is true, Plaintiff does not explain how *Bailey*'s holding can be squared with the case law in this district that "reject[s] . . . the principle that state requirements are permitted as long as the federal standard does not specifically address the terms or images at issue." *In re PepsiCo, Inc., Bottled Water Mktg. & Sales Pracs. Litig.*, 588 F. Supp. 2d 527, 538 (S.D.N.Y. 2008); *see Bimont*, 2015 WL 5256988, at *3 ("These cases hold that the relevant 'scope' of federal law is defined by the FDA's regulatory choices. If the FDA regulates a given subject matter, it preempts all non-identical state laws within that subject matter."); *see also Bowling v. Johnson & Johnson*, 65 F. Supp. 3d 371, 375 (S.D.N.Y. 2014) ("In settings where federal requirements address the subject matter that is being challenged through state law claims . . . the state requirements are not permitted unless they are *identical* to federal standards.") (emphasis in original). For example, in *In re PepsiCo.*, this Court held,

> Where federal requirements address the subject matter that is being challenged through state law claims, such state law claims are preempted to the extent they do not impose identical requirements. Thus, although the standard of identity does not define the term "pure" or specify when it is permissible to place a cartoon-like image of a mountain range on a purified water label, the FDA considered misrepresentations regarding source and chose to regulate the labeling requirements for the disclosure of source information, and in so doing it determined that purified water should be exempted. Accordingly, any state law claims premised on a misrepresentation about the source of purified water are preempted.

[3] Plaintiff did not respond to Defendants' notice of supplemental authority as to *Morgan,* (ECF No. 50).

588 F. Supp. 2d at 538. That the FDA did not use the exact words "rapid release" in its regulations surely cannot mean that the FDA does not regulate the subject matter of OTC acetaminophen dissolution standards where, as described in detail above, it has published regulations and guidance addressing when an OTC acetaminophen product can be considered "immediate release," "rapidly dissolving," and "very rapidly dissolving." As *Sapienza* noted, it would be nonsensical to allow a manufacturer to evade an FDA requirement simply by coming up with a phrase that addresses the subject matter of the regulation but in different phraseology. *See Sapienza*, 2022 WL 17404919, at *4. Because the FDA regulates the subject of dissolution standards, and "[b]ecause the TFM does not require any specific disclaimers concerning . . . the [comparative rate of dissolution among products, Plaintiff's] claims are preempted because she seeks to impose additional obligations on [Defendant] not imposed by the TFM." *Harris*, 538 F. Supp. 3d at 833 (rejecting argument that manufacturer of infant's acetaminophen should be required to specify that product was same formula as less expensive children's acetaminophen).[4]

Second, Plaintiff argues that the *Sapienza* court did not properly consider the reasonable consumer standard in determining that the Products were properly advertised as rapidly dissolving. (*See* ECF No. 47 at 3.) But Plaintiff misreads that decision. She claims that that the court in *Sapienza* considered whether the "rapid release" claim was true in isolation, without regard to whether the product's positioning with lower-priced non-rapid release tablets would be

[4] I am unpersuaded by Plaintiff's argument that the 1988 TFM only discusses acetaminophen tablets, not gelcaps, such that the 1988 TFM does not apply. (P's Opp. at 7.) The AC makes clear that gelcaps are a kind of tablet. (AC ¶ 3 n.3 (referring to "gelatin-coated, capsule-shaped tablets called gelcaps"); *id.* Ex. A at 2 ("Gelcap is [a] gelatin coated tablet"); *see Morgan*, 2023 WL 3607275, at *7 n.3 ("In a similar vein, Plaintiffs also suggest that the 1988 TFM only discusses acetaminophen tablets, not gelcaps, such that the 1988 TFM does not apply. But gelcaps are, by definition, gelatin-coated capsule-shaped tablets and are thus covered by the 1988 TFM.").

misleading. But the *Sapienza* court merely noted that the issue was not whether the labeling of the rapid release acetaminophen was literally true – there, as here, it was – and found that it was not relevant that other similar products "may dissolve just as (or even more) rapidly," because "acetaminophen dissolution rates . . . are covered under existing FDA guidance" and therefore the claims were preempted. 2022 WL 17404919, at * 3-4.

Finally, Plaintiff cites nineteen cases from district courts in the Second Circuit that she alleges demonstrate that "*Sapienza* is at odds with the decisions of Second Circuit courts in similar cases." (ECF No. 47 at 5.) But only two of those cases deal with express preemption under 21 U.S.C. § 379r(a), and those two cases are inapposite because they involved subject matter the FDA had not regulated. *See Canale*, 258 F. Supp. 3d at 320 (state law claims not preempted where FDA did not address product in relevant monograph); *Elkind v. Revlon Consumer Prods. Corp.*, No. 14-CV-2484, 2015 WL 2344134, at *8 (E.D.N.Y. May 14, 2015) (state law claims not preempted where there is "lack of any suggestion that the FDA is at all interested in issuing any relevant guidance").

Accordingly, Plaintiff's state law claims are preempted by the FDCA.[5]

IV. LEAVE TO AMEND

Leave to amend a complaint should be freely given "when justice so requires." Fed. R. Civ. P. 15(a)(2). "[I]t is within the sound discretion of the district court to grant or deny leave to

[5] Neither party briefed whether Plaintiff's express warranty claim is a product liability claim that is not preempted under the savings clause of 21 U.S.C. § 379r(e), which provides that "[n]othing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State." *Id.* But Defendants argued that all of Plaintiff's claims are preempted, (Ds' Mem. at 1-2), and Plaintiff made no attempt to carve out the express warranty claim. Accordingly, Plaintiff has abandoned any such argument. *See Goldstein v. Walmart, Inc.*, No. 22-CV-88, 2022 WL 16540837, at *12 n.7 (S.D.N.Y. Oct. 28, 2022). Further, for the reasons set forth by Judge Liman in *Goldstein*, *see id*., I would conclude that Plaintiff's express warranty claim is not an exempted product liability claim.

amend." *Kim v. Kimm*, 884 F.3d 98, 105 (2d Cir. 2018). "Leave to amend, though liberally granted, may properly be denied" for "'repeated failure to cure deficiencies by amendments previously allowed'" or "'futility of amendment,'" among other reasons. *Ruotolo v. City of N.Y.*, 514 F.3d 184, 191 (2d Cir. 2008) (quoting *Foman v. Davis*, 371 U.S. 178, 182 (1962)).

In her Opposition, Plaintiff requested that I either deny Defendant's motion or grant her leave to amend a second time. (P's Opp. at 25.) But because "[t]he problem[s] with [Plaintiff's] causes of action [are] substantive," and "better pleading will not cure [them]," *Cuoco v. Moritsugu*, 222 F.3d 99, 112 (2d Cir. 2000), amendment would be futile, *Trombetta v. Novocin*, 414 F. Supp. 3d 625, 634 (S.D.N.Y. 2019); *see Boswell v. Bimbo Bakeries USA, Inc.*, 570 F. Supp. 3d 89, 97 (S.D.N.Y. 2021); *Roundtree v. N.Y.C.*, No. 19-CV-2475, 2021 WL 1667193, at *6 (S.D.N.Y. Apr. 28, 2021) (collecting cases).

Moreover, Plaintiff – with the benefit of a pre-motion letter from Defendant, (*see* ECF No. 26) – already had the opportunity to amend but declined to do so, while acknowledging that the Court was unlikely to allow amendment later. (*See* Minute Entry dated Sept. 15, 2022.) Generally, the failure to fix deficiencies in an initial pleading, after being provided notice of those deficiencies, is alone sufficient ground to deny leave to amend. *See Nat'l Credit Union Admin. Bd. v. U.S. Bank Nat'l Ass'n*, 898 F.3d 243, 257-58 (2d Cir. 2018) ("When a plaintiff was aware of the deficiencies in his complaint when he first amended, he clearly has no right to a second amendment even if the proposed second amended complaint in fact cures the defects of the first. Simply put, a busy district court need not allow itself to be imposed upon by the presentation of theories seriatim."); *In re Eaton Vance Mut. Funds Fee Litig.*, 380 F. Supp. 2d 222, 242 (S.D.N.Y. 2005) (denying leave to amend because "the plaintiffs have had two opportunities to cure the defects in their complaints, including a procedure through which the

plaintiffs were provided notice of defects in the Consolidated Amended Complaint by the defendants and given a chance to amend their Consolidated Amended Complaint," and "plaintiffs have not submitted a proposed amended complaint that would cure these pleading defects"), *aff'd sub nom*. *Bellikoff v. Eaton Vance Corp.*, 481 F.3d 110, 118 (2d Cir. 2007) (*per curiam*) ("[P]laintiffs were not entitled to an advisory opinion from the Court informing them of the deficiencies in the complaint and then an opportunity to cure those deficiencies.").

Further, Plaintiff has not suggested that she is in possession of facts that would cure the deficiencies identified in this ruling. *See TechnoMarine SA v. Giftports, Inc.*, 758 F.3d 493, 505 (2d Cir. 2014) (plaintiff need not be given leave to amend if plaintiff fails to specify how amendment would cure the pleading deficiencies in the complaint); *Gallop v. Cheney*, 642 F.3d 364, 369 (2d Cir. 2011) (district court did not err in dismissing claim with prejudice in absence of any indication plaintiff could or would provide additional allegations leading to different result); *Olsen v. Sherry Netherland, Inc.*, No. 20-CV-103, 2022 WL 4592999, at *15 (S.D.N.Y. Sept. 30, 2022) (denying leave to amend where plaintiff did not "explain how any amendment would cure the deficiencies identified by the Court").

Accordingly, the Court declines to grant Plaintiff leave to amend.

V. CONCLUSION

For the foregoing reasons, Defendants' motion to dismiss is granted. The Clerk of the Court is respectfully directed to terminate the pending motion, (ECF No. 39), and close the case.

SO ORDERED.

Dated: June 26, 2023
White Plains, New York

Cathy Seibel

CATHY SEIBEL, U.S.D.J.