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App. 1

United States Court of Appeals
For the First Circuit

No. 22-1910

KRISTIN DICROCE,
individually and on behalf of
all persons similarly situated,

Plaintiff, Appellant,

v.

MCNEIL NUTRITIONALS, LLC and
JOHNSON & JOHNSON CONSUMER INC.,

Defendants, Appellees.

APPEAL FROM THE
UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

[Hon. Patti B. Saris, U.S. District Judge]

Before

Kayatta, Gelpi, and Montecalvo,
Circuit Judges.

John Peter Zavez, with whom Noah Rosmarin, Brendan M. Bridgeland, and Adkins, Kelston & Zavez, P.C. were on brief, for appellant.

Hannah Y. Chanoine, with whom Kayla N. Haran, Matthew D. Powers, and O'Melveny & Myers LLP were on brief, for appellees.

September 18, 2023

GELPI, Circuit Judge. Plaintiff-Appellant Kristin DiCroce ("DiCroce") challenges the district court's dismissal of her complaint against McNeil Nutritionals, LLC and Johnson & Johnson Consumer, Inc. (collectively, "Appellees") for their allegedly misleading labeling and marketing of Lactaid supplements. We agree with the dismissal outcome, albeit on different grounds. Therefore, we affirm.

I. BACKGROUND

Given that "[t]he maze of detail" in DiCroce's complaint is clearly laid out in the district court's opinion,[1] we recite only the facts needed "for purposes of th[is] appeal." Dukes Bridge LLC v. Beinhocker, 856 F.3d 186, 187 (1st Cir. 2017).

Lactose intolerance is "characterized by abdominal cramps and diarrhea after consumption of food that contains lactose," a sugar found in dairy products. Lactose Intolerance, Stedmans Medical Dictionary 452780, Westlaw (databased updated Nov. 2014). Individuals

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[1] DiCroce v. McNeil Nutritionals, LLC, 640 F. Supp. 3d 182 (D. Mass. 2022).

who suffer from lactose intolerance do not produce enough lactase – an enzyme that aids in the digestion of lactose. See id. Lactaid is a tablet form of the enzyme lactase – made and distributed by Appellees – that claims to prevent "gas," "bloating," and "diarrhea" "associated with digesting dairy," among other things.

DiCroce lives in Massachusetts and has purchased Lactaid supplements "on multiple occasions within the past four years." DiCroce filed this putative class action in October 2021 challenging certain statements on the packaging of Lactaid products.[2] Her general argument proceeds as follows:

(1) Lactose intolerance is a disease, per 21 C.F.R. § 101.93(g)(1)'s definition of a "disease";

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[2] DiCroce's complaint claims that: (1) Appellees engaged in deceptive acts or practices in violation of Mass. Gen. Laws ch. 93A (the Massachusetts Consumer Protection Act); (2) that Appellees engaged in false advertising in violation of Mass. Gen. Laws ch. 266, § 91; and (3) that Appellees were unjustly enriched because, by buying Lactaid, DiCroce conferred an economic benefit on Appellees. The district court granted Appellees' initial motion to dismiss for lack of standing, concluding that DiCroce had failed to plausibly allege an injury in fact because her claims that Lactaid's labeling "affected her purchasing decisions" were "vague," and, thus, she had no Article III standing.

With leave of court, DiCroce later filed an amended complaint, adding to her original allegations that she paid an "unwarranted premium" for Lactaid products because the products' "illegal disease claims" led her to reasonably believe that they were worth more than less expensive lactase supplements. DiCroce noted that Lactaid products cost $0.20 per dosage, while alternative products, which she cited specific examples of, cost at least $0.11 less. We draw the relevant facts from her amended complaint.

> (2) Lactaid, although marketed as a dietary supplement, claims to treat the disease of lactose intolerance, thereby violating 21 U.S.C. § 343(r)(6), and making it a drug, per § 101.93(f);
>
> (3) Because Lactaid is a drug under the relevant federal laws, it is misleading, and thus violative of state law, for Appellees to misbrand Lactaid as a dietary supplement, and to make statements on Lactaid's label disclaiming Food and Drug Administration ("FDA") approval, thereby implying that FDA approval is not required;
>
> (4) Had Lactaid's product not claimed to treat the disease of lactose intolerance, DiCroce would not have been misled into purchasing Lactaid products, which are more expensive than other lactase supplements.

The district court granted Appellees' second motion to dismiss, despite finding that DiCroce's amended complaint sufficiently alleged an injury in fact for purposes of Article III standing. DiCroce, 640 F. Supp. 3d at 185, 187–88. The district court held that DiCroce's false advertising and deceptive trade practices claims both failed because "no reasonable consumer could find Lactaid's product labels deceptive, nor has DiCroce identified a misrepresentation of fact." Id. at 188. Nor was the district court convinced by DiCroce's disclaimer argument, explaining that her "conclusory allegation d[id] not accord with the language of the disclaimers" and that no "reasonable consumer's purchasing decision" would be swayed by the fact that the product required FDA evaluation given that the label

disclosed that the product is not FDA approved. Id. at 188–89.

DiCroce timely appealed.

II. DISCUSSION

Before we proceed to the merits of DiCroce's appeal, we pause to address the issue of standing. See United States v. Catala, 870 F.3d 6, 9 (1st Cir. 2017) ("Because Article III standing is a sine qua non to federal judicial involvement, a federal court must resolve any doubts about such standing before proceeding to adjudicate the merits of a given case."). Contested by the parties is whether DiCroce has plausibly pled an injury in fact, as required for Article III and statutory standing, under chapter 93A of the Massachusetts General Laws. See Hochendoner v. Genzyme Corp., 823 F.3d 724, 731 (1st Cir. 2016) (explaining the injury requirement for standing in the Article III context); Shaulis v. Nordstrom, Inc., 865 F.3d 1, 10 (1st Cir. 2017) (discussing cognizable injuries under chapter 93A). We begin with DiCroce's Article III standing.

"[At] the pleading stage, the plaintiff bears the burden of establishing sufficient factual matter to plausibly demonstrate h[er] standing to bring the action." Hochendoner, 823 F.3d at 731. For an injury in fact to be plausibly pled, it "must be both concrete and particularized and actual or imminent, not conjectural or hypothetical." Id. (cleaned up). Concreteness requires that the injury "actually exist[s]." Id. (alteration in original) (quoting Spokeo, Inc. v. Robins, 578 U.S.

330, 340 (2016)). And particularization demands that, in addition to alleging "injurious conduct attributable to the defendant," a plaintiff must also claim to be "among the persons injured by that conduct." Id. at 731–32.

DiCroce's second amended complaint satisfies both requirements. DiCroce claims that she personally purchased Lactaid supplements on multiple occasions during the four years preceding the complaint. She further alleges that Lactaid supplements cost at least $0.11 more per tablet than other brands and that she was misled into purchasing overpriced lactase supplements because of Appellees' purportedly unlawful marketing statements. Put another way, DiCroce claims that she has personally suffered economic harm in the past as a result of Appellees' alleged misconduct. At the pleading stage, we find these allegations sufficient to meet the minimal plausibility standard for establishing Article III standing. See In re Evenflo Co., Inc., Mktg., Sales Pracs. & Prods. Liab. Litig., 54 F.4th 28, 35 (1st Cir. 2022) ("This court has repeatedly recognized overpayment as a cognizable form of Article III injury."); Gustaysen v. Alcon Lab'ys, Inc., 903 F.3d 1, 7–8 (1st Cir. 2018) (holding that plaintiffs sufficiently pled a concrete, actual, particularized injury for standing purposes where they claimed that they, themselves, had suffered "out-of-pocket loss of money" in the past because of defendants' conduct).

Appellees' remaining standing arguments are statutory in nature, insofar as they pertain to whether DiCroce "has a cause of action" under chapter 93A.

Catala, 870 F.3d at 10. Because statutory standing is not determinative of "a court's power to adjudicate a case," we choose to forgo this inquiry, "in the interest of efficiency," given our ultimate conclusion that DiCroce's claims were properly dismissed by the district court. See id. Having "resolve[d] any doubts" about DiCroce's Article III standing, we proceed to the merits. Id. at 9.

We review de novo the district court's order granting a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6). Sullivan v. etectRx, Inc., 67 F.4th 487, 491 (1st Cir. 2023). Accordingly, "we ask whether the well-pleaded factual allegations, viewed in the light most favorable to the plaintiff, . . . 'plausibly narrate a claim for relief.'" Id. (quoting Germanowski v. Harris, 854 F.3d 68, 71 (1st Cir. 2017)). In reaching a conclusion, we are not tied to the district court's reasoning "but may affirm the order of dismissal on any ground made manifest by the record." Gonzalez v. Velez, 864 F.3d 45, 50 (1st Cir. 2017) (quoting Katz v. Pershing, LLC, 672 F.3d 64, 71 (1st Cir. 2012)).

Before us, DiCroce argues that the district court's ruling was incorrect and continues to press her claim that Lactaid's label is misleading because it fails to comply with federal labeling requirements. DiCroce further contends that the district court should have allowed the matter of whether lactose intolerance is a disease to go beyond the pleading stage. Such arguments lack merit. DiCroce's claims are impliedly preempted by the FDA's statutory enforcement authority.

We begin with the relevant regulatory background. The Food, Drug, and Cosmetic Act ("FDCA") was enacted to protect consumers from "harmful products." In re Zofran (Ondansetron) Prods. Liab. Litig., 57 F.4th 327, 330 (1st Cir. 2023) (quoting Wyeth v. Levine, 555 U.S. 555, 574 (2009)). The FDA regulates dietary supplements through the FDCA, as amended by the Dietary Supplement Health and Education Act of 1994 ("DSHEA") and FDA regulations.[3] Ferrari v. Vitamin Shoppe Indus. LLC, 70 F.4th 64, 67–68 (1st Cir. 2023) (citing Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103–417, 108 Stat. 4325, 4325–26 (1994)). In Ferrari, we examined the legislative history related to DSHEA before concluding that "Congress intended dietary supplements to escape the regulatory gauntlet that drugs must go through." Id. at 73–74 ("It enacted the DSHEA to 'ensur[e] that the Federal Government erects no barriers that impede the ability of consumers to improve their nutrition through the free choice of safe dietary supplements' and 'to clarify that dietary supplements are not drugs . . . [and] should not be regulated as drugs.'" (alterations in original) (quoting S. Rep. No. 103–410 (1994), 1994 WL 562259, at *2)).[4] Unlike dietary supplements, drugs, which are

[3] DSHEA defines a dietary supplement as a product that is "intended to supplement the diet" and that contains certain "dietary ingredients." 21 U.S.C. § 321(ff).

[4] Under the FDCA and DSHEA, manufacturers are allowed to make "structure/function claims" about dietary supplements. Kaufman v. CVS Caremark Corp., 836 F.3d 88, 92 (1st Cir. 2016). DiCroce does not allege that Lactaid does not perform as advertised in the label. Therefore, we need not delve into whether Appellees possess substantiation for Lactaid's label claims.

also regulated under the FDCA, require prior FDA approval before they can be sold or marketed to consumers. In re Zofran, 57 F.4th at 330 (explaining that the FDA reviews a drug's efficacy and proposed label).

Importantly, only the FDA may enforce the FDCA, meaning that the FDCA provides no private right of action. 21 U.S.C. § 337(a); see Plourde v. Sorin Grp. USA, Inc., 23 F.4th 29, 33 (1st Cir. 2022) (explaining that § 337(a)'s "language shows 'that Congress intended that the [FDCA] be enforced exclusively by the Federal Government.'" (quoting Buckman Co. v. Plaintiffs' Legal comm., 531 U.S. 341, 352 (2001))).

DiCroce's legal action hinges on her assumption that Lactaid's labels violate the FDCA's labeling requirements and are therefore misleading to consumers. But we have made it clear that "§ 337(a) preempts any state-law claim that exists 'solely by virtue' of an FDCA infraction." Plourde, 23 F.4th at 33.

In Buckman, plaintiffs claimed injuries related to the placement of "orthopedic bone screws" in their spines. 531 U.S. at 343. Specifically, they alleged that a consulting company made fraudulent representations to the FDA during the screws' approval process, resulting in the FDA's subsequent approval of the devices. Id. The Court concluded that plaintiffs' "state-law fraud-on-the FDA" claims were impliedly preempted because "[p]olicing fraud against federal agencies is hardly 'a field which the States have traditionally occupied'" and said claims conflicted with the federal statutory scheme, which "amply empowers the FDA to

punish and deter fraud against the Administration." Id. at 347–48 (quoting Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947)).

More recently, we had the opportunity to consider Buckman's holding in the food-labeling context, in Dumont v. Reily Foods Company. 934 F.3d 35, 41–43 (1st Cir. 2019). There, we applied, without formally adopting, the Eighth and Ninth Circuits' test for deciding whether a state-law claim avoids preemption: "The plaintiff must be suing for conduct that violates the FDCA (or else his claim is expressly preempted by [the FDCA's medical device preemption provision, 21 U.S.C. § 360k], but the plaintiff must not be suing because the conduct violates the FDCA (such a claim would be impliedly preempted under Buckman))." Dumont, 934 F.3d at 42 (alteration in original) (quoting In re Medtronic, Inc., Sprint Fidelis Leads Prod. Liab. Litig., 623 F.3d 1200, 1204 (8th Cir. 2010)) (citing Perez v. Nidek Co., 711 F.3d 1109, 1120 (9th Cir. 2013)). We explained that, based on this test, a "complaint is preempted unless the conduct it pleads: (1) violates FDCA labeling requirements and (2) would also violate chapter 93A even if the FDCA did not exist."[5] Id. at 42. We approvingly referred to this test again in Plourde, where we were confronted with state-law negligence and

[5] States are prohibited from imposing food labeling requirements beyond what the FDCA requires. Kaufman, 836 F.3d at 91 (citing 21 U.S.C. § 343–1(a)(5)).Thus, if a manufacturer complies with the FDCA's labeling requirements, a plaintiff has no cause of action under state law for labeling claims. Id. at 92.

failure-to-warn claims related to a medical device. 23 F.4th at 33–34.

Returning to DiCroce's complaint, we hold that her state law claims – for unfair or deceptive trade practices, false advertising, and unjust enrichment[6] – "exist[] 'solely by virtue' of an FDCA infraction" and thus are impliedly preempted. Id. at 33. DiCroce, like the plaintiffs in Buckman, is alleging fraud under the FDCA, given that her claim that Lactaid's label is misleading is premised entirely on her belief that said label violates the FDCA.[7] See id. And DiCroce provides no other grounds on which her claims could survive. She does not contend that Lactaid did not perform as promised, nor does she provide any basis, independent of federal labeling laws, from which we could conclude that a consumer would be misled by Lactaid's label. In fact, DiCroce's complaint acknowledges that Lactaid's disclaimer statements are "literally true" before arguing that they are nevertheless misleading because they violate the FDCA.

If Lactaid's label conflicts with the FDCA's labeling requirements – an issue we decline to take a position on – Congress tasked the FDA with addressing

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[6] An unjust enrichment claim that "rests on the same improper conduct alleged in another claim . . . will stand or fall with the related claim." Kaufman, 836 F.3d at 96 (quoting Cleary v. Philip Morris, Inc., 656 F.3d 511, 517 (7th Cir. 2011)).

[7] While "state-law claim[s] based on 'traditional state tort law' that happen[] to 'parallel' the FDCA" are not necessarily preempted, Plourde, 23 F.4th at 33 (quoting Buckman, 531 U.S. at 353), DiCroce does not plead such a claim here.

said violations when it enacted § 337(a), not private citizens. See Blackman, 531 U.S. at 348; Plourde, 23 F.4th at 33.

III. CONCLUSION

Because we conclude that violation of the FDCA "is a critical element in [DiCroce's] case," we hold that her claims are impliedly preempted. Blackman, 531 U.S. at 353 (emphasis added). Thus, the district court's dismissal of DiCroce's amended complaint is

Affirmed.

United States Court of Appeals
For the First Circuit

No. 22-1910

KRISTIN DICROCE,
individually and on behalf of
all persons similarly situated,

Plaintiff, Appellant,

v.

MCNEIL NUTRITIONALS, LLC and
JOHNSON & JOHNSON CONSUMER INC.,

Defendants, Appellees.

JUDGMENT

Entered: September 18, 2023

This cause came on to be heard on appeal from the United States District Court for the District of Massachusetts and was argued by counsel.

Upon consideration whereof, it is now here ordered, adjudged and decreed as follows: The judgment of the district court is affirmed

By the Court:

Maria R. Hamilton, Clerk

cc: Noah Rosmarin, John Peter Zavez, Brendan M. Bridgeland, Christopher Bates Parkerson, James

App. 14

Michael Campbell, Hannah Y.S. Chanoine, Margaret J. Pastuszak, Kayla N. Haran, Matthew D. Powers

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

KRISTIN DICROCE, individually and on behalf of all persons similarly situated, Plaintiff, v. MCNEIL NUTRITIONALS, LLC, and JOHNSON & JOHNSON CONSUMER, INC., Defendants.	Civil Action No. 21-11660-PBS

MEMORANDUM AND ORDER

November 10, 2022

Saris, D.J.

INTRODUCTION

This putative class action returns to the court on Defendants McNeil Nutritionals, LLC ("McNeil") and Johnson and Johnson Consumer, Inc.'s ("J&J") motion to dismiss Plaintiff Kristin DiCroce's Amended Complaint. DiCroce alleges that Defendants unlawfully and misleadingly labeled their product Lactaid in violation of Massachusetts General Laws Chapter 93A and Chapter 266, Section 91. Defendants' motion argues that DiCroce lacks standing and that the Amended Complaint fails to plead facts in support of each cause

of action and is preempted. After hearing, the Court **ALLOWS** Defendants' motion to dismiss.

BACKGROUND

I. The Amended Complaint

The Amended Complaint challenges certain statements on the packaging of Lactaid, which Defendants market as a dietary supplement to assist with the digestion of dairy products. The core substantive allegation is that despite advertising Lactaid as a dietary supplement and not a drug, Defendants make statements on Lactaid labels suggesting that it is effective to treat a disease in violation of the Food, Drug, and Cosmetic Act ("FDCA") and Food & Drug Administration ("FDA") regulations. Thus, per DiCroce, the statements are materially misleading in violation of state law. DiCroce takes issue with the following statements found on labels for Lactaid's Fast Act Chewables, Fast Act Caplets, and Original Strength Caplets:

- "For the Prevention of Gas • Bloating • Diarrhea associated with digesting dairy."
- "Enjoy Dairy Again!"
- By taking Lactaid, "nothing can stop you from eating the foods you love. Our delicious vanilla chewables should be taken with your first bite of dairy, so that milk doesn't mess with you."
- "Don't let that annoying lactose get in the way of eating. LACTAID® Fast Act Caplets make

dairy easier to digest so you can enjoy your favorite foods anytime, anywhere."

- "Experience the Total Joy of Dairy."
- "It's easier than ever to manage your lactose intolerance. Take up to three caplets with your first sip or bite of dairy to ensure that milk doesn't mess with you. LACTAID® Original Strength Caplets lets you enjoy dairy anytime, anywhere."

Dkt. 45–1; Dkt. 45–2; Dkt. 45–3.

The Amended Complaint asserts that this labeling is false and misleading and therefore that the Lactaid products are misbranded. Specifically, a statement about a dietary supplement "may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases." 21 U.S.C. § 343(r)(6). And the label of any food or drug is misleading if it omits facts that are material either "in light of other representations made or suggested" or "with respect to consequences which may result from use of the article under (i) [t]he conditions prescribed in such labelling or (ii) such conditions of use as are customary or usual." 21 C.F.R. § 1.21(a). According to DiCroce, the above statements portray Lactaid as capable of diagnosing, preventing, treating, curing, or mitigating lactose intolerance, a disease. Thus, McNeil and J&J are effecting an "end-run" around FDA requirements by marketing Lactaid as a drug without obtaining FDA approval. Dkt. 45 ¶ 24.

Each of the Lactaid products' labels also contain disclaimers that DiCroce alleges compound the consumer confusion. First, after describing Lactaid as preventing gas, bloating, and diarrhea associated with digesting dairy, the labels add, "THIS STATEMENT HAS NOT BEEN EVALUATED BY THE FOOD & DRUG ADMINISTRATION." Dkt. 45–1; Dkt. 45–2; Dkt. 45–3. According to DiCroce, this warning is materially misleading because it suggests that FDA evaluation is not required even though Lactaid's packaging makes disease claims. Thus, FDA evaluation and approval as a drug is required under the prevailing regulations. Second, the labels caution that "THIS PRODUCT IS NOT INTENDED TO DIAGNOSE, TREAT, CURE OR PREVENT ANY DISEASE." Id. The Amended Complaint alleges this disclaimer, too, is misleading because it contradicts other statements on Lactaid packaging implying that Lactaid is intended to treat symptoms of the disease of lactose intolerance. Notably, the packages also proclaim that Lactaid "is a dietary supplement, **NOT A DRUG**, and may be used by adults and children 4 years old and over. May be used every time you eat food containing dairy every meal, every snack, every day." Id.[1]

DiCroce alleges that she purchased Lactaid products many times over the past four years based on the alleged misstatements on the products' labels, and that

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[1] Images of the front and back of the packaging for Lactaid's Fast Act Chewables, including many of the contested statements and disclaimers, are included as Appendix A to this opinion. See Dkt. 19–1 at 2–3.

had they been properly labeled, she would not have been misled by the claims. She maintains that if the products had been labeled correctly, she either would not have purchased Lactaid or would only have been willing to purchase Lactaid for a lower price. She adds that she "would have been able to compare the Lactaid Supplements to other lactose supplements that did not make illegal disease claims and see that those other lactose supplements were less expensive for treating lactose intolerance." Dkt. 45 ¶ 31. DiCroce cites data from Amazon.com showing that Lactaid sells for $0.20 per pill, while similar lactase supplements that purportedly do not make disease claims sell for $0.09 per pill or less. Thus, she asserts that she paid an "unwarranted premium" for Lactaid. Id. ¶ 33.

II. Procedural History

DiCroce filed the initial Complaint on October 12, 2021, and Defendants moved to dismiss. The Court allowed Defendants' motion and dismissed the action without prejudice on April 8, 2022, finding that the Complaint failed to plead an injury-in-fact sufficient to establish standing. DiCroce promptly filed an Amended Complaint that brings three causes of action: violation of the Massachusetts Consumer Protection Act, Mass. Gen. Laws ch. 93A, and other states' consumer protection statutes (Count I); unjust enrichment (Count II); and false advertising in violation of Mass. Gen. Laws ch. 266, § 91 (Count III). DiCroce brings the Amended Complaint on behalf of the proposed class of persons who purchased Lactaid products

and are from states with laws concerning consumer protection, unjust enrichment, and false advertising substantially similar to Massachusetts's. Defendants again moved to dismiss for failure to state a claim and for lack of standing. The Court heard argument on August 16, 2022.

DISCUSSION

I. Legal Standard

To survive a motion to dismiss under Rule 12(b)(6), a complaint must allege "a plausible entitlement to relief." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 559 (2007). "While a complaint attacked by a Rule 12(b)(6) motion 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 a cause of action's elements will not do." Id. at 555 (cleaned up); see also Rodriguez-Ortiz v. Margo Caribe, Inc., 490 F.3d 92, 95–96 (1st Cir. 2007).The plausibility standard requires the Court to proceed in two steps. First, the Court must "separate the complaint's factual allegations (which must be accepted as true) from its conclusory legal allegations (which need not be credited)." Morales-Cruz v. Univ. of P.R., 676 F.3d 220, 224 (1st Cir. 2012). The Court must next determine whether the factual allegations permit it "to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id. (quoting Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009)).

On a motion to dismiss under Rule 12(b)(1), the plaintiff must plead facts sufficient to establish Article III standing. See Hochendoner v. Genzyme Corp., 823 F.3d 724, 730 (1st Cir. 2016). The Court generally looks to whether the allegations in the complaint establish standing, although the Court may weigh evidence outside of the complaint where the defendant brings a factual challenge. See Laufer v. Acheson Hotels, LLC, 50 F.4th 259, 265 (1st Cir. 2022). The elements of standing are (1) an "injury in fact" which is "concrete and particularized" and "actual or imminent"; (2) a "causal connection between the injury and the conduct complained of"; and (3) a likelihood that the injury will be "redressed by a favorable decision." Lujan v. Defs. of Wildlife, 504 U.S. 555, 560–61 (1992).

II. Analysis

A. Article III Standing

DiCroce argues that the allegedly misleading Lactaid labels caused her an injury-in-fact because but for those statements, she would not have purchased Lactaid and may have purchased a cheaper alternative.

To satisfy the concreteness and particularization elements of an injury-in-fact, the harm must "actually exist" above and beyond a "bare procedural violation" and must affect the plaintiff "in a personal and individual way." Hochendoner, 823 F.3d at 731 (quoting Spokeo, Inc. v. Robins, 578 U.S. 330, 339–41 (2016)). The bar for pleading an economic injury is low; "even an `identifiable trifle'" suffices. Katz v. Pershing, LLC,

672 F.3d 64, 76 (1st Cir. 2012) (quoting Adams v. Watson, 10 F.3d 915, 924 (1st Cir. 1993)). A consumer who overpays for a product because of purportedly deceptive conduct by the manufacturer may suffer a legally cognizable injury for Article III purposes. See Gustavsen v. Alcon Labs., Inc., 903 F.3d 1, 7–8 (1st Cir. 2018) (holding plaintiffs adequately alleged an Article III injury by claiming they paid an extra $500–$1000 per year for eye drop bottles designed to dispense unnecessarily large drops).

Here, unlike in the initial Complaint, DiCroce has plausibly alleged a legally cognizable injury. She claims to have paid at least $0.11 per pill more for Lactaid than she would have paid for alternative products because Lactaid made disease claims. DiCroce naturally has a "legally protected interest in [her] own money." Id. at 7. The parties dispute whether Lactaid and the alternatives, Puritan's Pride and Vitamin Shoppe lactase supplements, are equivalent such that the price per pill can be fairly compared. The Court cannot resolve this factual dispute at this stage. It suffices that DiCroce alleges she paid a premium for Lactaid because of its marketing statements.

Defendants point to cases discussing whether a consumer's payment for a product because of deceptive advertising is a legally cognizable injury under Chapter 93A. See, e.g., Shaulis v. Nordstrom, Inc., 865 F.3d 1, 11 (1st Cir. 2017); Tyler v. Michaels Stores, Inc., 984 N.E.2d 737, 745 (Mass. 2013). These cases address a consumer's statutory standing. See Katz, 672 F.3d at 75 ("Article III standing presents a question of

justiciability; if it is lacking, a federal court has no subject matter jurisdiction over the claim. . . . By contrast, statutory standing goes to the merits of the claim."). The Court here only determines that DiCroce has succeeded in alleging a justiciable case or controversy. Whether the Amended Complaint establishes Chapter 93A standing is a closer question that the Court need not address, as the Amended Complaint fails on the merits on other grounds.

B. Consumer Deception

To plead a Chapter 93A deceptive trade practices claim, a plaintiff must allege "(1) a deceptive act or practice on the part of the seller; (2) an injury or loss suffered by the consumer; and (3) a causal connection between the seller's deceptive act or practice and the consumer's injury." Tomasella v. Nestle USA, Inc., 962 F.3d 60, 71 (1st Cir. 2020) (quoting Casavant v. Norwegian Cruise Line, Ltd., 919 N.E.2d 165, 168–69 (Mass. App. Ct. 2009)). "[Amn advertisement is deceptive when it has the capacity to mislead consumers, acting reasonably under the circumstances, to act differently from the way they otherwise would have acted (i.e., to entice a reasonable consumer to purchase the product)." Aspinall v. Philip Morris Cos., Inc., 813 N.E.2d 476, 488 (Mass. 2004). In reviewing allegations of deceptive labeling, the Court looks to "whether the complaint's allegations make it plausible that, on a full factual record, a factfinder could reasonably regard the label as having the capacity to mislead." Dumont v. Reily Foods Co., 934 F.3d 35, 40 (1st Cir. 2019). This

standard "depends on the likely reaction of a reasonable consumer rather than an ignoramus." Aspinall, 919 N.E.2d at 487.

Similarly, a false advertising claim under Mass. Gen. Laws ch. 266, § 91 requires a showing that the defendant disseminated an advertisement which "contains any assertion, representation or statement of fact which is untrue, deceptive or misleading."

Here, no reasonable consumer could find Lactaid's product labels deceptive, nor has DiCroce identified a misrepresentation of fact. Her primary claim is that a consumer reading a Lactaid label would be misled by Defendants (1) marketing of Lactaid as a supplement even though they (2) make claims on Lactaid's packaging suggesting that it is a drug while (3) also stating that Lactaid is not a drug and cannot treat a disease. Contrary to DiCroce's position, Lactaid's packaging is not misleading. As noted, the labels that DiCroce attaches to the Amended Complaint each plainly state that Lactaid is not a drug and is not intended to treat any disease. See Dkt. 45–1; Dkt. 45–2; Dkt. 45–3. Courts "routinely conclude that the presence of a disclaimer, considered in context, precludes the finding that a reasonable consumer would be deceived by the defendant's conduct." Bowring v. Sapporo U.S.A., Inc., 234 F. Supp. 3d 386, 390 (E.D.N.Y. 2017). Lactaid's disclaimers are conspicuously located on the front and back of each box. The statement that Lactaid is not a drug is in bold on the back. Any reasonable consumer reading Lactaid's label would conclude that Lactaid is

a supplement that assists with the digestion of dairy and is not a drug that can treat a disease.

DiCroce advances the alternative argument that the disclaimers on Lactaid's labels misled her because they falsely imply that Lactaid's packaging does not require FDA evaluation. This conclusory allegation does not accord with the language of the disclaimers, which say only that statements about Lactaid have not been evaluated by the FDA. See Fitzgerald v. Polar Corp., No. 20-cv-10877, 2020 WL 6586628, at *5 (D. Mass. Nov. 10, 2020). Further, whether Lactaid's label statements require FDA evaluation would not influence a reasonable consumer's purchasing decision where the product's label discloses that they are not FDA-approved. DiCroce's claims therefore fail.

ORDER

For the foregoing reasons, Defendants' motion to dismiss (Dkt. 50) is **ALLOWED**. The Amended Complaint is dismissed with prejudice.

/s/ PATTI B. SARIS
Hon. Patti B. Saris
United States District Judge

APPENDIX A


Lactaid
ENJOY DAIRY AGAIN!
FAST ACT
Lactase Enzyme Supplement
For the prevention of:
GAS, BLOATING
& DIARRHEA
Associated with digesting dairy*
Vanilla Twist® Flavor
NATURAL AND ARTIFICIAL FLAVOR
Enjoy Dairy Again
NO DISCOMFORT!*
ACTUAL SIZE
60 CHEWABLES
Single serve pouches,
1 chewable tablet per serving
*THESE STATEMENTS HAVE NOT BEEN EVALUATED BY THE FOOD & DRUG ADMINISTRATION. THIS PRODUCT IS NOT INTENDED TO DIAGNOSE, TREAT, CURE OR PREVENT ANY DISEASE.


Lactaid
ENJOY DAIRY AGAIN!
FAST ACT
Lactase Enzyme Supplement
Supplement Facts
Serving Size 1 Chewable Tablet
Servings Per Container 60
Per Tablet
Amount % Daily Value
Total Carb. <1 g <1%*
Sodium 5 mg <1%*
Lactase Enzyme 9000 FCC †
*Percent Daily Values are based on a 2,000 calorie diet.
†Daily Value not established.
Other Ingredients: Mannitol, Microcrystalline Cellulose, Croscarmellose Sodium, Crospovidone, Magnesium Stearate, Natural and Artificial Flavor, Citric Acid, Sucralose
Distributed By:
JOHNSON & JOHNSON CONSUMER INC.
McNeil Nutritionals, LLC Subsidiary
Fort Washington, PA
19034 USA
Made in Canada
Lactaid
ENJOY DAIRY AGAIN!
Vanilla Twist® Flavor
NATURAL AND ARTIFICIAL FLAVOR
FAST ACT
Lactase Enzyme Supplement
ACTUAL SIZE
60 CHEWABLES
Single serve pouches, 1 chewable tablet per serving
LACTAID® FAST ACT SUPPLEMENTS FOR THE PREVENTION OF: GAS, BLOATING, AND DIARRHEA
associated with digesting dairy*
DIRECTIONS:
Take at First Bite
Take 1 chewable with your first bite of dairy food. If necessary, you may take 2 chewables at one time.
Enjoy Dairy!
Repeat
If you continue to eat foods containing dairy after 30-45 minutes, take another chewable.
Consult your doctor if your symptoms continue after using this product or if your symptoms are unusual and seem unrelated to eating dairy.
Keep out of the reach of children.
HOW IT WORKS:
LACTAID® Fast Act Supplements contain a lactase enzyme that your body may not naturally produce enough of. It works in harmony with your body to help you digest dairy.
This is a dietary supplement, NOT A DRUG, and may be used by adults and children 4 years and over. May be used every time you eat food containing dairy- every meal, every snack, every day.
QUESTIONS OR COMMENTS?
For questions or comments in English or Spanish, call toll-free: 800-522-8243
Outside US dial collect: 215-273-8755
Or visit www.lactaid.com
DO NOT USE if carton or single-serve packet is open.
Store at or below 77°F. Keep away from heat and humidity.
*THESE STATEMENTS HAVE NOT BEEN EVALUATED BY THE FOOD & DRUG ADMINISTRATION. THIS PRODUCT IS NOT INTENDED TO DIAGNOSE, TREAT, CURE OR PREVENT ANY DISEASE.

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

KRISTIN DiCROCE, Plaintiff, v. McNEIL NUTRITIONALS, LLC ET AL, Defendants.	)	CIVIL ACTION NO. 21-11660-PBS

ORDER OF DISMISSAL

SARIS, D.J.

In accordance with the Court's Memorandum and Order dated November 10, 2022, allowing defendants' motion to dismiss (Docket No. 50), it is hereby ORDERED that the above-entitled action be and hereby is dismissed with prejudice.

By the Court,

/s/ Clarilde Geraldino-Karasek
Deputy Clerk

DATED: November 10, 2022

United States Court of Appeals
For the First Circuit

No. 22-1910

KRISTIN DICROCE, individually and on behalf of all persons similarly situated,

Plaintiff - Appellant,

v.

MCNEIL NUTRITIONALS, LLC; JOHNSON & JOHNSON CONSUMER, INC.,

Defendants - Appellees.

Before

Barron, Chief Judge,
Kayatta, Gelpi, Montecalvo,
and Rikelman, Circuit Judges.

ORDER OF COURT

Entered: November 29, 2023

The petition for rehearing having been denied by the panel of judges who decided the case, and the petition for rehearing en banc having been submitted to the active judges of this court and a majority of the judges not having voted that the case be heard en banc,

it is ordered that the petition for rehearing and the petition for rehearing en banc be denied.

By the Court:

Maria R. Hamilton, Clerk

cc:
Noah Rosmarin, John Peter Zavez, Brendan M. Bridgeland, Christopher Bates Parkerson, James Michael Campbell, Hannah Y.S. Chanoine, Margaret J. Pastuszak, Kayla N. Haran, Matthew D. Powers

TITLE 21—FOOD AND DRUGS

§ 343. Misbranded food

A food shall be deemed to be misbranded—

(a) False or misleading label

If (1) its labeling is false or misleading in any particular, or (2) in the case of a food to which section 350 of this title applies, its advertising is false or misleading in a material respect or its labeling is in violation of section 350(b)(2) of this title.

(b) Offer for sale under another name

If it is offered for sale under the name of another food.

(c) Imitation of another food

If it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word "imitation" and, immediately thereafter, the name of the food imitated.

(d) Misleading container

If its container is so made, formed, or filled as to be misleading.

(e) Package form

If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count, except that under clause (2) of this paragraph reasonable variations

shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

(f) Prominence of information on label

If any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(g) Representation as to definition and standard of identity

If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by section 341 of this title, unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard, and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food.

(h) Representation as to standards of quality and fill of container

If it purports to be or is represented as—

(1) a food for which a standard of quality has been prescribed by regulations as provided by section 341 of this title, and its quality falls below

such standard, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard;

(2) a food for which a standard or standards of fill of container have been prescribed by regulations as provided by section 341 of this title, and it falls below the standard of fill of container applicable thereto, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard; or

(3) a food that is pasteurized unless—

(A) such food has been subjected to a safe process or treatment that is prescribed as pasteurization for such food in a regulation promulgated under this chapter; or

(B)(i) such food has been subjected to a safe process or treatment that—

(I) is reasonably certain to achieve destruction or elimination in the food of the most resistant microorganisms of public health significance that are likely to occur in the food;

(II) is at least as protective of the public health as a process or treatment described in subparagraph (A);

(III) is effective for a period that is at least as long as the shelf life of the food when stored under normal and moderate abuse conditions; and

(IV) is the subject of a notification to the Secretary, including effectiveness

data regarding the process or treatment; and

(ii) at least 120 days have passed after the date of receipt of such notification by the Secretary without the Secretary making a determination that the process or treatment involved has not been shown to meet the requirements of subclauses (I) through (III) of clause (i).

For purposes of paragraph (3), a determination by the Secretary that a process or treatment has not been shown to meet the requirements of subclauses (I) through (III) of subparagraph (B)(i) shall constitute final agency action under such subclauses.

(i) Label where no representation as to definition and standard of identity

Unless its label bears (1) the common or usual name of the food, if any there be, and (2) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient and if the food purports to be a beverage containing vegetable or fruit juice, a statement with appropriate prominence on the information panel of the total percentage of such fruit or vegetable juice contained in the food; except that spices, flavorings, and colors not required to be certified under section 379e(c) of this title[1] unless sold as spices, flavorings, or such colors, may be designated as spices, flavorings, and colorings without naming each. To the extent that compliance with the requirements of

[1] So in original. Probably should be followed by a comma.

clause (2) of this paragraph is impracticable, or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary.

(j) Representation for special dietary use

If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Secretary determines

* * *

shall be deemed to be denied unless an extension is mutually agreed upon by the Secretary and the petitioner. If the Secretary denies the petition or the petition is deemed to be denied, the petition shall not be made available to the public. If the Secretary files the petition, the Secretary shall deny the petition or issue a proposed regulation to take the action requested in the petition not later than 90 days after the date of such decision. If the Secretary does not act within such 90 days, the petition shall be deemed to be denied unless an extension is mutually agreed upon by the Secretary and the petitioner. If the Secretary issues a proposed regulation, the rulemaking shall be completed within 540 days of the date the petition is received by the Secretary. If the Secretary does not issue a regulation within such 540 days, the Secretary shall provide the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate the reasons action on the regulation did not occur within such 540 days.

(ii) Any person may petition the Secretary for permission to use in a claim described in subparagraph (1)(A) terms that are consistent with the terms defined by the Secretary under subparagraph (2)(A)(i). Within 90 days of the submission of such a petition, the Secretary shall issue a final decision denying the petition or granting such permission.

(iii) Any person may petition the Secretary for permission to use an implied claim described in subparagraph (1)(A) in a brand name. After publishing notice of an opportunity to comment on the petition in the Federal Register and making the petition available to the public, the Secretary shall grant the petition if the Secretary finds that such claim is not misleading and is consistent with terms defined by the Secretary under subparagraph (2)(A)(i). The Secretary shall grant or deny the petition within 100 days of the date it is submitted to the Secretary and the petition shall be considered granted if the Secretary does not act on it within such 100 days.

(B) A petition under clause (A)(i) respecting a claim described in subparagraph (1)(A) or (1)(B) shall include an explanation of the reasons why the claim meets the requirements of this paragraph and a summary of the scientific data which supports such reasons.

(C) If a petition for a regulation under subparagraph (3)(B) relies on a report from an authoritative scientific body of the United States, the Secretary shall

consider such report and shall justify any decision rejecting the conclusions of such report.

(5)(A) This paragraph does not apply to infant formulas subject to section 350a(h) of this title and medical foods as defined in section 360ee(b) of this title.

(B) Subclauses (iii) through (v) of subparagraph (2)(A) and subparagraph (2)(B) do not apply to food which is served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments.

(C) A subparagraph (1)(A) claim made with respect to a food which claim is required by a standard of identity issued under section 341 of this title shall not be subject to subparagraph (2)(A)(i) or (2)(B).

(D) A subparagraph (1)(B) claim made with respect to a dietary supplement of vitamins, minerals, herbs, or other similar nutritional substances shall not be subject to subparagraph (3) but shall be subject to a procedure and standard, respecting the validity of such claim, established by regulation of the Secretary.

(6) For purposes of paragraph (r)(1)(B), a statement for a dietary supplement may be made if—

(A) the statement claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States, describes the role of a nutrient or dietary ingredient intended to affect the structure or

function in humans, characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or describes general well-being from consumption of a nutrient or dietary ingredient,

(B) the manufacturer of the dietary supplement has substantiation that such statement is truthful and not misleading, and

(C) the statement contains, prominently displayed and in boldface type, the following: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.".

A statement under this subparagraph may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. If the manufacturer of a dietary supplement proposes to make a statement described in the first sentence of this subparagraph in the labeling of the dietary supplement, the manufacturer shall notify the Secretary no later than 30 days after the first marketing of the dietary supplement with such statement that such a statement is being made.

(7) The Secretary may make proposed regulations issued under this paragraph effective upon publication pending consideration of public comment and publication of a final regulation if the Secretary determines that such action is necessary—

(A) to enable the Secretary to review and act promptly on petitions the Secretary determines provide for information necessary to—

(i) enable consumers to develop and maintain healthy dietary practices;

(ii) enable consumers to be informed promptly and effectively of important new knowledge regarding nutritional and health benefits of food; or

(iii) ensure that scientifically sound nutritional and health information is provided to consumers as soon as possible; or

(B) to enable the Secretary to act promptly to ban or modify a claim under this paragraph.

Such proposed regulations shall be deemed final agency action for purposes of judicial review.

(s) Dietary supplements

If—

(1) it is a dietary supplement; and

(2)(A) the label or labeling of the supplement fails to list—

* * *

Section 187. The term "misbranded" as used in this chapter shall apply to each drug, or article of food, or article which enters into the composition of food, the package or label of which bears any statement, design or device regarding such article or the ingredients or substance contained therein, which is false or misleading in any particular, and also to any food or drug product which is falsely branded as to the state or country where it was manufactured or produced.

For the purposes of said sections an article shall also be deemed to be misbranded:—

In the case of a drug: First, if it is so designated by the United States Food and Drug Administration, or if it is an imitation of or offered for sale under the name of another article. The department of public health shall maintain lists of drugs so designated as misbranded which shall be made available to physicians and pharmacists.

Second, if the contents of the package as originally put up have been removed, in whole or in part, and other contents placed therein.

Third, if its package or wrapper bears or contains any false or misleading statement, design, or device regarding the curative or therapeutic effect of such article or of any of the ingredients or substances contained therein.

Fourth, if in package form it fails to bear a label containing the name and place of business of the manufacturer, packer or distributor.

Fifth, if it is for use by man and contains any quantity of the narcotic or hypnotic substance alpha-eucaine, barbituric acid, beta-eucaine, bromal, cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, marihuana, morphine, opium, paraldehyde, peyote or sulphonmethane; or any chemical derivative of any such substance, unless its label bears the name and quantity or proportion of such substance or derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Sixth, if it is a drug and is not designated solely by a name recognized in an official compendium, unless its label bears (1) the common or usual name of the drug, if such there be; and (2) in case it is fabricated from two or more ingredients, the common or usual name of each active ingredient, including the kind and quantity or proportion of any alcohol, and also including whether active or not, the name and quantity or proportion of any bromides, ether, chloroform, acetanilid,

acetophenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid or any derivative or preparation of any such substances, contained therein; provided, that to the extent that compliance with the requirements of clause (2) of this paragraph is impracticable, exemptions may be established by regulations promulgated by the department of public health, which conform to the regulations promulgated under the Federal Food, Drug and Cosmetic Act for the enforcement of federal law.

Seventh, if its label fails to bear adequate directions for use and such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health or against unsafe dosage or methods or duration of administration or application in such manner and form as are necessary for the protection of the users.

Eighth, if it is dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

Ninth, if it is an unstable drug and does not bear upon its container a label stating a date beyond which it should not be used. The words "unstable drug", as used herein, shall mean an antibiotic drug or any other drug upon the container of which the manufacturer has placed a label bearing an expiration date by the use of such words as "not to be used after (specifying a date)" or similar language specifying a date after which the drug should not be used.

The labeling provisions of this section shall not apply to the compounding and dispensing of drugs on the oral or written prescription, as hereinafter defined, of a physician, dentist or veterinarian, except as above provided with respect to an unstable drug.

In the case of food: First, if its labeling is false or misleading in any particular;

Second, if it is offered for sale under the name of another food;

Third, if it is in imitation or semblance of any other food; provided, that this paragraph shall not apply to an imitation of a food for which a standard of quality or identity has been adopted under the provisions of section one hundred and ninety-two nor to an imitation of any other food for which no standard has been established by law or regulation, if its label bears in type of uniform size and prominence, the word "imitation", and immediately thereafter the name of the food imitated; and, provided further, that this paragraph shall not be construed to permit the imitation of any food for which a standard has been established by law, other than as specifically provided herein;

Fourth, if its container is so made, formed, or filled as to be misleading;

Fifth, if the package containing it or its label bears any statement, design or device regarding the ingredients or the substances contained therein which is false or misleading in any particular;

Sixth, if it is in package form and fails to bear a label showing (1) the name and place of business of the manufacturer, packer, or distributor;

(2) an accurate statement of the quantity of the product in terms of weight, measure, or numerical count; provided that reasonable variations may be permitted, and exemptions as to small packages may be established for food products by regulations prescribed by the department;

Seventh, if any word, statement, or other information required by or under authority of this chapter to appear on the label or other labeling is not prominently placed thereon with such conspicuousness, as compared with other words, statements, designs, or devices in the labeling, and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

Eighth, if it purports to be or is represented as a food for which a standard of quality has been prescribed by the department and its quality falls below such standard, unless its label bears a statement as to its true nature;

Ninth, if it purports to be or is represented as a food for which a definition and standard of identity or composition has been prescribed by the regulations of the department unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard and, insofar as may be required by such regulations, the

common names of optional ingredients, other than spices, flavoring and coloring, present in such food;

Tenth, if it purports to be or is represented as a food for which a standard or standards of fill of container have been prescribed by regulations of the department and it falls below the standard of fill of container, applicable thereto, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard;

Eleventh, if it is not subject to the provision of paragraph Ninth unless its label bears (1) the common or usual name of the food in order of predominance, if any there be, and (2) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient; except that spices, flavorings, and colorings may, when authorized by the department, be designated as spices, flavorings, and colorings without naming each; provided that, to the extent that compliance with the requirements of this clause is impracticable, or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the department;

Twelfth, if it purports to be or is represented for special dietary uses, its label bears such information concerning its vitamin, mineral and other dietary properties as the department determines to be, and by regulations prescribes as, necessary in order to fully inform purchasers as to its value for such uses;

Thirteenth, if it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless

it bears labeling stating that fact: provided that, to the extent that compliance with the requirements of this chapter is impracticable, exemptions shall be established by regulations promulgated by the department;

Fourteenth, in the case of meat or meat food product or poultry or poultry products, if it fails to bear, directly thereon and on its containers, as the department may by regulations prescribe, the official inspection legend and establishment number of the establishment where the product was prepared, and, unrestricted by any of the foregoing, such other information as the department may require in such regulations to assure that it will not have false or misleading labeling.

For the purposes of this section and section one hundred and eighty-seven A, the following terms shall have the following meanings:—

"Oral prescription", that prescription of a physician, dentist or veterinarian which has been verbally transmitted to a pharmacist by said physician, dentist or veterinarian or his expressly authorized representative and immediately recorded by said pharmacist on a regular prescription form, and which contains the name and address of the prescriber, and the name of the expressly authorized representative, if any, the date of the prescription, the name and amount of the drug prescribed, the serial number given to the prescription by the pharmacist dispensing the same, the name of the pharmacist receiving the prescription, the name of the patient unless a veterinary prescription, the directions for use and any cautionary statements if

stated in the prescription, and the number of times to be refilled.

"Written prescription", that prescription which has been issued by a physician, dentist or veterinarian either on paper or electronically, and bears the handwritten or electronic signature and address of the prescriber, the date of the prescription, the name and amount of the drug prescribed, the name of the patient, directions for use, the number of times to be refilled, and any cautionary statements needed.

"Pharmacist", a person duly registered under chapter one hundred and twelve and actively engaged as a practitioner or employed in an established and licensed place of business for the sale, compounding and dispensing of drugs.

In the case of a cosmetic: First, if in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; *Provided*, that under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established by regulations promulgated by the department of public health.

Second, if any word, statement, or other information required by or under authority of this chapter to appear on the label is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the label) and

in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

Third, if its container is so made, formed, or filled as to be misleading.

The department of public health shall promulgate regulations exempting from any labeling requirement of this chapter cosmetics which are in accordance with the practices of the trade, to be processed, labeled, or repackaged in substantial quantities at establishments other than those where originally processed or packaged, on condition that such cosmetics are not adulterated or misbranded under the provisions of this chapter upon removal from such processing, labeling, or repackaging establishment.

In the case of a device: First, if it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended or suggested in the labeling thereof.

Second, if it is in package form and it does not bear a label containing the name and place of business of the manufacturer, packer or distributor.

Third, if it is in package form and it does not bear a label containing an accurate statement of the quantity of the contents in terms of weight, measure or numerical count. Reasonable variations shall be permitted, and exemptions as to small packages shall be established by regulations.

Fourth, if the labeling thereof does not bear adequate directions for use, provided that where the requirement as applied to any device is not necessary for the protection of the public health, the commissioner shall promulgate regulations exempting such drug or device from such requirement.

Fifth, if the labeling thereof does not bear such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users.

Sixth, if any word, statement or other information required to appear on the label or labeling thereof is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

105 CMR: DEPARTMENT OF PUBLIC HEALTH

105 CMR 500.000: GOOD MANUFACTURING PRACTICES FOR FOOD

Section

Supplemental Fluid Milk and Milk Products Regulations

Supplemental Regulations for Manufacturers of Frozen Desserts, Frozen Dessert Mixes, Butter, and Cheese

Supplemental Regulations for the Manufacture, Collection, Bottling, and Labeling of Bottled Water and Carbonated Non-alcoholic Beverages

Administration and Enforcement

500.001: Purpose

The purpose of 105 CMR 500.000 is to establish minimum standards for those persons engaged in the business of preparing, processing, or distributing food for sale in Massachusetts. 105 CMR 500.000 shall be liberally construed and applied to promote the underlying purpose of protecting the public health.

500.002: Scope

(A) 105 CMR 500.000 applies to every person who prepares, manufactures, packs, repacks, cans, bottles, keeps, exposes, stores, handles, sells, transports, or distributes food in Massachusetts, whether or not for profit.

It applies to wholesale food processing operations within food establishments licensed by local boards of health, but does not apply to activities regulated by 105 CMR 590.000: *State Sanitary Code, Chapter X - Minimum Sanitation Standards for Food Establishments.*

(B) The requirements of 105 CMR 500.000 include but are not limited to every person who:

(1) Operates a residential kitchen to prepare or process food for wholesale sale;

(2) Operates as a retail seafood dealer, a wholesale seafood dealer, or a wholesale seafood truck;

(3) Cooks, smokes, or otherwise processes seafood, or combines seafood with non-seafood ingredient(s), for sale at wholesale;

(4) Engages in the business of slaughtering livestock or poultry or processing meat or poultry for sale at wholesale; engages in the business of custom slaughtering of livestock or poultry; or engages in the business of custom processing of meat or poultry;

(5) Operates a milk pasteurization plant;

(6) Manufactures butter or cheese for sale at wholesale;

(7) Manufactures within Massachusetts frozen desserts or frozen dessert mix, or manufactures frozen desserts or frozen dessert mix outside Massachusetts and sells such products in Massachusetts;

(8) Manufactures or bottles within Massachusetts carbonated non-alcoholic beverages or bottled water, whether carbonated or non-carbonated, for human consumption; or engages in such business outside Massachusetts and sells such products in Massachusetts;

(9) Manufactures juice or apple cider for sale at wholesale;

(10) Operates a cold storage or refrigerating warehouse, or a food warehouse;

(11) Transports or causes to be transported any bakery product into Massachusetts for the purpose of sale; or

(12) Manufactures, processes, or distributes any food not specifically named in 105 CMR 500.002(B)(1) through (11), including dietary supplements, for sale at wholesale.

500.003: Definitions

For the purposes of 105 CMR 500.000, the following terms shall have the following meanings.

Administrative Penalty means a civil monetary fine that the Department may assess pursuant to statutory authority.

Adulterated Food means the definition in M.G.L. c. 94, § 186.

500.004: Federal Regulations Applicable to All Licensees and Permit Holders

All licensees and permit holders shall comply with all federal regulations that are applicable to the type of food processing that they conduct. Such regulations include but are not necessarily limited to the following.

(A) Food Processing.

(1) 21 CFR Part 106: Infant Formula Quality Control Procedures;

(2) 21 CFR Part 110.00: *Current Good Manufacturing Practice in Manufacturing, Packing or Holding Human Food*;

(3) 21 CFR Part 111: *Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements*;

(4) 21 CFR Part 113.00: *Thermally Processed Low-acid Foods Packaged in Hermetically Sealed Containers*, and 21 CFR § 108.35: *Thermal Processing of Low-acid Foods Packaged in Hermetically Sealed Containers;*

(5) 21 CFR Part 114.00: *Acidified Foods*, and 21 CFR § 108.25: *Acidified Foods*;

(6) 21 CFR 173.315: *Chemicals Used in Washing or to Assist in the Peeling of Fruits and Vegetables*;

(7) Enforcement of 105 CMR 500.005(A)(1) through (6). When the Department receives a complaint alleging a violation of any provision of 105 CMR 500.004(A)(1) through (6) with respect to a business that participates in interstate commerce, the Department may refer the complainant to the U.S. Food and Drug Administration or take other appropriate action.

(B) Food Labeling.

(1) 9 CFR Part 317: *Labeling, Marking Devices, and Containers*;

(2) 9 CFR Part 381: *Poultry Products Inspection Regulations*:

(a) Subpart N: *Labeling and Containers*;

(b) Subpart Y: *Nutrition Labeling.*

(3) 21 CFR Part 1: *General Enforcement Regulations*:

(a) Subpart A: *General Provisions*;

(b) Subpart B: *General Labeling Requirements.*

(4) 21 CFR Part 100: *General*:

(a) Subpart F: *Misbranding for Reasons Other than Labeling*;

(b) Subpart G: *Specific Administrative Rulings and Decisions.*

(5) 21 CFR Part 101: *Food Labeling*;

(6) 21 CFR Part 102: *Common or Usual Name for Nonstandardized Foods*;

(7) 21 CFR Part 104: *Nutritional Quality Guidelines for Foods*;

(8) 21 CFR Part 105: *Foods for Special Dietary Use*;

(9) 21 CFR Part 107: *Infant Formula*;

(10) Enforcement of 105 CMR 500.004(B)(1) through (9). When the Department receives a complaint alleging a violation of any provision of 105 CMR 500.004(B)(1) through (9) with respect to a business that participates in interstate commerce, the Department may refer the complainant to the U.S. Department of Agriculture or the U.S. Food and Drug Administration, or take other appropriate action.

(C) Standards of Identity.

(1) 21 CFR Part 130: *Food Standards: General*;

(2) 21 CFR Part 131: *Milk and Cream*;

(3) 21 CFR Part 133: *Cheeses and Related Cheese Products*;

(4) 21 CFR Part 135: *Frozen Desserts*;

(5) 21 CFR Part 136: *Bakery Products*;

(6) 21 CFR Part 137: *Cereal Flours and Related Products*;

(7) 21 CFR Part 139: *Macaroni and Noodle Products*;

(8) 21 CFR Part 145: *Canned Fruits*;

(9) 21 CFR Part 146: *Canned Fruit Juices*;

(10) 21 CFR Part 150: *Fruit Butters, Jellies, Preserves, and Related Products*;

(11) 21 CFR Part 152: *Fruit Pies*;

(12) 21 CFR Part 155: *Canned Vegetables*;

(13) 21 CFR Part 156: *Vegetable Juice*;

(14) 21 CFR Part 158: *Frozen Vegetables*;

(15) 21 CFR Part 160: *Eggs and Egg Products*;

(d) Names and contact information for the primary suppliers of ingredients to the facility (to enable trace-back) and for the facility's primary customers (to enable trace-forward).

(2) A licensee or permit holder shall notify the Department immediately when an imminent danger to the public health is present in the facility or its products.

(3) Any licensee or permit holder may present for advance review and approval by the regulatory agency a plan to continue operations during an emergency and/or to respond to an emergency due to natural or man-made causes.

(K) Product Recall.

(1) A facility operator who knows or has reason to believe that circumstances exist that may adversely affect the safety of

products, including but not limited to major spills, serious accidents, introduction of toxins or contaminants, natural disasters, or major breakdowns in production, shall notify the Program immediately.

(2) Each facility operator shall develop and maintain on file a current written contingency plan for use in initiating and accomplishing a product trace and recall, and shall follow the plan as appropriate. The plan shall include procedures for the notification of the Program, consumer notification, and recall of the product.

(a) Recalls of meat or poultry products shall conform to the procedures and policies established by USDA.

(b) Recalls of products other than meat or poultry products shall conform to the procedures and policies of 21 CFR Part 7: *Enforcement Policy.*

(3) The facility shall use sufficient coding of products to make possible positive lot identification and to facilitate effective recall of all violative lots. The code shall be designed to remain affixed to the container during retail distribution and consumer use.

(4) The facility shall maintain such product distribution records as are necessary to enable location of products if a recall is initiated. These records shall be maintained for two years after December

31st of the year in which the product was processed.

(5) The facility shall implement the recall procedures as necessary with respect to any product which the facility or the Department knows or has reason to believe may adversely affect its safety for the consumer.

(6) If the Department determines that the circumstances present an imminent danger to the public health and that a form of consumer notice and/or product recall can effectively avoid or significantly minimize the threat to public health, the Department may advise the facility:

(a) To initiate a level of product recall approved by the Department, and/or

(b) If appropriate, to issue a form of notification to consumers.

1. The facility shall be responsible for disseminating the notice in a manner designed to inform consumers who may be affected.

2. The facility shall, where appropriate, provide the notice to the news media serving the affected public, and/or shall directly notify affected consumers when doing so effectively avoids or minimizes the risk to health.

(L) Maintenance of Records. All records required to be kept by 105 CMR 500.000 shall be maintained on file for at least two years, or for the time required by another specific record-keeping requirement in 105 CMR 500.000, and shall be made available to agents of the regulatory agency for inspection and copying upon request.

500.006: Labeling of Food

(A) All packaged food products shall comply with the federal labeling regulations specified in 105 CMR 500.004(B) and (C), and shall be labeled in accordance with all additional relevant state and/or federal labeling requirements.

(B) Open Date Labeling.

(1) Open Dating of Perishable and Semi-perishable Food Products.

(a) No person shall sell, offer for sale, or have in his or her possession with intent to sell any prepackaged perishable or semi-perishable food products unless it is identified with an open date determined by the manufacturer, processor, packer, repacker, retailer, or other person who packaged such food products, and which is displayed in the form specified in 105 CMR 500.006(B)(5).