UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

KRISTIE CONROY, individually and on behalf of all others similarly situated, Plaintiff, v. THE DANNON COMPANY, INC., Defendant.	**MEMORANDUM DECISION** 12 CV 6901 (VB)

Briccetti, J.:

This case raises the question of whether Activia® yogurt is, in fact, yogurt.

Plaintiff, Kristie Conroy, brings this putative class action on behalf of purchasers of Dannon Activia, Activia Light, Activia Parfait, Activia Fiber, and Activia 24 oz. Tubs (collectively "Activia®") against defendant The Dannon Company, Inc. ("Dannon") alleging defendant's product is misbranded as "Yogurt," "Lowfat Yogurt," and "Nonfat Yogurt." Plaintiff brings claims for breach of express warranty, breach of the implied warranty of merchantability, breach of the implied warranty of fitness for a particular purpose, unjust enrichment, violation of New York General Business Law §§ 349 and 350, negligent misrepresentation, and fraud. Now pending is defendant's motion to dismiss the complaint under Rule 12(b)(6). (Doc. #11).

Similar suits have recently been filed against other yogurt manufacturers across the country. One action has been dismissed without prejudice applying the common-law doctrine of primary jurisdiction. See Taradejna v. Gen. Mills Inc., 2012 WL 6113146 (D. Minn. Dec. 10, 2012). Another two have been dismissed for failure to state a claim. See Smith v. Cabot Creamery Co-op., Inc., 2013 WL 685114 (N.D. Cal. Feb. 25, 2013); Tamas v. Safeway Inc., No. RIC 1206341 (Cal. Super. Ct., Riverside Cnty. Nov. 21, 2012).

For the following reasons, defendant's motion is GRANTED.

The Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332.

BACKGROUND

For purposes of deciding the pending motion, the Court accepts all well-pleaded factual allegations in the complaint as true.

Plaintiff is a purchaser of Activia®. Between 2009 and 2012, she purchased vanilla-flavored Activia® once or twice per year and paid approximately $3.29 for packages of 4 single-serving containers. She thought she was buying authentic yogurt, but now claims Activia® is not yogurt at all.

Yogurt is created by fermenting milk with food-grade bacteria. Plaintiff alleges Activia® is different because it is not made the way yogurt is supposed to be made under the standards of identity promulgated by the Food and Drug Administration ("FDA"). According to the complaint, Dannon adds fillers, including food starch, corn starch, acacia gum, xanthan gum, gelatin, inulin, and milk protein concentrate ("MPC") "to make a cheaper product." Although plaintiff's complaint raises issues with respect to each of these fillers, the gravamen of plaintiff's complaint concerns the use of MPC.[1]

MPC is typically created as a byproduct of cheese manufacturing. According to the complaint, "[a]fter separating the curds from the whey following fermentation . . . the liquid whey is passed through an extremely fine filter." The filter retains milk proteins in a powder

[1] Plaintiff alleges there are other "filler materials" in Activia® that render the product misbranded, including certain ingredients characterized by defendant as stabilizers (e.g. corn starch and guar gum) and flavoring ingredients (i.e. wheat bran and water). However, plaintiff did not respond to defendant's arguments that her claims concerning these other "filler materials" should be dismissed for failure to state a claim. Accordingly, the Court deems claims concerning these ingredients abandoned. See Lipton v. Cnty. of Orange, N.Y., 315 F. Supp. 2d 434, 446 (S.D.N.Y. 2004) ("[W]hen a plaintiff fails to respond to a defendant's arguments that the claim should be dismissed," a court "may, and generally will, deem a claim abandoned.").

form. "It is called Milk Protein Concentrate if it contains whey protein and casein proteins in the same proportion as it appears in cow's milk (about 20% and 80%, respectively)."

Plaintiff alleges MPC is banned by the FDA for use in yogurt and is not generally recognized as safe. Therefore, plaintiff contends Activia® is misbranded and adulterated.

Defendant moves to dismiss the complaint arguing plaintiff's allegations are premised on a misunderstanding of the FDA's standard of identity for yogurt. In support of this contention, defendant argues (1) the FDA has permitted the use of MPC in yogurt for thirty years; and (2) plaintiff fails to allege any facts to support her claim that MPC is not safe for use in yogurt. Defendant further argues in the alternative that the FDA has primary jurisdiction over plaintiff's claims. Finally, defendant argues plaintiff's state law claims are preempted because they would impose a standard of identity for yogurt that is not identical to the FDA's regulations, and plaintiff has no private right of action to enforce the FDA's standard of identity for yogurt.

DISCUSSION

I. Legal Standard

The function of a motion to dismiss is "merely to assess the legal feasibility of the complaint, not to assay the weight of the evidence which might be offered in support thereof." Ryder Energy Distrib. v. Merrill Lynch Commodities, Inc., 748 F.2d 774, 779 (2d Cir. 1984) (internal quotation marks omitted). In deciding a motion to dismiss pursuant to Rule 12(b)(6), the Court evaluates the sufficiency of the complaint under the "two-pronged approach" suggested by the Supreme Court in Ashcroft v. Iqbal. See 556 U.S. 662, 679 (2009). First, "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements," are not entitled to the assumption of truth and are thus not sufficient to withstand a motion to dismiss. Id. at 678; Hayden v. Paterson, 594 F.3d 150, 161 (2d Cir. 2010). Second, "[w]hen there are well-pleaded factual allegations, a court should assume their veracity and then

determine whether they plausibly give rise to an entitlement for relief." Ashcroft v. Iqbal, 556 U.S. at 679.

To survive a Rule 12(b)(6) motion to dismiss, the allegations in the complaint must meet a standard of "plausibility." Id. at 678; Bell Atl. Corp. v. Twombly, 550 U.S. 544, 564 (2007). A claim is facially plausible "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Ashcroft v. Iqbal, 556 U.S. at 678. "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." Id.

II. Whether Activia® is Misbranded Because It Contains MPC

The foundation of plaintiff's claim that Activia® is misbranded rests on whether MPC is a permitted ingredient under the standard of identity for yogurt. Plaintiff argues the standard of identity "is an exclusive whitelist of permissible ingredients" and MPC does not appear in the standard of identity. Therefore, plaintiff contends, MPC may not be used.

Dannon argues MPC is a permitted "other optional ingredient." The Court agrees.

A. The FDA and Standards of Identity for Yogurt

The Federal Food, Drug, and Cosmetic Act of 1938 grants the FDA broad power to regulate the food industry. See 21 U.S.C. §§ 301 et seq. To promote "honesty and fair dealing," the FDA promulgates regulations prescribing a "reasonable definition and standard of identity" for food under its common or usual name. 21 U.S.C. § 341. In prescribing these standards of identity, the FDA may also designate certain "optional ingredients" that may also be used in foods. Id.

Standardized foods must conform to the standards of identity promulgated by the FDA. See Fed. Sec. Adm'r v. Quaker Oats Co., 318 U.S. 218, 232 (1943) ("The statutory purpose to

fix a definition of identity of an article of food sold under its common or usual name would be defeated if producers were free to add ingredients, however wholesome, which are not within the definition."). A food is deemed misbranded "[i]f it purports to be or is represented as a food for which a definition and standard of identity has been prescribed . . . 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." 21 U.S.C. § 343(g).

The standards of identity for yogurt are codified under 21 C.F.R. §§ 131.200 (standard for regular yogurt), 131.203 (standard for lowfat yogurt), and 131.206 (standard for nonfat yogurt). Because these regulations are nearly identical and any variances are irrelevant to the issues raised in this case, the Court refers to and cites the standard for regular yogurt for the remainder of this opinion. The standard of identity for yogurt provides, in relevant part, that yogurt must be made by culturing certain dairy ingredients and may include other optional ingredients:

> Yogurt is the food produced by culturing one or more of the optional dairy ingredients specified in paragraph (c) of this section with a characterizing bacterial culture that contains the lactic acid-producing bacteria, Lactobacillus bulgaricus and Streptococcus thermophilus. One or more of the other optional ingredients specified in paragraph (b) and (d) of this section may also be added. . . . All ingredients used are safe and suitable. Yogurt . . . contains not less than 3.25 percent milkfat and not less than 8.25 percent milk solids not fat, and has a titratable acidity of not less than 0.9 percent, expressed as lactic acid.

21 C.F.R. § 131.200(a). Optional dairy ingredients under paragraph (c) include: "[c]ream, milk, partially skimmed milk, or skim milk, used alone or in combination." Id. Other optional ingredients are defined in subsections of paragraph (d) and include ingredients to increase the

nonfat solids content of the food, nutritive carbohydrate sweeteners, flavoring ingredients, color additives, and stabilizers.

Defendant argues MPC may be added as an ingredient to increase the nonfat solids content of yogurt under paragraph (d)(1).

B. History of 21 C.F.R. § 131.200(d)(1) Concerning Ingredients to Increase the Nonfat Solids Content of the Food

In 1977, the FDA first proposed standards of identity for yogurt that included a broad category of optional ingredients defined as "other milk-derived ingredients to increase the nonfat solids content of the food." Proposal to Establish Standards of Identity for Yogurts, 42 Fed. Reg. 29919, at 22921 (proposed June 10, 1977). At oral argument, plaintiff agreed that MPC is a milk-derived ingredient. Thus, it appears MPC would have been allowed under the language of the rule as initially proposed in 1977. In 1981, however, when the FDA promulgated the standards for yogurt as published today, it modified the definition of "other optional ingredients" from a broad category of "other milk-derived ingredients" to a limited list of milk-derived ingredients that, notably, does not include MPC:

> Concentrated skim milk, nonfat dry milk, buttermilk, whey, lactose, lactalbumins, lactoglobulins, or whey modified by partial or complete removal of lactose and/or minerals, to increase the nonfat solids content of the food: *Provided*, That the ratio of protein to total nonfat solids of the food, and the protein efficiency ratio of all protein present shall not be decreased as a result of adding such ingredients.

Cultured and Acidified Milks, Cultured and Acidified Buttermilks, Yogurts, and Eggnog; Standards of Identity, 46 Fed. Reg. 9924, at 9939 (Jan. 30, 1981) (codified at 21 C.F.R. 131.200(d)(1)). Objections were filed regarding the changed language. In 1982, in response to these objections and before the regulations became effective on July 1, 1983, the FDA stayed the

effective date of certain provisions. Stay of Effective Date of Certain Provisions, 47 Fed. Reg. 41519 (Sept. 21, 1982).

Whether MPC may be added as an ingredient turns on the proper interpretation of the stay as imposed by the FDA.

C. Effect of the 1982 Stay

Plaintiff argues the stay effectively strikes the entire subsection (d)(1) from the standard of identity such that no milk-derived ingredients may be added to yogurt. Under plaintiff's reading, only "optional dairy ingredients" identified in paragraph (c), vitamins, sweeteners, flavoring ingredients, color additives, and stabilizers may be added, and none of those categories include MPC. In support of this contention, plaintiff refers the Court to the history of development of the regulation, and statements made by the FDA in a proposed new rule that would govern the standard of identity for yogurt. See FDA's Proposal to Revoke the Standards for Lowfat Yogurt and Nonfat Yogurt and to Amend the Standard for Yogurt, 74 Fed. Reg. 2443, at 2452-53 (proposed Jan. 15, 2009) (the "2009 Proposal").

The Court rejects plaintiff's interpretation of the 1982 stay.

When issuing the stay, the FDA explained that the stay was a response to objections concerning the replacement of the phrase "other milk-derived ingredients . . . with a limited list of names of milk-derived ingredients." 47 Fed. Reg. 41519. The objectors had argued the replacement of the broad term with a limited list did not promote honesty and fair dealing because it barred the use of other safe, nutritional, and functional milk-derived ingredients, and did not appear to have any rational factual basis. Id. The FDA concluded that "the objectors raise[d] a genuine and substantial issue of fact that must be resolved at a public hearing," and issued a stay. Id.

The precise words of the FDA's final rule establishing the stay was as follows:

> Therefore, the FDA is staying the effective date of the provisions of [131.200(d)(1)][2] that restrict the kinds of safe and suitable milk-derived ingredients that may be used as optional ingredients to increase the nonfat solids contents of these foods, pending the outcome of a public hearing.

47 Fed. Reg. 4159. On its own, the language of the stay is ambiguous as to whether the stay results in no other milk-derived ingredients being permitted, or permits any milk-derived ingredients to be added. However, in the context of the FDA's responding to objections made concerning the limitation on the ingredients that may be used, it becomes clear that staying "provisions . . . that restrict the kinds of safe and suitable milk-derived ingredients that may be used," means that paragraph (d)(1) is only stayed insofar as it limits the kinds of safe and suitable milk-derived ingredients that may be used.

In other words, the effect of the stay is that the FDA's 1981 proposed limitation on what milk-derived ingredients may be added is not in effect, and because there is no limitation in effect, other optional milk-derived ingredients may be added "to increase the nonfat solids content of the food: *Provided*, that the ratio of protein to total nonfat solids of the food, and the protein efficiency ratio of all protein present shall not be decreased as a result of adding such ingredients." 21 C.F.R. § 131.200(d)(1).

Indeed, over the years, the FDA has repeatedly clarified that the effect of the stay was to allow other milk-derived ingredients to be added to yogurt. For example, in an advanced notice of proposed rulemaking for yogurt, 68 Fed. Reg. 39873, at 39874 (proposed July 3, 2003), the FDA described the stayed provisions as follows:

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[2] To avoid confusion, the Court notes the standard of identity as proposed in 1981 listed the other optional milk-derived ingredients in paragraph (c)(1). Once the stay was imposed, that section was moved to what is now published as paragraph (d)(1). See id. ("[T]he paragraphs listed above which are affected by this stay will be changed from § 131.200(c) to § 131.200(d)(1)."). Thus, the Court hereafter refers to the stayed section as paragraph (d)(1).

> The stayed provisions are: (1) Those provisions of [§ 131.200(d)(1)] that restrict the type of milk-derived ingredients that may be used, to those so named, to increase the nonfat solids content of . . . yogurts."

Id. (emphasis added). In other words, the stay applies only to the restriction of the kinds of milk-derived ingredients that may be used, not to the addition of milk-derived ingredients generally.

More importantly for purposes of this suit, in 2004, the FDA expressly stated that MPC may be added to yogurt. This statement is contained in an FDA-issued memorandum from the Milk Safety Branch to all Regional Food and Drug Directors. The memorandum includes questions and answers from a Regional Milk Seminar, an Advanced Milk Processing Course, and a Special Problems in Milk Protection Course held during the second half of fiscal year 2004. At this seminar the question was asked: "May whey protein concentrate (WPC) and/or milk protein concentrate (MPC) be used as ingredients in yogurt to increase the nonfat solids content?" And the answer given was, "*Yes. 21 CFR 131.200(d), which would have precluded WPC or PMC use, was one of several provisions of the standard of identity for yogurt that were stayed in 1982, 47 FR 41519, September 21, 1982.*" FDA, Milk Safety References National Conference on Interstate Milk Shipments (NCIMS) M-I-04-10: Questions and Answers from a FY'04 Regional Milk Seminar, an Advanced Milk Processing Course and a Special Problems in Milk Protection Course ("FDA Q&A"), Question No. 2 (Dec. 27, 2004).

"The FDA's views are 'controlling unless plainly erroneous or inconsistent with the regulation[s]' or there is any other reason to doubt that they reflect the FDA's fair and considered judgment." PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2575 (2011) (quoting Auer v. Robbins, 519 U.S. 452, 461, 462 (1997), and affording deference to FDA's interpretation of its regulations concerning warning labels of brand-name and generic copy drugs); see also Biediger v. Quinnipiac Univ., 691 F.3d 85, 94, 97 (2d Cir. 2012) (concluding agency letters were entitled to

substantial deference because "they reflect reasonable agency interpretations of ambiguities in its own regulations, and there is no reason to think that the agency's interpretations do not reflect its 'fair and considered judgment on the matter in question.'").

Two other courts have already found that the FDA Q&A is entitled to such deference on the question presented in this case. See Smith v. Cabot, 2013 WL 685114, at *4 (applying PLIVA, Inc. v. Mensing and Ninth Circuit law and affording deference to the FDA Q&A); Tamas v. Safeway, Inc., slip op. at 5 (affording deference under Auer v. Robbins). This Court agrees that the FDA's interpretation is neither plainly erroneous, nor inconsistent with the regulation, nor is there any reason to doubt that a memorandum issued from the Milk Safety Branch to all Regional Food and Drug Directors reflects anything but the fair and considered judgment of the FDA on the question of whether MPC is a permitted ingredient in yogurt in light of the 1982 stay.

D. The FDA Q&A Does Not Directly Contradict the Plain Reading of Yogurt's Standard of Identity

Plaintiff contends the FDA Q&A is not entitled to deference because it directly contradicts the plain reading of yogurt's standard of identity.[3] Specifically, plaintiff argues that defendant's interpretation must be wrong because that interpretation would stand in "stark contrast to the very purpose of the standards of identity, because the term milk-derived ingredient has never been defined. So the defendant's interpretation would leave the standard of identity for yogurt too open to accomplish its purpose." (Oral Argument Tr., May 3, 2013, at 35:11-16).

[3] In her brief in opposition to the motion to dismiss, plaintiff also argues that informal comments by a staffer are not authoritative, but she cites no law in support of that argument, or otherwise attempts to distinguish any of the above cited law. The Court is unpersuaded that the FDA Q&A is not entitled to deference in these circumstances.

The Court disagrees. Section 341 of Title 21 of the United States Code requires the FDA to promulgate "so far as practicable, a reasonable definition and standard of identity" that will "promote honesty and fair dealing in the interest of consumers." 21 U.S.C. § 341. When promulgating these standards, the FDA determined that using concepts like "safe and suitable" along with "functional groups of ingredients" allows for technological flexibility "without adversely affecting the characteristics of the food" and "minimizes any future amendment of the standards for additional specific ingredients." 42 Fed. Reg. 29919, at 22920.

Plaintiff cites no law supporting the proposition that the FDA may not use concepts and functional groups of ingredients when defining a standard of identity, and the Court is not persuaded that a provision that permits any milk-derived ingredient, as opposed to a limited list of milk-derived ingredients, leaves the standard of identity too open to accomplish, "so far as practicable, a reasonable definition and standard of identity" for yogurt. 21 U.S.C. § 341.

Plaintiff further argues defendant's interpretation fails because there is no section header in paragraph (d)(1) the way there is in paragraph (d)(2), which describes the kinds of sweeteners that may be added as other optional ingredients. Paragraph (d)(2) provides:

> Nutritive carbohydrate sweeteners. Sugar (sucrose), beet or cane; invert sugar (in paste or sirup form); brown sugar; refiner's sirup; molasses (other than blackstrap); high fructose corn sirup; fructose; fructose sirup; maltose; maltose sirup, dried maltose sirup; malt extract, dried malt extract; malt sirup, dried malt sirup; honey; maple sugar; or any of the sweeteners listed in part 168 of this chapter, except table sirup.

If defendant's interpretation were correct, plaintiff contends, paragraph (d)(1) would have a section header called "milk-derived ingredients." Perhaps the effect of the stay would be less ambiguous if there was a section header; however, the problem with plaintiff's argument is that the FDA has repeatedly clarified what the effect of the stay is, and the absence of a header does

not render the FDA's own interpretations of its regulation plainly erroneous or inconsistent with the regulation.

E. The 2009 Proposal Does Not Support Plaintiff's Interpretation of Yogurt's Standard of Identity

Plaintiff also contends that the FDA's written guidance from the 2009 Proposal to amend the standard of identity for yogurt makes clear that the stay effectively struck paragraph (d)(1). See 74 Fed. Reg. 2443, at 2452-53. The Court disagrees.

Plaintiff first argues the 2009 Proposal makes clear § 131.200(d)(1) has "never [been] in effect." 74 Fed. Reg. 2443, at 2444. But, this quotation is taken out of context. Earlier in the paragraph, the FDA explains that it "stayed the effective date for provisions regarding certain milk products . . . as well as the following: (1) Those provisions of [§ 131.200(d)(1)] that restricted the type of milk-derived ingredients that may be used to increase the nonfat solids content of cultured milk and yogurts to those listed in these sections." Id. (emphasis added). In the 2009 Proposal, the FDA further explains why the restrictive part of paragraph (d)(1) remains stayed – because the FDA has not held a public hearing to resolve the issues – and what is permitted under the current regulation:

> To date, due to competing priorities and limited resources, FDA has not held a public hearing to resolve these issues and the effective date for these provisions remains stayed. Therefore, these provisions were never in effect. Consequently, cultured milk and yogurts may deviate from the relevant standards in the previously mentioned respects. For example, although the current standards do not permit the use of certain ingredients such as preservatives or a reconstituted dairy ingredient as a basic ingredient, because of the stayed provisions, FDA has not taken enforcement action against the use of these ingredients in yogurt, lowfat yogurt, or nonfat yogurt.

Id. (emphasis added). In context, the statement that "these provisions were never in effect" refers to the limitation on what kinds of milk-derived ingredients may be used, (i.e., the

provisions "that restricted the type of milk-derived ingredients . . . to those listed in these sections"), and not to the entire paragraph. Id.

This reading is further confirmed by the FDA's explanation for why it has not brought enforcement actions against yogurt companies that use certain ingredients such as reconstituted dairy ingredients; namely, because the effect of the stay is to permit other milk-derived ingredients to be added. Indeed, the FDA makes clear that those ingredients are not permitted as "basic ingredients" (i.e., "optional dairy ingredients" as defined in paragraph (c)).[4] Thus, it is the stay that allows these kinds of ingredients to be added.

Plaintiff also relies on two statements from a section of the 2009 Proposal entitled "Use of whey protein concentrate as a basic ingredient." See 74 Fed. Reg. 2443, at 2444, 2452. First, plaintiff argues that the statement "[National Yogurt Association] also mistakenly believes that the stayed provisions of [§ 131.200(d)] would have permitted [whey protein concentrate's] inclusion," means that MPC is prohibited as an optional ingredient. This too is taken out of context. Setting aside the issue of whether whey protein concentrate is the same as milk protein concentrate, this section makes clear that whey protein concentrate may not be included as a paragraph (c) "optional dairy ingredient." It says nothing about the use of whey protein concentrate as an "other optional ingredient" under paragraph (d).

[4] The parties agreed at oral argument that the term "basic ingredient" is synonymous with "optional dairy ingredients" defined in paragraph (c). The Court agrees based on a review of the history of the regulation governing the standard of identity for yogurt and the way in which that term has been used by the FDA. See, e.g., 42 Fed. Reg. 29919, at 29920 ("Additionally, all the proposed standards provide for the basic dairy ingredients cream, milk, partially skimmed milk or skim milk, with the further provision that other forms of milk-derived ingredients may be used to increase the nonfat solids content of these foods."); see also 74 Fed. Reg. 2443, at 2453 ("The list of basic milk ingredients in paragraph (c) . . ."); id. at 52 ("The current standards of identity for yogurt, lowfat yogurt, and nonfat yogurt do not allow the use of whey protein concentrate as a basic ingredient (§§ 131.20(c), 131.203(c), and 131.200(c))").

Second, at oral argument, plaintiff directed the Court to a statement in this section discussing the 1982 stay:

> FDA clarifies that the 1982 stayed provisions include paragraph (d)(1) of the current yogurt standard (§ 131.200), which limits the use of optional milk-derived ingredients to the ones specifically listed under that paragraph. The list of basic milk ingredients in paragraph (c) of the current yogurt standard was not among the provisions that were stayed and, therefore, the current standard makes no allowance for the use of whey protein concentrate as a basic ingredient in yogurt.

74 Fed. Reg. 2443, 2453 (emphasis added). Plaintiff contends the placement of the first comma in the first sentence makes clear that all of paragraph (d)(1) was stayed as a result of the 1982 stay.

The placement of the comma in this sentence is unfortunate in that it contributes to the ambiguity created by the language of the 1982 stay. However, this comma alone does not rebut the FDA's otherwise clear and unambiguous statement that MPC may be added to yogurt. Nor does it rebut the statement made just a few pages earlier explaining that the FDA has not taken enforcement action against manufacturers that use certain ingredients in yogurt that are not allowed as "optional dairy ingredients" (i.e., paragraph (c) ingredients) because the stay allows those ingredients to be added. 74 Fed. Reg. 2444.

That comma does not rebut those statements because those statements were directed at explaining the effect and scope of the 1982 stay. In contrast, the sentence plaintiff cites is taken from a section focusing on whether whey protein concentrate should be added to the list of permitted "optional dairy ingredients." Thus, the focus of the sentence is not on clarifying the effect of the 1982 stay generally, but rather on clarifying that the stay had no bearing on optional dairy ingredients listed in paragraph (c).

In short, the Court is persuaded by the considered judgments and statements by the FDA that are focused on the question at hand, not a one-off remark directed at a different issue.

F. Conclusion

The Court concludes that because of the stay imposed in 1982, MPC may be added as an "other optional ingredient" to yogurt. Therefore, Activia® is not misbranded and plaintiff's state law claims based on that argument must be dismissed.

III. Whether Activia® is Adulterated Because It Contains MPC

Plaintiff contends MPC is not safe because the FDA has never determined that it is generally recognized as safe ("GRAS"), nor has a manufacturer conducted an internal self-determination and submitted evidence to the FDA establishing that MPC is GRAS. And, because MPC is not GRAS and is an ingredient in Activia®, plaintiff contends the yogurt is adulterated.

Defendant contends that although the FDA maintains a list of ingredients that are GRAS, the list is not exhaustive. Further, because the standard of identity for yogurt requires that "[a]ll ingredients used [be] safe and suitable," 21 C.F.R. § 131.200(a), and the FDA has expressly stated that MPC may be used in yogurt, see FDA Q&A, it must be concluded that the FDA views MPC as "safe and suitable" for use in yogurt.[5]

The Court agrees with the reasoning of the court in Smith v. Cabot Creamery Co-op, that the FDA would not have made the clear and unambiguous statement that MPC may be used in yogurt "if that same permissible addition would render the yogurt illegally adulterated." 2013 WL 685714, at *7. Because plaintiff fails to allege any facts plausibly to support her contention

[5] Further to this point, in the 2009 Proposal, the FDA notes that manufacturers use a variety of safe and suitable milk-derived ingredients in yogurt, and that the FDA is not aware of any information that would suggest there would be an adverse effect on the safety of yogurt by adopting a new rule that expands the list of optional milk-derived ingredients. See also 74 Fed. Reg. 2443, 2450 ("FDA is not aware of any data or other information that would suggest that expanding the current list of optional milk-derived ingredients to permit the use of any safe and suitable milk-derived ingredient, under the conditions stated in the current standard to maintain the nutritional quality of yogurt, would have an adverse effect on the overall quality or safety of yogurt.").

that MPC is not safe and suitable, she fails to "nudge[] [her] claim across the line from conceivable to plausible." Bell Atl. Corp. v. Twombly, 550 U.S. at 570. Accordingly, this claim must be dismissed.

IV. Leave to Amend

In her opposition brief, plaintiff informally requests leave to amend the complaint pursuant to Rule 15(a)(2) in the event the Court dismisses any of her claims; however, plaintiff did not propose any amendment. Rule 15(a)(2) provides that a party may amend its complaint only with the opposing party's consent or leave of court. While leave to amend should be "freely give[n] . . . when justice so requires," Fed.R.Civ.P. 15(a) (2), "motions to amend should generally be denied in instances of futility, undue delay, bad faith or dilatory motive . . . or undue prejudice to the non-moving party." Burch v. Pioneer Credit Recovery, Inc., 551 F.3d 122, 126 (2d Cir. 2008) (citing Foman v. Davis, 371 U.S. 178, 182 (1962)).

Because plaintiff's informal request did not include any proposed amendments and the Court has already determined that the facts alleged are insufficient as a matter of law, she has not demonstrated that amendment would not be futile. Therefore, plaintiff's request for leave to amend the complaint is denied. See, e.g., Acito v. IMCERA Grp., Inc., 47 F.3d 47, 55 (2d Cir. 1995) (affirming denial of leave to amend when district court "examined plaintiff's supplementary allegations and determined the additional information did not cure the complaint"); see also In re Cybershop.com Sec. Litig., 189 F. Supp. 2d 214, 236 (D.N.J. 2002) (leave denied when plaintiff "failed to proffer any proposed, substantive amendment that would satisfy applicable pleading requirements; indeed, it d[id] not suggest any amendment at all.").

V. Defendant's Other Arguments

Because plaintiff's claims fail for the reasons stated above, the Court need not address defendant's other arguments regarding primary jurisdiction, preemption, and whether plaintiff has a private right of action to enforce the FDA's standard of identity for yogurt.

CONCLUSION

Defendants' motion to dismiss is GRANTED.

The Clerk is instructed to terminate the motion (Doc. # 11) and close this case.

Dated: May 9, 2013
White Plains, NY

SO ORDERED:

Vincent L. Briccetti
United States District Judge