UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

RHONDA MUSIKAR-ROSNER,	*	
Plaintiff,	*	
v.	*	
	*	Civil Action No. 23-cv-11746-ADB
JOHNSON & JOHNSON CONSUMER INC.,	*	
Defendant.	*	

MEMORANDUM AND ORDER

BURROUGHS, D.J.

Rhonda Musikar-Rosner ("Plaintiff") filed this putative class action against Defendant Johnson & Johnson Consumer Inc. ("J&J" or "Defendant"), alleging that the company's marketing of its over-the-counter ("OTC") rapid release gelcaps is false, misleading, and deceptive. Currently pending before this Court is J&J's motion to dismiss Plaintiff's Complaint pursuant to Federal Rule of Civil Procedure 12(b)(6) or, in the alternative, to transfer venue to the District of New Jersey. [ECF No. 33]. For the reasons set forth below, J&J's motion to dismiss, [id.], is GRANTED.

I. BACKGROUND

A. Factual Background

The following relevant facts are taken primarily from the Complaint, the well pleaded allegations of which the Court assumes to be true when considering a motion to dismiss. Ruivo v. Wells Fargo Bank, N.A., 766 F.3d 87, 90 (1st Cir. 2014).

Plaintiff, a citizen and domiciliary of Massachusetts, brings this putative class action against Defendant J&J, specifically its consumer health care division. [Compl. ¶¶ 12–13]. J&J is a leading consumer health and personal care products company and "produces, manufactures, markets, and distributes over the counter ['OTC'] products" to customers worldwide, including "analgesic or pain-relieving medicines under the Tylenol® brand name." [Id. ¶¶ 1, 24–25]. Most of J&J's Tylenol® products contain acetaminophen, also known as paracetamol or N-acetyl-para-aminophenol (APAP), an OTC pain reliever and fever reducer used to treat various conditions such as headaches, muscle aches, arthritis, and colds. [Id. ¶¶ 17, 18, 26]. Tylenol® is one of J&J's "most familiar product lines." [Id. ¶ 24]. As of 2005, adult Tylenol was the "fastest-growing brand in the Internal Analgesics category — making it a bigger brand than Crest, Gillette, Dove or Listerine," resulting in Tylenol becoming "the only pharmaceutical franchise [worth] over $1 billion available without a prescription" at that time. [Id. ¶ 27 (quoting Tylenol, BrandSearch 118, 118 (2005))]. In total, J&J offers thirty-three Tylenol® medications, and only three do not contain acetaminophen. [Id. ¶ 26].

As relevant here, in 2005, J&J introduced a new line of Tylenol® products, the rapid release gelcaps, with the launch of Tylenol® Extra Strength Rapid Release Gels.[1] [Compl. ¶¶ 2, 36]. Plaintiff alleges that since introducing its rapid release gelcaps into the market, J&J has "misled and continues to mislead consumers about the nature, quality, and effectiveness" of its products. [Id. ¶ 3]. Specifically, Plaintiff contends that J&J promises that its rapid release gelcaps "work faster than other acetaminophen products,"[2] when, in fact, they "dissolve more slowly than J&J's non-rapid release products" such as traditional Tylenol® tablets. [Id. ¶¶ 6, 52, 63]. In support of her allegations, Plaintiff relies on a 2018 study entitled "Rapid and Fast Release Acetaminophen Gelcaps Dissolve Slower than Acetaminophen Tablets" (the "2018 Dissolution-Rate Study"), which indicated that the rapid-release products "not only fail to work faster, [but] actually work slower than their traditional acetaminophen counterparts, such as tablets." [Id. ¶ 57]. As a result of J&J's false and misleading advertising, Plaintiff asserts that

---

[1] The Tylenol® Extra Strength Rapid Release Gels are designed with "laser-drilled holes to release medicine quickly." [Compl. ¶ 2 (quoting Extra Strength TYLENOL® Rapid Release Gels, Tylenol (last accessed Jul. 31, 2023), https://www.tylenol.com/products/tylenol-rapid-release-gels)].

[2] Plaintiff highlights the following statements in J&J's commercial campaigns:

J&J advertised that its rapid release gelcaps "work[] at the speed of life" and that "only Tylenol® Rapid Release Gels have laser-drilled holes" that "release medicine fast for fast pain relief." [Compl. ¶ 49].

"Tylenol® Rapid Release Gels start to dissolve in seconds and effectively relieve pain at rapid speed." [Id. ¶ 51(a)].

"TYLENOL® Rapid Release Gels start to dissolve in seconds and effectively relieve pain at rapid speed. Its unique laser drilled holes help release medicine faster!" [Id. ¶ 51(b)].

"New Tylenol® Rapid Release Gels. Gelcaps with specially designed holes to release powerful medicine even faster than before." [Id. ¶ 51(e)].

unassuming consumers like herself have been deceived into paying a premium price for rapid release gelcaps when they could have bought the cheaper, but more effective, non-fast release products. [Id. ¶¶ 7, 34, 66–72].

Plaintiff asserts claims for violation of Massachusetts General Laws Chapter 93A, breach of implied warranty of merchantability under Mass. Gen. Laws ch. 106, § 2-314, breach of express warranty under Mass. Gen. Laws ch. 106, § 2-313, unjust enrichment, and declaratory relief. [Compl. ¶¶ 92–143].

B. Procedural History

Plaintiff initiated this action on July 31, 2023. [ECF No. 1]. Defendant filed its motion to dismiss or, alternatively, to transfer venue to the District of New Jersey, [ECF No. 33], on October 20, 2023. Plaintiff responded on December 15, 2023, [ECF No. 39 ("Opp'n")], and Defendant replied on January 12, 2024, [ECF No. 40].

II. MOTION TO DISMISS

A. Legal Standard

On a motion to dismiss for failure to state a claim pursuant to Rule 12(b)(6), the Court must accept as true all well pleaded facts, analyze them in the light most favorable to the plaintiff, and draw all reasonable inferences from those facts in favor of the plaintiff. United States ex rel. Hutcheson v. Blackstone Med., Inc., 647 F.3d 377, 383 (1st Cir. 2011). Additionally, "a court may not look beyond the facts alleged in the complaint, documents incorporated by reference therein and facts susceptible to judicial notice." MIT Fed. Credit Union v. Cordisco, 470 F. Supp. 3d 81, 84 (D. Mass 2020) (citing Haley v. City of Boston, 657 F.3d 39, 46 (1st Cir. 2011)). A complaint "must provide 'a short and plain statement of the claim showing that the pleader is entitled to relief[,]'" Cardigan Mountain Sch. v. N.H. Ins. Co., 787

F.3d 82, 84 (1st Cir. 2015) (quoting Fed. R. Civ. P. 8(a)(2)), and must "set forth factual allegations, either direct or inferential, respecting each material element necessary to sustain recovery under some actionable legal theory[,]" Gooley v. Mobil Oil Corp., 851 F.2d 513, 515 (1st Cir. 1988). Although detailed factual allegations are not required, a complaint must set forth "more than labels and conclusions," Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007), and "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice[,]" Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). Rather, a complaint "must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Id. (quoting Twombly, 550 U.S. at 570).

B. Regulatory Framework

"The Supremacy Clause of the U.S. Constitution, which makes federal law 'the supreme Law of the Land,' U.S. Const. art. VI, cl. 2, means that Congress 'has the power to pre-empt state law.'" Medicaid & Medicare Advantage Prods. Ass'n of P. R., Inc. v. Emanuelli Hernández, 58 F.4th 5, 10 (1st Cir. 2023). Federal preemption "may be either expressed or implied, and is compelled whether Congress' command is explicitly stated in the statute's language or implicitly contained in its structure and purpose." Gade v. Nat'l Solid Wastes Mgmt. Ass'n, 505 U.S. 88, 98 (1992) (internal quotation marks omitted). "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." Bischoff v. Albertsons Cos., Inc., 678 F. Supp. 3d 518, 522 (S.D.N.Y. 2023) (quoting Truss v. Bayer Healthcare Pharms. Inc., No. 21-cv-09845, 2022 WL 16951538, at *2 (S.D.N.Y. Nov. 15, 2022)). However, "where . . . [as in the instant case], Congress has expressly manifested its intent to preempt state law, no presumption against preemption arises." Id. at 522–23 (quoting Canale v. Colgate-Palmolive

Co., 258 F. Supp. 3d 312, 319 (S.D.N.Y. 2017)). In such circumstances "[w]here a federal statute contains a clause expressly purporting to preempt state law, '[the Court] focus[es] on the plain wording of the clause, which necessarily contains the best evidence of Congress' preemptive intent.'" Medicaid & Medicare, 58 F.4th at 11 (quoting Chamber of Com. of U.S. v. Whiting, 563 U.S. 582, 594 (2011) (internal quotation marks omitted)). As such, Congressional intent "is the ultimate touchstone of an express preemption analysis." First Med. Health Plan, Inc. v. Vega-Ramos, 479 F.3d 46, 51 (1st Cir. 2007) (quoting Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996)).

In 1938, Congress enacted the Federal Food, Drug, & Cosmetic Act ("FDCA"). Bischoff, 678 F. Supp. 3d at 523. It did so "as part of a comprehensive federal regulatory scheme to protect consumers from fraud or misrepresentation in the sale of food, drugs, and cosmetics." Id. (quoting Critcher v. L'Oreal USA, Inc., No. 18-cv-05639, 2019 WL 3066394, at *2 (S.D.N.Y. July 11, 2019), aff'd, 959 F.3d 31 (2d Cir. 2020)). Specifically, "[t]he FDCA authorizes the FDA to regulate the labeling of OTC drugs." Id.; see also 21 U.S.C. § 301 et seq.; 21 C.F.R. § 201.66.

The FDCA contains an express preemption provision stating that:

> [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 [such as the OTC product at issue here]; and
>
> (2) that 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).

States are thus preempted from imposing "any requirement" that is "different from or in addition to" or "otherwise not identical with" the FDCA's labeling requirements. See Canale, 258 F. Supp. 3d at 319–20 ("Where federal law specifically regulates the subject matter of a plaintiff's state law claims, and those claims seek to impose requirements not identical to federal requirements, those state law claims are preempted."). Preemption, however, is not absolute; it 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-07749, 2015 WL 5256988, at *2 (S.D.N.Y. Sept. 9, 2015).

"In addition to requirements established under state law, rules established by common law can be considered 'requirement[s]' subject to preemption." Sapienza v. Albertson's Cos., Inc., No. 22-cv-10968, 2022 WL 17404919, at *2 (D. Mass. Dec. 2, 2022) (citing Cipollone v. Liggett Grp., 505 U.S. 504, 521 (1992)). Thus, a common law rule "requir[ing] that manufacturers label or package their products in [a] particular way" constitutes a requirement under the FDCA preemption provision. Bischoff, 678 F. Supp. 3d at 523 (quoting Bates v. Dow Agrosciences LLC, 544 U.S. 431, 444 (2005)).

The FDA has two systems for regulating new OTC medications. As relevant here, one system involves the appointment of expert advisory review panels tasked with evaluating the safety and effectiveness of OTCs, and reviewing their labeling, as well as advising the FDA on promulgating so-called monographs, which establish the parameters or conditions under which certain categories of OTCs may be marketed. Morgan v. Albertsons Cos., Inc., No. 22-cv-02948, 2023 WL 3607275, at *2 (N.D. Cal. Mar. 13, 2023) (citing Kanter v. Warner-Lambert Co., 122 Cal. Rptr. 2d 72, 77 (Cal. Ct. App. 2002)). These proposed or tentative final monographs conceived by the advisory review panel are published by the FDA for public review

and comment, and the agency eventually promulgates "'final monograph[s] in the form of regulations in the Code of Federal Regulations,' which 'establish conditions under which a category of [OTC] is recognized as safe and effective and not misbranded.'" Id. (citing Kanter, 122 Cal. Rptr. 2d at 77). Notably, through the Coronavirus Aid, Relief, Economic Security ("CARES") Act, Congress has "deemed" certain tentative final monographs to be final administrative orders. Sapienza, 2022 WL 17404919, at *2; 21 U.S.C. § 355h(b)(8)(A).

In 1988, the FDA published a tentative final monograph entitled the "Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use; Tentative Final Monograph" ("1988 TFM"), establishing the "conditions under which [OTC] [] internal analgesic [like acetaminophen]. . . drug products are generally recognized as safe and effective and not misbranded."[3] Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use; Tentative Final Monograph, 53 Fed. Reg. 46204-01 (proposed Nov. 16, 1988) (to be codified at 21 C.F.R. pt. 310, 343, and 369). The 1988 TFM "include[d] by reference the dissolution standard for acetaminophen . . . tablets as contained in [the United States Pharmacopeia]."[4] Id. at 46251. The USP designates acetaminophen tablets as "immediate release" when they dissolve by at least 80% after 30 minutes. See [ECF No. 36-1 ("USP") at 9–14 (stating that in order for a drug to be designated "immediate release" it has to meet the relevant criteria of that specific drug)]; United States Pharmacopeial Convention, USP,

[3] The 1988 TFM added acetaminophen as an approved active ingredient for analgesic OTC drugs. See [Compl. ¶ 91(a)].

[4] The United States Pharmacopeia ("USP") is an independent standards-setting organization that publishes an annual compendium of drug information, The Pharmacopeia. See USP principles – for a robust and trusted pharmacopeia, 202104-usp-principles-for-a-robust-and-trusted-pharmacopeia.pdf. The Pharmacopeia sets forth standards enforced by the FDA. See [ECF No. 36 at 3].

2033 ("USP Convention") (35th rev. 2011) (providing immediate release criteria for acetaminophen tablets); Morgan, 2023 WL 3607275, at *3. The 1988 TFM became a final order on March 27, 2020 under the CARES Act. See In re Acetaminophen - ASD-ADHD Prods. Liab. Litig., No. 22-cv-09011, 2022 WL 17348351, at *5 (S.D.N.Y. Nov. 14, 2022), reconsideration denied, No. 22-cv-09011, 2023 WL 3126574 (S.D.N.Y. Apr. 27, 2023); Final Administrative Orders for Over-the-Counter Monographs, 86 Fed. Reg. 52474, 52474-75 (Sept. 21, 2021).

Separately, the FDA also issued two industry guidance documents relevant to the instant case. The 2018 "Dissolution Testing and Acceptance Criteria for Immediate-Release Solid Oral Dosage Form Drug Products Containing High Solubility Drug Substances," [ECF No. 36-2 (the "Dissolution Testing Guidance")], and the 2017 "Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate-Release Solid Oral Dosage Forms Based on a 0.Biopharmaceutics Classification System," [ECF No. 36-3 (the "Immediate-Release Guidance")]. Whereas the former provides that "[f]or immediate release solid oral drug products containing a high solubility drug substance [] [such as acetaminophen], the dissolution criterion is Q=80% in 30 minutes," [Dissolution Testing Guidance at 9], the Immediate-Release Guidance states that "[a]n [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," [Immediate-Release Guidance at 7 (emphasis omitted)]. The same guidance also considers a drug substance to be "very rapidly dissolving" "when a mean of 85 percent or more of the

labeled amount of the drug substance dissolves within 15 minutes." [Immediate-Release Guidance at 7].[5]

III. DISCUSSION

Defendant argues that Plaintiff's claims are expressly preempted under 21 U.S.C. § 379r(a) for two reasons. First the FDA, not the states, regulates the labeling of OTC acetaminophen products, and, second, Plaintiff seeks to impose "additional" and "different" labeling requirements from what the FDCA requires for J&J's rapid release gelcaps. [ECF No. 34 at 15]. Defendant contends that the rapid release gelcaps "readily satisfy" the USP Convention's "immediate release" criterion as incorporated in the 1988 TFM. [Id. at 15–16]. As such, Plaintiff's requested relief, requiring the removal of "rapid release," "would create different and additional obligations" for J&J. [Id.].

Plaintiff responds that preemption is not relevant here because there is no "federal requirement [] apply[ing] to the rapid release gelcap products and J&J's deceptive conduct in marketing them." [Opp'n at 7]. According to Plaintiff, first, neither the 1988 TFM nor the USP provisions "address 'rapid release drugs' of any kind." [Id. at 8]. Plaintiff avers that the incorporated dissolution standard in the 1988 TFM applies only to acetaminophen tablets, and

---

[5] The Court takes judicial notice of the USP, Dissolution Testing Guidance, and Immediate-Release Guidance. See Watson v. United States, 37 F.4th 22, 28 (1st Cir. 2022) (quoting Fed. R. Evid. 201(b)(2)) ("A trial court may take judicial notice of adjudicative facts not subject to reasonable dispute where, inter alia, they 'can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned.'"); see also In re Hartop, 311 F.2d 249, 255 (C.C.P.A. 1962) (the court took judicial notice of standard reference works relating to chemicals and drugs); Blue Engine Biologics v. Arteriocyte Med. Sys., Inc., No. 21-cv-11098, 2022 WL 407409, at *4 (D. Mass. Feb. 10, 2022) (finding that "the Court may take judicial notice of government agency reports."); Rock v. Lifeline Sys. Co., No. 13-cv-11833, 2014 WL 1652613, at *12 (D. Mass. Apr. 22, 2014) (the court may take judicial notice and consider documents posted on a government website).

"not other acetaminophen products, such as gelcaps, and certainly not supposed 'rapid release' gelcaps." [Id.]. Second, the USP provisions refer to "immediate release," "extended-release," and "delayed-release" dosage, but, importantly, not to "rapid release." [Id. at 8–9].

The Court first turns to Plaintiff's argument that the 1988 TFM does not apply to gelcaps because it only references tablets.[6, 7] [Opp'n at 8]. Although the 1988 TFM does not reference "gelcaps," other courts, when confronted with this exact same question, have noted that "gelcaps are, by definition, gelatin-coated capsule shaped tablets and thus covered by [the monograph]." Morgan, 2023 WL 3607275, at *7 n.3 (citing Gelcap, Merriam-Webster Online Dictionary, https://www.merriam-webster.com/dictionary/gelcap (last visited July 24, 2024) (defining a gelcap as "a capsule-shaped tablet coated with gelatin for easy swallowing")); see also Bischoff, 678 F. Supp. 3d at 527 n.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."). In fact, both Bischoff and Sapienza highlight that the 2018 Dissolution-Rate Study provides that gelcaps are "gelatin coated tablet[s]." Bischoff, 678 F. Supp. 3d at 527 n.4 (emphasis added); Sapienza, 2022 WL 17404919, at *4 n.4; see also 2018 Dissolution-Rate Study at 2 ("In the case of

[6]The Court notes that it is not the first to consider "whether Plaintiff's state law claims are preempted by the FDCA in that they create additional requirements for labeling acetaminophen gelcaps as 'rapid release.'" Bischoff, 678 F. Supp. 3d at 525; see also Bailey v. Rite Aid Corp., No. 18-cv-06926, 2019 WL 4260394 (N.D. Cal. Sept. 9, 2019); Sapienza, 2022 WL 17404919; Morgan, 2023 WL 3607275. Defendant encourages the Court to follow Sapienza, Bischoff, and Morgan, which found that claims identical to the ones put forward by Plaintiff here were preempted by the FDCA. [ECF No. 34 at 15–17].

[7] Although Plaintiff asserts in the Complaint that the 1988 TFM remains a proposed rule and therefore lacks preemptive effect because it is not final, [Compl. ¶ 91(a)], she concedes in her Opposition that it became a final order on March 27, 2020, [Opp'n at 8 n.1].

acetaminophen, coated capsule-shaped tablets, or caplets, are commonly marketed as gelcaps."). The Court is therefore unpersuaded by Plaintiff's argument.

Plaintiff's second argument that preemption does not apply because the USP and 1988 TFM only considered "immediate release," whereas the present action concerns "rapid release," is equally unavailing. "FDA preemption regulates dissolution standards generally," meaning state law is preempted even "if the wordings slightly differ." Sapienza, 2022 WL 17404919, at *3 (citing Colella v. Atkins Nutritionals, Inc., 348 F. Supp. 3d 120, 137 (E.D.N.Y. 2018) (quoting Canale, 258 F. Supp. 3d at 322–323 ("[I]t is the case here . . . that, 'while the FDA may not have considered the exact language addressed . . ., it had clearly addressed the substance of the claims at issue.'")).

Here, "rapid release" is "significantly similar," Sapienza, 2022 WL 17404919, at *4, to the "immediate release" requirement in the USP Convention, which Tylenol's gelcaps satisfy. Compare USP Convention (providing the criterion of "immediate release" is satisfied when at least 80% of the acetaminophen tablet is dissolved after 30 minutes), with 2018 Dissolution-Rate Study, Table 2 at 5 (Tylenol's rapid release gelcaps reached 80% dissolution in less than four minutes); see also Morgan, 2023 WL 3607275, at *7 ("the term 'immediate' is [sic] subsumes the term 'rapid' such that the FDA's designation of the gelcaps as 'immediate release' necessarily includes the lesser representation 'rapid release.'"). As other courts have recognized, a different conclusion would require the "FDA to list phrases in every possible permutation of similar words to have preemptive effect . . . limiting the FDCA's preemptive power in such a way [that] would undermine the latitude Congress gives agencies to have authority over matters

in which they have subject matter expertise[.]" Sapienza, 2022 WL 17404919, at *4;[8] Bischoff, 678 F. Supp. 3d at 526–27. ("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").

Plaintiff counters that Morgan, Sapienza, and Bischoff were wrongly decided because they "all rest on findings that the language [of 'immediately dissolve' and 'rapidly dissolve'] [are] 'similar' enough." [Opp'n at 11]. Plaintiff directs the Court to three other cases, McFall v. Perrigo, Bailey v. Rite Aid Corp., and Canale v. Colgate-Palmolive, where defendants did not prevail on their preemption arguments because the courts found that two similar terms were not necessarily synonymous. [Opp'n at 11–13].

In McFall v. Perrigo, Plaintiffs alleged that they were misled by Walmart's marketing of its OTC acetaminophen products as "Infant's Equate" and "Children's Equate," which suggested that one was more appropriate for infants, when both products had the same chemical composition, including the same acetaminophen content. No. 20-cv-07752, 2021 WL 2327936, at *1 (C.D. Cal. Apr. 15, 2021). Although the Court rejected defendant's argument that the relevant TFM used "children" and "infant" interchangeably, it did so because it found that the TFM in fact provided a "distinction" between the terms and defendant had failed to comply with the requirements of the monograph. Id. at *9–10 (finding that the "1988 TFM and the FDA draw a distinction" between "infants" and "children over 2 years of age"). As such, "[d]efendants

[8] Plaintiff further points out that Defendant's reliance on the Immediate-Release Guidance and Dissolution Testing Guidance is misguided, as they "merely represent 'current thinking' of the FDA" and therefore lack any binding force. [Opp'n at 9]. The Court observes that while J&J's rapid release gelcaps meet both the "rapidly dissolving" (Immediate-Release Guidance) and "immediate release" (Dissolution Testing Guidance) standards, see supra, they also meet the USP criterion for "immediate release" and, as a result, the Court's findings do not rely solely on the guidance documents.

ha[d] failed to establish [that] [p]laintiffs' claims seek enforcement of any requirement that is different from or in addition to, or that is otherwise not identical with" the FDA labeling requirement. Id. at *9. Here, however, Defendant has met the TFM dissolution standard, see supra, and, as a result, Plaintiff's claims are preempted.

Canale v. Colgate-Palmolive Co. similarly does not support the position put forth by Plaintiff. There, plaintiff alleged that defendant falsely labelled and advertised that its toothpaste, "Optic White," could "deeply" whiten teeth because it contained peroxide. 258 F. Supp. 3d at 316. Plaintiff argued that because peroxide is not a whitening agent, defendant's statements were false and misleading. Id. at 316–17. The Court found that plaintiff's claims were not preempted because, among other things, the final and non-final monographs relied on by defendant did not contemplate products related to teeth whitening. Id. at 321–22. The final monograph on regulating "anticaries" OTC drugs, for example, expressly noted that only three active ingredients, which did not include peroxide, came under the purview of the monograph. Id. at 321 (noting that "[t]here is nothing in the monograph regarding whitening toothpastes or products."). Likewise, the TFM did not contemplate peroxide, but rather discussed whether a warning was appropriate when products containing stannous fluoride caused teeth staining. Id. at 322. Congress had thus not addressed the substance of the claims at issue and plaintiff's state claims were, as a result, not preempted. Id. at 321–23. Here, on the other hand, the subject matter—the dissolution standards of acetaminophen tablets—is specifically regulated by the FDA, and preemption applies. Id. at 320 ("Where federal law specifically regulates the subject matter of a plaintiff's state law claims, and those claims seek to impose requirements not identical to federal requirements, those state law claims are preempted.").

Bailey v. Rite Aid Corp., which seems to be an outlier, concluded that there was no relationship between the 1988 TFM and the standards espoused in the USP and that "immediate" and "rapid" are not synonymous. No. 18-cv-06926, 2019 WL 4260394, at *5 (N.D. Cal. Sept. 9, 2019). This Court agrees with its sister court that Plaintiff does not "explain how Bailey's holding can be squared," Bischoff, 678 F. Supp. 3d at 526, with the principle that "[i]f the FDA regulates a given subject matter, it preempts all non-identical state laws within that subject matter." Bimont, 2015 WL 5256988, at *3.[9,10] Accordingly, this Court too declines to follow Bailey.

Finally, Plaintiff's argument that although "[t]he FDCA and FDA regulations govern how OTC acetaminophen drugs are labeled," they "do not regulate how companies choose to advertise, market, or set pricing of those same OTC acetaminophen products," [Opp'n at 14], misconstrues the issue at hand. The gravamen of Plaintiff's case is that rapid release gelcaps do not dissolve as quickly as regular acetaminophen tablets, which renders J&J's advertising of its product false and misleading. See generally [Compl.]. However, as discussed above, advertising gelcaps as "rapidly dissolving" is accurate pursuant to the TFM and FDA guidance on the

---

[9] In Morgan, the court determined that Bailey had wrongly concluded that a subset ("rapid release") of an approved category ("immediate release") does not come under the purview of preemption, and therefore "decline[d] to follow [it]." 2023 WL 3607275, at *6.

[10] Plaintiff further cites to Edwards v. Walmart, Inc., which found, among other things, that the TFM only regulates the dissolution standards related to aspirin. No. 18-09655, at *6 (C.D. Cal. Apr. 18, 2019). The 1988 TFM, however, provides that "the agency is also including by reference the dissolution standard for acetaminophen and aspirin tablets as contained in U.S.P. XXI at page 14[.]" Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use; Tentative Final Monograph, 53 Fed. Reg. at 46251. As such, the TFM plainly regulates the dissolution standards of acetaminophen by incorporation. See supra. Separately, the Court notes that 21 C.F.R. § 343 refers to internal analgesic drug products, which encompass acetaminophen. See id. The Court therefore respectfully declines to follow Edwards.

dissolution standards for acetaminophen OTC tablets. See supra. Thus, "[b]ecause the FDA regulates the subject of dissolution standards and '[] 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.'" Bischoff, 678 F. Supp. 3d at 527 (quoting Harris v. Topco Assocs., LLC, 538 F. Supp. 3d 826, 833 (N.D. Ill. 2021)); see also Kanter, 122 Cal. Rptr. at 84–85 ("[W]hen a state law claim, however couched, would effectively require a manufacturer to include additional or different information on a federally approved label, it is preempted."); Sapienza, 2022 WL 17404919, at *3 (because the labeling description complies with FDA guidance, the fact "[t]hat similar [J&J Tylenol] products may dissolve just as (or even more rapidly) is no more relevant as a comparison than is a bag of ice labeled 'frozen' as opposed to one simply branded as 'ice'" for the purpose of preemption).

IV. CONCLUSION

For the reasons set forth above, Plaintiff's claims are preempted, as they would impose requirements on the labeling of J&J's rapid release gelcaps that are "different from or in addition to" federal regulation. Canale, 258 F. Supp. 3d at 319–20. Defendant's motion to dismiss, [ECF No. 33], is therefore GRANTED.[11]

SO ORDERED.

July 31, 2024

/s/ Allison D. Burroughs
ALLISON D. BURROUGHS
U.S. DISTRICT JUDGE

[11] Consequently, the Court need not consider Defendant's motion to transfer venue to the District of New Jersey.