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

# **Harrisburg Division**

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	Civil Action No.

U.S. FOOD AND DRUG ADMINISTRATION; SCOTT GOTTLIEB, in his official capacity as Commissioner of the U.S. Food and Drug Administration; and RUSSELL C. REDDING, in his official capacity as Pennsylvania Secretary of Agriculture,

Defendants.

Plaintiff,

VS.

#### COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiff South Mountain Creamery, LLC (the "Creamery"), by and through its undersigned counsel, hereby files this Complaint for Declaratory and Injunctive Relief and sues the U.S. Food and Drug Administration (the "FDA"); its commissioner Scott Gottlieb (the "Commissioner"), in his official capacity; and Pennsylvania Secretary of Agriculture Russell C. Redding (the "Pennsylvania Secretary"), in his official capacity, as follows:

## **INTRODUCTION**

1. This is a First Amendment challenge on behalf of South Mountain Creamery, LLC—a family-owned creamery in northern Maryland that responsibly produces and home-delivers milk and other dairy items to over 10,000 customers across state lines. The challenge aims to vindicate the right of the Creamery to use an honest, clear label on its all-natural, additive-free, pasteurized skim milk. The Creamery cannot do so in Pennsylvania because of FDA regulations mandating that skim milk sold across state lines may only be called "skim milk" if other ingredients are added to it. Pure skim milk without additives is banned by the FDA regulations from being described as skim milk and must instead be labeled as "imitation." These requirements serve only to mislead and confuse customers, which the Creamery refuses to do.

#### **PARTIES**

2. Plaintiff Creamery is a Maryland limited liability company founded by Randy Sowers and his wife Karen Sowers and owned by the Sowers and their family members. The Creamery is located on the Sowers family's farm in Frederick County, Maryland. Randy's and Karen's son-in-law Tony Brusco is the Creamery's Chief Operating Officer and is an owner.

- 3. Defendant U.S. Food and Drug Administration is a federal agency charged with regulating food labeling. It is part of the United States Department of Health and Human Services.
- 4. Defendant Scott Gottlieb is Commissioner of the FDA. Commissioner Gottlieb has direct authority over the FDA's personnel and is charged with the responsibility of enforcing the related laws, regulations, and policies of the United States. He is being sued only in his official capacity.
- 5. Defendant Russell C. Redding is the Pennsylvania Secretary of Agriculture. Secretary Redding has direct authority over the Pennsylvania Department of Agriculture's personnel and is charged with the responsibility of enforcing the related laws, regulations, and policies. Although the Pennsylvania Department of Agriculture has no independent objection to the Creamery selling pure skim milk in Pennsylvania with the honest, nonmisleading labels proposed by the Creamery, Secretary Redding must be included as a Defendant because the relevant FDA regulations forced the Pennsylvania Department of Agriculture to reject the Creamery's request to do so. He is being sued only in his official capacity.

#### **JURISDICTION AND VENUE**

6. Plaintiff Creamery brings this civil rights lawsuit pursuant to the First Amendment to the United States Constitution, the Fourteenth Amendment to the

United States Constitution, the Civil Rights Act of 1871, 42 U.S.C. § 1983, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02, for violations of the First and Fourteenth Amendments to the United States Constitution.

- 7. Plaintiff Creamery seeks declaratory and injunctive relief against the FDA's restrictions on, and compelled speech requirements related to, the labeling of skim milk. These regulations and related laws are listed below at ¶¶ 33-58.
- 8. This Court has subject-matter jurisdiction under 28 U.S.C. § 1331, as Plaintiff's claim arises under federal law.
- 9. Venue lies in this Court pursuant to 28 U.S.C. § 1391(b)(2) and 28 U.S.C. § 1391(e)(1), as a substantial part of the events giving rise to Plaintiff's claims against the United States agency, its officer, and the Pennsylvania Department of Agriculture occurred in this Court's District.

## STATEMENT OF ALLEGED FACTS

10. Plaintiff is a family-owned creamery located in Frederick County, Maryland. It was founded in 1981 by Randy and Karen Sowers after they rented 152 acres of land and obtained a loan to buy 100 cows. Today, the Creamery covers over 2,000 acres, employs over 75 people, and delivers dairy items like milk, yogurt, and cheese to over 10,000 families across state lines.

- 11. The Creamery sells to customers in Washington, D.C., Maryland, and Virginia. It is currently in the process of expanding its delivery operations into Pennsylvania.
- 12. The founders and owners of the Creamery believe in responsible farming. Their cows are pasture-raised; their chickens are cage-free; and their dairy is as pure and additive-free as the law allows.
- 13. This responsible farming philosophy is shared by the Creamery's customers, many of whom purchase the Creamery's goods because of its commitment to its natural, additive-free approach.
- 14. Ideally, the Creamery would like all of its milk, including skim milk, to have no ingredients other than pure milk. The Creamery does not object to pasteurization, since the pasteurization process simply heats up the milk. But the Creamery objects to being forced to add any additional ingredients to its milk.
- 15. According to the FDA's regulations, however, to sell skim milk as "skim milk," the fat-soluble vitamins A and D that are removed when the cream is skimmed off must be added back into the skim milk.
- 16. This is so even though a substantial portion of the injected vitamins dissipate by the time the skim milk is consumed by the customer, since the injected vitamins are fat-soluble and have a tendency to dissipate without fat present.

- 17. The FDA's own official materials discuss this issue of fat-soluble vitamins dissipating after being added to skim milk, but the FDA requires the addition anyway in order for skim milk to be labeled as "skim milk."
- 18. Despite these obstacles created by the FDA, the Creamery continues to be committed to one day being allowed to sell additive-free skim milk with a truthful and nonmisleading label.
- 19. The Creamery believed that Pennsylvania provided an opportunity to do so.
- 20. Pennsylvania's statutes and state regulations contain Pennsylvania's own definition for skim milk, which is met by pure skim milk without additives.
- 21. Pennsylvania has adopted, at least in part, the *Grade "A" Pasteurized Milk Ordinance* (the "PMO"), a voluntary model state regulation created by the United States Department of Health and Human Services.
- 22. Pennsylvania's general adoption of the PMO is superseded by specific carve-outs, like Pennsylvania's definition of skim milk.
- 23. When the Creamery began undertaking actions to expand its sales into Pennsylvania, the Creamery learned of Pennsylvania's laws regarding pure skim milk.
- 24. Consequently, this past November, the Creamery contacted the Commonwealth of Pennsylvania to find out whether it would be allowed to

truthfully label its pure skim milk as "skim milk" if it did not add back the fatsoluble vitamins lost during the skimming process.

- 25. During the resulting conversations with Pennsylvania's officials, the Creamery learned that the Commonwealth of Pennsylvania had no independent objection to the Creamery selling pure skim milk in Pennsylvania as "skim milk."
- 26. During those same conversations, the Creamery also learned that Pennsylvania was nonetheless required to enforce the federal regulations and laws mandating that pure skim milk sold across state lines cannot be called "skim milk" and must instead be called "imitation."
- 27. The Pennsylvania Governor's Office of General Counsel sent official correspondence to the Creamery also explaining that if the FDA had no problem with such a label, then the Commonwealth of Pennsylvania would not either. *See* Letter from Governor's Office of General Counsel, Commonwealth of Pennsylvania (Dec. 20, 2017), a true and correct copy of which is attached hereto as Exhibit "A."
- 28. But the FDA does object. The FDA's rules unambiguously prohibit the Creamery from labeling its skim milk as "skim milk" unless it agrees to inject it with the fat-soluble vitamins A and D that are lost when the cream is skimmed from the milk.

- 29. As discussed below, FDA officials have also confirmed this in the past to Randy Sowers.
- 30. Pennsylvania was correct that federal regulations and laws barred it from allowing the Creamery to label pure skim milk without additives as "skim milk," regardless of the additional information the Creamery offered to provide.
- 31. The federal regulations and laws are unambiguous in all ways material to the lawsuit.
- 32. Although unambiguous, the federal regulations and laws can be complicated, so the most relevant ones are listed here.

## MATERIAL FDA REGULATIONS AND RELATED LAWS

- 33. 21 U.S.C. § 343(b) states that a food shall be deemed to be misbranded if "it is offered for sale under the name of another food."
- 34. 21 U.S.C. § 343(c) states that 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."
- 35. 21 U.S.C. § 343(g) states that a food shall be deemed to be misbranded if "it purports to be or is represented as a food for which the definition and standard of identity has been prescribed" unless it "conforms to such definition

and standard" and "bears the name of the food specified in the definition and standard."

- 36. 21 C.F.R. § 101.3(e) states that, under the Federal Food, Drug, and Cosmetic Act, "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."
- 37. 21 U.S.C. § 331 prohibits the introduction of misbranded food into interstate commerce.
- 38. Pursuant to 21 U.S.C. § 333, each violation of 21 U.S.C. § 331 can result in imprisonment of up to one year, a fine of up to \$1,000, or both.
  - 39. The standard of identity for "milk" is located at 21 C.F.R. § 131.110.
- 40. The standard of identity for "milk" allows for additional vitamins to be added, but does not allow for reduced vitamin levels.
- 41. The FDA's criteria for when the nutrient-content claim "skim" can be used to precede the term "milk" are found in 21 C.F.R. § 101.62(b).
- 42. The FDA's criteria for the nutrient-content claim "skim" provides for a reduction in fat content but not for a reduction in vitamins.
- 43. 21 C.F.R. § 130.10(b) states that a nutrient-content claim can only be used if the product is not "nutritionally inferior" to the standard of identity.

- 44. 21 C.F.R. § 101.3(e)(4) states that nutritional inferiority includes any "reduction in the content of an essential nutrient that is present in a measurable amount, but does not include a reduction in the caloric or fat content…"
- 45. The FDA's list of essential nutrients is found at 21 C.F.R. § 101.9(c)(8)(iv).
- 46. Vitamins A and D are essential nutrients according to 21 C.F.R. § 101.9(c)(8)(iv).
  - 47. Vitamins A and D are found in whole milk.
- 48. Vitamins A and D are fat-soluble and are therefore located in the cream.
- 49. When cream is skimmed from milk, the fat-soluble vitamins located in the cream are removed with the cream.
- 50. Pursuant to the FDA's regulations, pure skim milk without vitamin A and D additives is therefore nutritionally inferior to the standard of identity for "milk."
- 51. As pure skim milk without vitamin additives is considered by the FDA to be nutritionally inferior to the standard of identity for "milk," pure skim milk without vitamin additives cannot be labeled as "milk" or "skim milk."
- 52. As pure skim milk without vitamin additives is considered by the FDA to be nutritionally inferior to the standard of identity for "milk," pure skim

milk without additives is banned from describing itself in any way that includes the word "milk," other than as part of the mandatory "imitation" disclaimer described below.

- 53. 21 C.F.R. § 101.3(e)(1) states that a food is an imitation if it "is a substitute for and resembles another food but is nutritionally inferior to that food."
- 54. Pure skim milk without additives is a substitute for and resembles products that meet the FDA's definition of "skim milk."
- 55. Pure skim milk without additives is a substitute for and resembles products that meet the FDA's definition of "milk."
- 56. In 21 C.F.R. § 1240.3(j), the FDA defines the term "milk product" to include, among other things, skim milk.
- 57. Pure skim milk without additives is a substitute for and resembles products that meet the FDA's definition of "milk product."
- 58. Consequently, pure skim milk without additives is deemed misbranded unless it is labeled as either "imitation milk," "imitation skim milk," or "imitation milk product."

# ADDITIONAL FACTUAL ALLEGATIONS

59. The effect of the relevant regulations and laws is that any product labeled as "skim milk" must have three ingredients: (i) skim milk; (ii) vitamin A additives; and (iii) vitamin D additives.

- 60. The effect of the relevant regulations and laws is that any product consisting entirely of skim milk can never be labeled as "skim milk."
- 61. The effect of the relevant regulations and laws is that any product consisting entirely of skim milk must be labeled as "imitation."
- 62. The Creamery brings this lawsuit for declaratory and injunctive relief to protect the Creamery's right to tell the truth and honestly label additive-free skim milk as "skim milk."
- 63. The Creamery 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.
  - 64. For example, one label suggested by the Creamery is as follows:

PURE PASTEURIZED SKIM MILK NO VITAMINS ADDED OR REPLACED THE ONLY INGREDIENT IS SKIM MILK

65. The Creamery would also happily agree to use the following label, which was agreed upon by the Florida Department of Agriculture after it lost a similar challenge at the United States Court of Appeals for the Eleventh Circuit brought by a Florida creamery. *See Ocheesee Creamery LLC v. Putnam*, 851 F.3d 1228 (11th Cir. 2017):

PASTEURIZED SKIM MILK VITAMINS A & D REMOVED WITH CREAM

- 66. These are merely two of the numerous labels that the Creamery would accept, all of which are less burdensome and more effective than the mandated label.
- 67. These labels are in addition to the information about the Creamery provided by the Creamery on its bottles.
  - 68. Pure skim milk without additives is legal to sell across state lines.
  - 69. Pure skim milk without additives is legal to sell in Pennsylvania.
- 70. The pure, pasteurized skim milk that the Creamery wants to sell in Pennsylvania contains a single ingredient: skim milk.
- 71. The government recognizes that skim milk is one of the ingredients in the product defined by the FDA as "skim milk."
- 72. Pure, additive-free skim milk is considered by the Creamery's owners and customers to be skim milk.
- 73. Pure, additive-free skim milk is considered by the general public to be skim milk.
- 74. The FDA's definition for the product "skim milk" conflicts with the definition of "skim milk" understood by the Creamery's owners and customers.
- 75. Pure, additive-free skim milk meets the publicly-understood definition for "skim milk."

- 76. The FDA's definition for the product "skim milk" conflicts with the publicly-understood definition for "skim milk."
- 77. Pure, additive-free skim milk meets the definition of "skim milk" found in Webster's Dictionary and other common dictionaries. *See* SKIM MILK, Merriam-Webster's Collegiate Dictionary (11th ed. 2003) (defining "skim milk" as "milk from which the cream has been taken—called also *skimmed milk*") (emphasis in original).
- 78. The FDA's definition for the product "skim milk" conflicts with the definition of "skim milk" found in Webster's Dictionary and other common dictionaries.
- 79. Labeling pure, additive-free skim milk as "imitation skim milk" is misleading and confusing to customers.
- 80. Labeling pure, additive-free skim milk as "imitation milk product" is misleading and confusing to customers.
- 81. Labeling pure, additive-free skim milk as "imitation milk" is misleading and confusing to customers.
- 82. Labeling pure, additive-free skim milk as "imitation" is misleading and confusing to customers.
- 83. The FDA's labeling requirements directly result in customers becoming unnecessarily confused.

- 84. Over the years, the Creamery's owners have discussed this problem with numerous state and federal officials.
- 85. For example, over a decade ago, Creamery founder Randy Sowers personally met with officials from the FDA and the State of Maryland, but the result of these meetings was always the same—the FDA does not allow pure skim milk to be called skim milk and requires that it be labeled instead as "imitation."
- 86. Even though the Creamery is committed to responsible farming, it has been forced to inject the additives into the skim milk in order to label it "skim milk," as following the labeling requirements for pure skim milk would cause disastrous levels of confusion to the Creamery's customers. According to Randy Sowers, the founder of the Creamery, injecting pure skim milk with additives "eats him up inside every time."
- 87. Selling pasteurized skim milk without complying with the challenged regulations and laws could result in substantial fines for the Creamery and numerous other problems, including the possible forced closure of the entire Creamery.
- 88. Selling pasteurized skim milk without complying with the challenged regulations and laws could result in incarceration of up to one year per offense for the Creamery's owners.

- 89. Selling pasteurized skim milk without complying with the challenged regulations and laws could result in seizure and condemnation of skim milk being shipped across state lines.
- 90. The challenged regulations and laws are unreasonable, unnecessary, do not advance any legitimate government interest, and are not tailored to any legitimate government interest.
- 91. The challenged regulations and laws are more burdensome than numerous other alternatives, including but not limited to the alternative label agreed to by the Florida Department of Agriculture after losing the *Ocheesee Creamery* case involving similar claims.
- 92. The challenged regulations and laws are content-based regulations of speech.
- 93. The challenged regulations and laws do not address any real problem in a meaningful way, but instead create an artificial one.
  - 94. The challenged regulations and laws are not in the public interest.
- 95. The challenged regulations and laws create confusion and misleading speech where none previously existed.
- 96. The challenged regulations and laws have no positive impact on society.

- 97. The challenged regulations and laws would fail any level of First Amendment scrutiny.
- 98. The challenged regulations and laws are currently causing irreparable harm.
- 99. The irreparable harm increases every day the challenged regulations and law remain in effect.
  - 100. FDA procedures are inadequate to prevent this irreparable injury.
- 101. Any additional efforts to contact the FDA to attempt to resolve these issues would be futile.
- 102. Pure pasteurized skim milk without additives still meets the FDA's requirements for being Grade "A."
- 103. Pure pasteurized skim milk without additives still meets Pennsylvania's requirements for being Grade "A."
- 104. Pure pasteurized skim milk without additives meets the definition for "Grade 'A' Milk and Milk Products" in § 1(GG)(6) of the PMO.
- 105. Pure pasteurized skim milk without additives is legal to sell in Pennsylvania, provided that the labeling requirements are met.
- 106. Pure pasteurized skim milk without additives is legal to sell across state lines, provided that the labeling requirements are met.

- 107. Other than the labelling requirements challenged here, the Creamery has met all FDA requirements for the sale across state lines of pure pasteurized skim milk without additives.
- 108. The challenged regulations and laws unambiguously violate the Creamery's constitutional rights.

#### **INJURY TO PLAINTIFF**

- 109. But for the challenged regulations and laws, the Creamery would currently be selling its all-natural, additive-free, pasteurized skim milk with an honest, accurate, non-misleading label. Instead, it is forced to inject its pure skim milk with vitamin A and vitamin D additives, in order not to be forced to mislabel skim milk as "imitation."
- 110. If the Creamery were allowed to use an honest, nonmisleading label for its all-natural, additive-free, pasteurized skim milk, then it would do so.
- 111. The inability to sell additive-free, all-natural skim milk with an honest, nonmisleading label has caused the Creamery to suffer substantial financial harm.
- 112. Because its customers prefer foods without additives, Plaintiff
  Creamery is suffering ongoing and irreparable harm each day it is not allowed to
  sell its pasteurized skim milk without vitamin A and D additives with an honest,
  nonmisleading label describing skim milk as skim milk.

- 113. The Creamery's customers and the general public have been harmed by the Creamery's inability to lawfully offer all-natural, additive-free, pasteurized skim milk with an honest, nonmisleading label due to the challenged regulations and laws.
- 114. The term "imitation" is a controversial and unduly harmful way to describe pure, additive-free skim milk.
- 115. The Creamery challenges these regulations and laws both facially and as applied to the Creamery.

## **CAUSES OF ACTION**

# Claim I: Unconstitutional Censorship of the Words "Skim Milk"

- 116. Plaintiff Creamery reasserts and realleges paragraphs 1 through 115 as if fully set forth therein.
- 117. According to the First Amendment to the United States Constitution, "Congress shall make no law . . . abridging the freedom of speech."
- 118. The First Amendment has been incorporated to apply to the states through the Fourteenth Amendment.
- 119. Labeling pasteurized skim milk as "pasteurized skim milk" is non-misleading speech about a lawful activity.
- 120. By banning an honest, accurate, and non-misleading description of skim milk as "skim milk," the challenged regulations and laws have abridged the

freedom of speech of the Creamery and of anyone else who would otherwise sell perfectly safe, pasteurized skim milk without additives and with an honest, accurate, non-misleading label.

- 121. The challenged restrictions on skim milk labeling irreparably harm the Creamery by preventing it from engaging in truthful speech about lawful goods that it wants to sell.
- 122. The challenged restrictions on skim milk labeling also irreparably harm consumers by denying them access to truthful information about lawful goods in the marketplace.
- 123. The additive-free skim milk that the Creamery wants to sell under the label "skim milk" contains no ingredients other than skim milk.
- 124. The FDA's ban on calling skim milk "skim milk" keeps consumers under-informed and confused about what is actually being offered by the seller.
- 125. The challenged restrictions on skim milk labeling are content-based regulations of speech; the restrictions only prohibit speech about skim milk without additives, and only by sellers of skim milk without additives.
- 126. Compelling the use of certain terms like "imitation" is inherently content-based.
- 127. The challenged restrictions on skim milk labeling result in a suppression of truthful speech about the sale of a lawful item.

- 128. The challenged restrictions on skim milk labeling are not reasonably related to preventing or correcting any misleading or deceptive speech.
- 129. The FDA's interest in preventing skim milk from being labeled as "skim milk" is not legitimate, substantial, or compelling.
- 130. The challenged restrictions on skim milk labeling are not appropriately tailored to any government interest.
- 131. The challenged restrictions on skim milk labeling do not directly or materially advance any legitimate government interest.
- 132. The challenged restrictions on skim milk labeling are overly extensive and unduly burdensome.
- 133. On their face and as applied, the challenged label requirements violate the Creamery's right to free speech guaranteed by the First Amendment to the United States Constitution.
- 134. Unless the Defendants are enjoined from enforcing the challenged labeling requirements, the Creamery will continue to suffer irreparable harm.

# Claim II: Unconstitutionally Compelling Misleading and Confusing Speech

- 135. Plaintiff Creamery reasserts and realleges 1 through 115 as if fully set forth therein.
- 136. According to the First Amendment to the United States Constitution, "Congress shall make no law . . . abridging the freedom of speech."

- 137. The First Amendment has been incorporated to apply to the states through the Fourteenth Amendment.
  - 138. Freedom of speech includes freedom from coerced speech.
- 139. By requiring the Creamery to label all-natural, additive-free, pasteurized skim milk as "imitation," the Defendants have abridged the freedom of speech of the Creamery and of anyone else who would otherwise sell perfectly safe, pasteurized skim milk without additives and would prefer not to confuse or mislead their own customers.
- 140. The challenged compelled label requirements harm the Creamery by requiring it to confuse and mislead its own customers in order to sell an otherwise lawful item.
- 141. The challenged compelled label requirements also harm consumers by preventing them from having an option of purchasing a legal item with an honest, accurate, and non-misleading label. Neither the Creamery's customers nor society in general would understand the terms "imitation skim milk," "imitation milk product," or "imitation milk" to mean pure skim milk without additives.
- 142. If the Creamery were to follow the challenged regulations and laws with regard to labeling additive-free skim milk, the result would be to create confusion and misunderstanding.

- 143. There is no reason to believe that the Creamery's customers would be confused, deceived, or misled if the Creamery were to label its additive-free skim milk "skim milk."
- 144. The label required by the FDA is not limited to purely factual and uncontroversial information.
- 145. The challenged compelled label requirements are content-based regulations of speech; they force sellers of skim milk to engage in confusing and misleading speech about their skim milk.
- 146. The challenged compelled label requirements coerce misleading speech about the sale of a lawful item.
- 147. The challenged compelled label requirements are not reasonably related to preventing or correcting any misleading or deceptive speech.
- 148. The government's interest in forcing pure, safe, lawful skim milk to be labeled as an "imitation" is not legitimate, substantial, or compelling.
- 149. The challenged compelled label requirements are not appropriately tailored to any government interest.
- 150. The challenged compelled label requirements do not directly or materially advance any legitimate government interest.
- 151. The challenged compelled label requirements are overly extensive and unduly burdensome.

- 152. On their face and as-applied, the challenged compelled label requirements violate the Creamery's right to free speech guaranteed by the First Amendment to the United States Constitution.
- 153. Unless the Defendants are enjoined from compelling the labeling of additive-free skim milk as an "imitation," the Creamery will continue to suffer irreparable harm.

## REQUEST FOR RELIEF

Therefore, Plaintiff respectfully requests the following relief:

- A. A declaratory judgment by the Court that, facially and as applied to Plaintiff, the challenged restrictions preventing Plaintiff from labeling pure, pasteurized, additive-free skim milk as "skim milk" violate the First and Fourteenth Amendments to the United States Constitution;
- B. A permanent injunction prohibiting the Defendants or their agents from preventing Plaintiff from labeling its pure, pasteurized, additive-free skim milk as "skim milk;"
- C. A declaratory judgment by the Court that, facially and as applied to Plaintiff, the challenged requirements that Plaintiff label its pure, pasteurized, additive-free, skim milk as "imitation" violate the First and Fourteenth Amendments to the United States Constitution;

D. A permanent injunction prohibiting the Defendants or their agents from requiring Plaintiff to label its pure, pasteurized, additive-free, skim milk as "imitation," "imitation skim milk," "imitation milk product," "imitation milk," or any similar compelled label giving the impression that pure, pasteurized, additive-free skim milk is not skim milk;

- E. An award of attorney's fees, costs, and expenses in this action; and
- F. Any other legal or equitable relief to which Plaintiff may show itself to be justly entitled.

DATED: April 5, 2018.

Respectfully submitted,

# \_s/Bradley C. Baird\_

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Counsel for Plaintiff South Mountain Creamery, LLC

# EXHIBIT A

Complaint for Declaratory and Injunctive Relief



#### COMMONWEALTH OF PENNSYLVANIA GOVERNOR'S OFFICE OF GENERAL COUNSEL

December 20, 2017

Randy and Karen Sowers South Mountain Creamery 8405 Bolivar Road Middletown, MD 21769

Re: Skim Milk Label Requirements

Dear Mr. and Ms. Sowers:

You recently contacted the Pennsylvania Department of Agriculture to: (1) advise of your plan to sell skim milk produced from your Maryland dairy operation in Pennsylvania; and (2) ask whether there is any specific language Pennsylvania would require you add to container labels for this product if Vitamin A removed in the production process has not been added back into the product.

Pennsylvania has adopted the current Grade "A" Pasteurized Milk Ordinance, published by the Food and Drug Administration of the United States Department of Health and Human Services (FDA), as its regulatory standards for milk. For this reason, if you engage with FDA on this subject and develop label language that is acceptable to FDA, this agency would accept that label language and allow the sale of your skim milk (to which replacement Vitamin A has not been added) in Pennsylvania with that label language.

I am providing this confirmation at the request of your legal counsel. If there is anything else I can answer or provide on this, please let me know.

Respectfully

Dwight-Jared Smith Assistant Counsel

cc by e-copy only:

Greg Hostetter, Deputy Secretary, PDA Lydia Johnson, Director, Bureau of Food Safety and Laboratory Services, PDA Justin Pearson, Esq.

