

**IN THE UNITED STATES DISTRICT COURT  
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA**

<b>SOUTH MOUNTAIN CREAMERY, LLC,</b>	:	
<b>Plaintiff</b>	:	<b>No. 1:18-cv-00738</b>
<b>v.</b>	:	<b>(Judge Kane)</b>
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<b>U.S. FOOD AND DRUG ADMINISTRATION, <u>et al.</u>,</b>	:	
<b>Defendants</b>	:	

**MEMORANDUM**

Before the Court are: (1) Defendants the U.S. Food and Drug Administration (“FDA”) and Commissioner Scott Gottlieb, M.D. (“Commissioner Gottlieb”) (collectively referred to herein as the “Federal Defendants”)’ motion to dismiss Plaintiff South Mountain Creamery, LLC (“Plaintiff ”)’s complaint pursuant to Federal Rule of Civil Procedure 12(b)(1) for lack of subject-matter jurisdiction (Doc. No. 24); and (2) the Federal Defendants and Defendant Russell C. Redding (“Defendant Redding”)’s joint motion to stay discovery pending the Court’s ruling on the Federal Defendants’ motion to dismiss.<sup>1</sup> For the reasons provided herein, the Court will deny the Federal Defendants’ motion to dismiss for lack of subject-matter jurisdiction and deny Defendants’ joint motion to stay discovery as moot.

**I. BACKGROUND**

**A. Procedural Background**

Plaintiff initiated the above-captioned action by filing a complaint on April 5, 2018. (Doc. No. 1.) The two-count complaint asserts First Amendment claims of unconstitutional censorship (Count I) and unconstitutional compulsion of misleading and confusing speech

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<sup>1</sup> The Court refers to all defendants collectively as “Defendants” herein.

(Count II) relating to FDA regulations of the labeling of additive-free skim milk, which Plaintiff produces and seeks to sell in the Commonwealth of Pennsylvania. (Id. at 19-24.) Plaintiff seeks declaratory and injunctive relief “to protect the Creamery’s right to tell the truth and honestly label additive-free skim milk as ‘skim milk.’” (Id. ¶ 62.) On May 1, 2018, Defendant Redding filed an answer in response to Plaintiff’s complaint. (Doc. No. 15.) On July 11, 2018, the Federal Defendants filed the instant motion to dismiss for lack of subject-matter jurisdiction pursuant to Federal Rule of Procedure 12(b)(1). (Doc. No. 24.) On October 2, 2018, Defendants filed the instant motion to stay discovery. (Doc. No. 29.) Having been fully briefed (Doc. Nos. 25, 27, 28, 30, 32-34), both motions are ripe for disposition.

**B. Factual Background<sup>2</sup>**

**1. South Mountain Creamery**

The allegations in the complaint stem from Plaintiff’s purported apprehension to sell additive-free skim milk that does not comply with federal labeling requirements. (Doc. No. 1.) Plaintiff is a creamery located in Frederick County, Maryland and owned by Randy and Karen Sowers and their family members. (Id. ¶ 2.) Plaintiff produces and sells dairy products, including milk, yogurt, and cheese. (Id. ¶ 10.) Plaintiff purports to embrace a “responsible farming philosophy” and a “natural, additive-free approach.” Its preference is to sell its milk with no added ingredients, although it does not object to pasteurization. (Id. ¶ 14.) Plaintiff explains that during the skimming process, in which whole milk becomes skim milk, the cream—which contains fat-soluble vitamins, including vitamins A and D—is skimmed and removed from the milk. (Id. ¶¶ 47-49.) Thus, according to Plaintiff, additive-free skim milk

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<sup>2</sup> Unless otherwise noted, the following background information is derived from Plaintiff’s complaint. (Doc. No. 1.)

contains lower levels of Vitamins A and D than whole milk. (Id. ¶¶ 49, 50.) Plaintiff contends that even if the removed Vitamins A and D are added back to the skim milk, however, the vitamins will substantially dissipate because they are fat-soluble and the fat has been removed. (Id. ¶¶ 15-17.)

Plaintiff wishes to label its additive-free skim milk in an “honest, non[-]misleading” manner and not be constrained to labeling its product as “imitation.”<sup>3</sup> (Id. ¶¶ 18, 61-63.) Plaintiff contends that over a decade ago, owner Randy Sowers met with FDA officials, who told him that the FDA requires additive-skim milk to be labeled with the term “imitation.” (Id. ¶ 85.) Plaintiff alleges that after it decided to pursue the idea of selling its additive-free skim milk in Pennsylvania, it contacted Pennsylvania officials in November of 2017 to discuss whether it could sell its additive-free skim milk in Pennsylvania with the label “skim milk.” (Id. ¶¶ 23, 24.) Plaintiff contends that Pennsylvania officials stated that although the Commonwealth did not have any independent objections to labeling additive-free skim milk as “skim milk,” it was required to enforce federal statutes and regulations, which required additive-free skim milk to be labeled with “imitation” if sold across state lines. (Id. ¶¶ 25, 26.) Plaintiff avers that it received a letter from the Pennsylvania Governor’s Office of General Counsel stating that if the FDA did not have a problem with Plaintiff’s labeling, the Commonwealth would not object, either. (Id. ¶ 27.) Plaintiff contends that federal law and FDA regulations unambiguously prohibit additive-free skim milk from being labeled as “skim milk” without the label of “imitation.” (Id. ¶ 28.) Plaintiff further contends that pursuant to these statutes and regulations, additive-free skim milk is considered misbranded unless it is labeled as “imitation milk,” “imitation skim milk,” or

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<sup>3</sup> Plaintiff notes that it “would happily use any reasonable label that allows it to honestly and clearly describe its pure skim milk without being forced to mislead or confuse its customers.” (Id. ¶ 63.)

“imitation milk product.” (Id. ¶ 58.) Plaintiff alleges that its inability to sell its additive-skim milk with an “honest, non[-]misleading” label has caused it substantial financial harm. (Id. ¶ 111.)

The Federal Defendants represent in their motion to dismiss (Doc. No. 24), that Dr. Susan T. Mayne, director of the FDA’s Center for Food Safety and Applied Nutrition (“CFSAN”), sent Defendants a letter on July 10, 2018, after the above-captioned action was initiated, stating that CFSAN plans to take no action to require additive-free skim milk to be labeled as “imitation.” (Doc. No. 24-1 at 2.) Dr. Mayne’s letter also provides several labeling options for Plaintiff,<sup>4</sup> along with an offer to discuss other possible labeling options. (Id.) The letter also notes that the FDA has been unable to identify a single instance in which the FDA took any misbranding enforcement action related to additive-free skim milk. (Id. at 2-3.) In declarations to the Court dated August 22, 2018 and October 11, 2018, Dr. Mayne notes that she is unaware of any contact between Plaintiff and the FDA regarding labeling requirements for additive-free skim milk between 2002 and the initiation of the instant action. (Doc. Nos. 28-1 at 5, 31-1 at 3.) Dr. Mayne also asserts that had Plaintiff contacted the FDA before initiating the instant action, as suggested to Plaintiff by Pennsylvania officials, the FDA would have taken the same position articulated in the FDA’s July 10, 2018 letter. (Doc. Nos. 28-1 at 5, 31-1 at 3.) Dr. Mayne also asserts that CFSAN’s position was discussed and reviewed at length by top FDA officials, including “leadership in the Office of Compliance, the Office of Nutrition and Food Labeling, and the Office of Regulations and Policy,” and CFSAN does not plan to change that position. (Doc. No. 28-1 at 5-6.) The Federal Defendants further represent that Dwight-Jared Smith of the

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<sup>4</sup> These options include: “(a) ‘Non-fortified skim milk, 0% DV vitamins A&D’; (b) ‘Non-fortified non-fat milk, 0% DV vitamins A&D’; (c) ‘Skim milk, 0% DV vitamins A&D’; [and] (d) ‘Non-fat milk, 0% DV vitamins A&D.’” (Doc. No. 24-1 at 2.)

Pennsylvania Governor's Office of General Counsel sent a letter to Plaintiff's owners, dated July 13, 2018, that reaffirms the Commonwealth's position that any labeling deemed acceptable by the FDA will also be deemed acceptable by the Commonwealth. (Doc. Nos. 25 at 10; 25-1 at 2.)

## 2. Statutes and Regulations at Issue

Plaintiff identifies several statutes and regulations that allegedly require it to label its additive-free skim milk as "imitation." (Doc. No. 1 at 8-11.) 21 U.S.C. § 343 provides that a food shall be considered misbranded "[i]f it is offered for sale under the name of another food," "[i]f 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," or "[i]f it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations . . . 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." See 21 U.S.C. §§ 343(b), (c), (g). Receipt and delivery of misbranded food in interstate commerce are prohibited by 21 U.S.C. § 331 and are punishable by imprisonment of up to one year and a fine of up to \$1,000. See id. §§ 331(c), 333(a)(1).

Pursuant to 21 C.F.R. § 101.3(e), "a food shall be deemed to be misbranded 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." See id. § 101.3(e). 21 C.F.R. § 131.110 defines "milk"<sup>5</sup> and provides that vitamins may be added to milk optionally.

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<sup>5</sup> 21 C.F.R. § 131.110(a) states:

Milk is the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows. Milk that is in final package form for beverage use shall have been pasteurized or ultrapasteurized, and shall contain not less than 8 1/4 percent milk solids not fat and not less than 3 1/4 percent

See id. § 131.110(a), (b). 21 C.F.R. § 101.62(b) explains the criteria for the use of the term “skim” before “milk.” See id. § 101.62(b). This provision addresses a reduction in fat content but does not address a reduction in vitamins. See id. In order for a food to be labeled with a nutrient content claim and a standardized term, “[n]utrients [must] be added to the food to restore nutrient levels so that the product is not nutritionally inferior . . . to the standardized food.” See id. § 130.10(b). Nutritional inferiority includes “any reduction in the content of an essential nutrient that is present in a measurable amount.” See id. § 101.3(e)(4). Vitamins A and D are amongst the FDA’s list of essential nutrients. See id. § 101.9(c)(8)(iv). A food product is deemed an imitation “if it is a substitute for and resembles another food but is nutritionally inferior to that food.” See id. § 101.3(e)(1). “Milk product,” as defined by federal regulation, includes skim milk. See id. § 1240.3(j).

## II. LEGAL STANDARD

Pursuant to Federal Rule of Civil Procedure 12(b)(1), a court may dismiss a claim for lack of subject-matter jurisdiction. See Fed. R. Civ. P. 12(b)(1). The Court must first determine whether the moving party’s attack on the claim is facial or factual, “because that distinction determines how the pleading must be reviewed.” See Constitution Party v. Aichele, 757 F.3d 347, 357 (3d Cir. 2014) (citing In re Schering Plough Corp. Intron, 678 F.3d 235, 243 (3d Cir. 2012)). In reviewing a facial attack, a court must apply the same standard of review as it does in the context of a Rule 12(b)(6) motion, considering only the allegations of the complaint, the documents referenced in the complaint, and any exhibits attached to the complaint in the light

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milkfat. Milk may have been adjusted by separating part of the milkfat therefrom, or by adding thereto cream, concentrated milk, dry whole milk, skim milk, concentrated skim milk, or nonfat dry milk. Milk may be homogenized.

21 C.F.R. § 131.110(a).

most favorable to the plaintiff. See id. at 358. In reviewing a factual attack, on the other hand, the Court may weigh and consider evidence beyond the pleadings in its analysis. See id.

### III. DISCUSSION

#### A. Legal Standard for Justiciability of a Pre-enforcement Challenge

Article III of the Constitution limits the federal judiciary’s jurisdiction to actual “cases or controversies.” See U.S. Const. art. III, § 2. “The existence of a case and controversy is a prerequisite to all federal actions, including those for declaratory or injunctive relief.” Presbytery of the Orthodox Church v. Florio, 40 F.3d 1454, 1462 (3d Cir. 1994) (citing Cardinal Chem. Co. v. Morton Int’l, Inc., 508 U.S. 83 (1993); Skelly Oil Co. v. Phillips Petroleum Co., 339 U.S. 667, 671 (1950)). Courts enforce this requirement “‘through the several justiciability doctrines that cluster about Article III,’ including ‘standing, ripeness, mootness, the political-question doctrine, and the prohibition on advisory opinions.’” See Plains All Am. Pipeline L.P. v. Cook, 866 F.3d 534, 539 (3d Cir. 2017) (quoting Toll Bros., Inc. v. Twp. of Readington, 555 F.3d 131, 137 (3d Cir. 2009)).

The Third Circuit has noted that in the context of pre-enforcement challenges, the justiciability issue “can equally be described in terms of standing” as in terms of ripeness. See id. (citing MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118, 128 n.8 (2007); Free Speech Coal., Inc. v. Att’y Gen. of United States, 825 F.3d 149, 167 n.15 (3d Cir. 2016); Presbytery, 40 F.3d at 1462)); see also Susan B. Anthony List v. Driehaus, 573 U.S. 149, 157 n.5 (2014) (hereinafter SBA List) (citing DaimlerChrysler Corp. v. Cuno, 547 U.S. 332, 335 (2006); MedImmune, 549 U.S. at 128 n.8) (explaining that the Court chose to use the term “standing” in its opinion, but noting that “[t]he doctrines of standing and ripeness ‘originate’ from the same Article III limitation” and “the Article III standing and ripeness issues in this case ‘boil down to

the same question’’). The Third Circuit applies a three-step test, first articulated in Step-Saver Data Systems, Inc. v. Wyse Tech., 912 F.2d 643 (3d Cir. 1990), to assess justiciability in the context of declaratory judgment cases. See Plains, 866 F.3d at 539-40 (citing Khodara Envtl., Inc. v. Blakey, 376 F.3d 187, 196 (3d Cir. 2004); Step-Saver, 912 F.2d). Under the Step-Saver test, a court must consider “(1) the adversity of the parties’ interests, (2) the conclusiveness of the judgment, and (3) the utility of the judgment.” See id. at 540 (quoting Khodara, 376 F.3d at 196) (internal quotation marks omitted). The Third Circuit has noted that the Step-Saver test “is merely a different framework for conducting the same justiciability inquiry” as the ripeness test set forth in Abbott Laboratories v. Gardner, 387 U.S. 136 (1967) (hereinafter Abbott Labs), abrogated on other grounds by Califano v. Sanders, 430 U.S. 99 (1977),<sup>6</sup> and the standing test set forth in SBA List.<sup>7</sup> In a court’s application of the Step-Saver test, “Abbott Labs’s ‘hardship’ and ‘fitness’ factors still guide [the court’s] analysis, as does the standing test set forth in SBA List.”

## **B. Parties’ Arguments**

The Federal Defendants argue that they are not blocking or hindering Plaintiff’s preferred labeling method, and there is thus not a proper case or controversy under Article III. (Doc. No. 25 at 12.) They argue that (1) Plaintiff lacks Article III standing; and (2) Plaintiff’s claims are not ripe. (Id. at 12-24.) In response, Plaintiff argues that mootness, rather than standing or

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<sup>6</sup> In Abbott Labs, the Supreme Court held that in determining whether a case is ripe, a court must consider (1) “the fitness of the issues for judicial decision” and (2) “the hardship to the parties of withholding court consideration.” See 387 U.S. at 149.

<sup>7</sup> In SBA List, the Supreme Court held that to have standing, a plaintiff must show the following: “(1) an ‘injury in fact,’ (2) a sufficient ‘causal connection between the injury and the conduct complained of,’ and (3) a ‘likel[i]hood’ that the injury ‘will be redressed by a favorable decision.’” See 573 U.S. at 157-58 (quoting Lujan v. Defenders of Wildlife, 504 U.S. 555, 560 (1992)). The Supreme Court further held that in determining whether an injury-in-fact has been sufficiently alleged in a pre-enforcement context, a court must consider whether the plaintiff has alleged a credible threat of enforcement. See id. at 159-61.

ripeness, is the proper justiciability framework under which the Federal Defendants' motion to dismiss should be considered. (Doc. No. 27 at 18-19.) It contends that it has standing, its case is ripe, and its claims are not moot. (Id. at 19, 22.)

In regard to standing, the Federal Defendants argue that Plaintiff has failed to demonstrate an injury in fact because it has failed to allege a credible threat of prosecution. (Doc. No. 25 at 12-14.) They argue that the FDA's assurances to Defendant that it will not take any enforcement action against Plaintiff requiring its additive-free skim milk to be labeled as "imitation" due to its absence of added vitamins negates any claim by Plaintiff that it is at risk of enforcement action. (Id. at 14-15.) The Federal Defendants also argue that the absence of evidence that the FDA has ever taken enforcement action in a similar context further indicates the lack of a credible threat of enforcement. (Id. at 15-16.)

In regard to ripeness, the Federal Defendants argue that Plaintiff's claims are not ripe pursuant to the Step-Saver test. First, they argue that the interests of Plaintiff and the FDA are not adverse. (Id. at 19-20.) They contend that because the FDA has indicated that it has no intention of taking enforcement action against Plaintiff with respect to its preferred labeling, Plaintiff does not face a substantial threat of real harm, and the parties' interests are, therefore, not adverse. (Id.) Next, the Federal Defendants argue that the claims cannot be conclusively decided without further factual development. (Id. at 20-22.) Specifically, they argue that the Court would need to consider the specific labeling language in its analysis, and in the instant case, although the FDA has offered numerous labeling options to Plaintiff and offered to discuss other options with Plaintiff, Plaintiff has failed to engage with the FDA regarding the offered labeling options or other yet-to-be formulated options. (Id. at 21-22.) Finally, the Federal Defendants argue that no useful purpose would be served by the Court's issuance of a judgment

at this point due to the positions taken by the FDA and Pennsylvania. (Id. at 22- 24.) They claim that Plaintiff is not presently barred from taking the action that it has brought this case to be able to take, and thus would suffer no hardship if a Court did not address its claims. (Id. at 23-24.)

In response, Plaintiff argues that it has standing to bring its case and its case is ripe because it has suffered a “concrete, particularized, actual, and imminent” injury-in-fact, the injury is traceable to the challenged conduct, and a favorable decision would redress the injury. (Doc. No. 27 at 19.) It argues that it has alleged prior restraint of speech, contrary to the Federal Defendants’ characterization of its case as a pre-enforcement challenge. (Id. at 20.) It also argues that even if it had alleged a pre-enforcement challenge, pre-enforcement challenges are not devoid of standing or ripeness and a lack of enforcement history does not necessarily indicate a lack of standing or ripeness. (Id. at 20-22.)

Plaintiff argues that the proper framework for this Court’s justiciability analysis is one of mootness. (Id. at 18-19.) It contends that because the Federal Defendants are relying on a letter sent after the commencement of the instant action, the Federal Defendants’ challenge is one of mootness. (Id.) Plaintiff further argues that even if the Federal Defendants’ argument is viewed as a mootness challenge, its claims are not moot. (Id. at 22-26.) It contends that the FDA’s letter to Plaintiff indicating it does not intend to take enforcement action, in which it does not formally repudiate the challenged regulations, does not meet the heavy burden required for an instance of voluntary cessation to render Plaintiff’s claims moot. (Id. at 22-25.) Specifically, it argues that the FDA’s letter was not the result of substantial deliberation and it provides no binding assurance that the labeling requirements will not be enforced against Plaintiff in the future. (Id. at 25.)

In response, the Federal Defendants first assert that standing and ripeness challenges are proper in this case and reiterate their earlier arguments that Plaintiff's claims lack standing and are not ripe. (Doc. No. 28 at 6-18.) They also argue that even if the justiciability issue is approached through the framework of mootness, Plaintiff's claims are moot and non-justiciable. The Federal Defendants contend that the voluntary cessation doctrine does not apply in this case because the FDA did not cease enforcement of the challenged regulations because of the litigation of this case. (Id. at 18-19.) They further argue that even if the voluntary cessation doctrine does apply, Plaintiff's claims are still moot because the FDA's voluntary cessation was genuine, its timing was not suspicious because Plaintiff had not engaged with the FDA after it discussed the issue with Pennsylvania officials, and its letter was the result of substantial deliberation. (Id. at 19-20.)

### **C. Whether Plaintiffs' Claims Are Justiciable**

As an initial matter, the Court notes that although the Federal Defendants appear to attempt to assert a factual attack on Plaintiff's complaint, the Court is constrained to construe the Federal Defendants' motion as a facial attack on Plaintiff's complaint. For a 12(b)(1) motion to be construed as a factual attack, the defendant must first controvert the plaintiff's factual allegations by filing an answer or by otherwise disputing the plaintiff's factual allegations, such as attaching a signed declaration of competing facts to the motion. See Constitution Party, 757 F.3d at 358-59 (citing Mortensen v. First Fed. Sav. & Loan Ass'n, 549 F.3d 884, 892 n.17 (3d Cir. 1977)); see also Davis v. Wells Fargo, 824 F.3d 333, 346 (3d Cir. 2016) (citing Int'l Ass'n of Machinists & Aerospace Workers v. Nw. Airlines, Inc., 673 F.3d 700, 711 (3d Cir. 1982)) (construing the defendant's attack on subject-matter jurisdiction as a factual attack because the defendant submitted a signed declaration with its motion to dismiss). Here, the Federal

Defendants filed their motion before filing an answer or otherwise presenting a competing set of facts. Although the Federal Defendants eventually filed signed factual declarations from Dr. Susan T. Mayne (Doc. Nos. 28-1, 31-1), those declarations were filed after Plaintiff filed its brief in opposition to the motion to dismiss, providing Plaintiff no opportunity to respond to the competing facts presented in the declarations. Thus, the Federal Defendants' challenge is a facial challenge. See Constitution Party, 757 F.3d at 358 (citing Mortensen, 549 F.3d at 892 n.17) ("The [defendant] filed the attack before it filed any answer to the [c]omplaint or otherwise presented competing facts. Its motion was therefore, by definition, a facial attack."); Long v. SEPTA, 903 F.3d 312, 320 (3d Cir. 2018) (concluding that a motion to dismiss asserted pursuant to Rule 12(b)(1) was a facial attack on subject-matter jurisdiction because it was asserted before the moving party filed an answer or otherwise presented competing facts). Accordingly, the Court is barred from considering anything, including the July 10, 2018 letter attached as an exhibit to the Federal Defendants' motion to dismiss (Doc. No. 24-1), and Dr. Mayne's declarations (Doc. Nos. 28-1, 31-1), aside from the allegations of Plaintiff's complaint, any exhibits attached to the complaint, and any documents referenced within the complaint. See Constitution Party, 757 F.3d at 358 (citing In re Schering Plough, 678 F.3d at 243).

The Court applies the Step-Saver test to determine whether Plaintiff's pre-enforcement challenges are justiciable.<sup>8</sup> See Plains, 866 F.3d at 539-40. Applying the first prong of the Step-

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<sup>8</sup> While the Step-Saver test is a ripeness test, the Court's analysis is also guided by the SBA List test, which is a standing analysis. See Plains (noting that the court's Step-Saver analysis for ripeness is guided by the SBA List standing test).

Although Plaintiff argues that its action is not a pre-enforcement challenge and mootness is the proper justiciability framework for its claims, the Court concludes that Plaintiff's claims are pre-enforcement challenges and a standing- and ripeness-based analysis pursuant to Step-Saver is proper. Here, Plaintiff is challenging the constitutionality of a policy that it claims is chilling its protected speech, and the government has not taken any enforcement action against Plaintiff. These circumstances mirror those of other cases in which courts, including the

Saver test—the consideration of the adversity of the parties’ interests—the Court finds that the parties’ interests are adverse. “Parties’ interests are adverse where harm will result if the declaratory judgment is not entered.” Id., 866 F.3d 534 at 541 (quoting Travelers Ins. Co. v. Obusek, 72 F.3d 1148, 1154 (3d Cir. 1995)) (internal quotation marks omitted). In the context of a pre-enforcement challenge, for parties’ interests to be adverse, there must be “a ‘substantial threat of real harm’” and the threat must “remain real and immediate throughout the course of the litigation.” See id., 866 F.3d 534, 541 (3d Cir. 2017) (quoting Presbytery, 40 F.3d at 1463) (internal quotation marks omitted). Here, Plaintiff wishes to label its additive-free skim milk in an “honest, non[-]misleading” manner and not be required to label its product as “imitation.” (Doc. No. 1 ¶¶ 18, 61-63.) Plaintiff purports that FDA regulations and federal law require it to label its additive-free skim milk as “imitation” and that FDA officials provided confirmation to Plaintiff that its interpretation was correct. (Id. ¶¶ 61, 85.) Thus, Plaintiff faces a real threat of enforcement action if it chooses to sell its additive-free skim milk in the manner that it prefers, without the “imitation” label. See Peachlum v. City of York, 333 F.3d 429, 435 (3d Cir. 2003) (citing Presbytery, 40 F.3d at 1464) (“[I]n cases involving fundamental rights, even the remotest threat of prosecution, such as the absence of a promise not to prosecute, has supported a holding of ripeness.”). Accordingly, the Court concludes that in the context of the first prong of the Step-Saver test, the parties’ interests are adverse.

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Supreme Court and the Third Circuit, have characterized actions as pre-enforcement challenges and deemed standing- or ripeness-based analyses proper. See, e.g., SBA List, 573 U.S. at (identifying the plaintiff’s action as a pre-enforcement challenge and applying standing analysis to a First Amendment challenge of an Ohio statute where no enforcement action was pending, but the plaintiff alleged that its speech was nonetheless chilled); Presbytery, 40 F.3d at 1463 (identifying the plaintiffs’ action as pre-enforcement challenge and applying ripeness analysis to a First Amendment challenge of a New Jersey anti-discrimination statute where no enforcement action was pending, but the plaintiffs alleged that their speech was nonetheless chilled).

In reviewing the second prong of the Step-Saver test—the conclusiveness of the judgment—the Court finds that the claims facilitate a conclusive judgment. In evaluating the conclusiveness of the judgment, a court must “determine whether judicial action at the present time would amount to more than an advisory opinion based upon a hypothetical set of facts.” See Presbytery, 40 F.3d at 1468 (citing Step-Saver, 912 F.2d at 649). “[P]redominantly legal questions are generally amenable to a conclusive determination in a pre[-]enforcement context.” Id. In the instant case, Plaintiff is challenging the constitutionality of the requirement that its additive-free skim milk be labeled as “imitation.” Because this is a predominately legal question, the Court finds that adjudication of the case would not require significant factual development, and Plaintiff’s claims are, therefore, conducive to a conclusive judgment.

Finally, as to the third Step-Saver prong—the utility of the judgment—the Court concludes that a judgement in the instant action would create substantial utility for Plaintiff. In a court’s utility evaluation, it must “consider ‘whether the parties’ plans of actions are likely to be affected by a declaratory judgment.’” Id. at 1469 (citing Step-Saver, 912 F.2d at 649 n.9). In the instant case, Plaintiff seeks to proceed with the interstate sale of its additive-free skim milk without an “imitation” label, but it has refrained from doing so, to its financial detriment, out of compliance with the challenged laws and regulations. (Doc. No. 1 ¶¶ 109-12.) A ruling in Plaintiff’s favor would permit Plaintiff to proceed with its plan to sell additive-free skim milk in the Commonwealth of Pennsylvania without having to use the “imitation” label to which it objects. Thus, the Court finds that the utility of a judgment on Plaintiff’s claims would be substantial. Accordingly, because all three prongs of the Step-Saver test weigh in favor of justiciability, the Court concludes that Plaintiffs’ claims against the Federal Defendants are justiciable.

#### **IV. CONCLUSION**

Based upon the foregoing, the Court will deny the Federal Defendants' motion to dismiss for lack of jurisdiction without prejudice to the filing of a subsequent motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(1) for lack of subject-matter jurisdiction.<sup>9</sup> The Court will also deny Defendants' motion to stay discovery as moot. An Order consistent with this Memorandum follows.

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<sup>9</sup> The Court notes that in order for the Court to construe any subsequently-filed motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(1) for lack of subject-matter jurisdiction as a factual attack on Plaintiff's complaint, the moving defendant must first controvert the factual allegations of the complaint through an answer to the complaint or by otherwise contesting the factual allegations of the complaint, such as attaching a signed declaration of facts to its motion.