# EXHIBIT 1

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

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| SOUTH MOUNTAIN CREAMERY, LLC, | : | No. 1:18-cv-00738 |
| Plaintiff, | : | |
| vs. | : | (Kane, J.) |
| U.S. FOOD AND DRUG ADMINISTRATION, et al., | : | Filed Electronically |
| Defendants. | : | |

**DECLARATION OF SUSAN T. MAYNE, PH.D. IN SUPPORT OF THE FEDERAL DEFENDANTS' RENEWED MOTION TO DISMISS AND CONTESTING CERTAIN FACTUAL ALLEGATIONS IN THE COMPLAINT**

Susan T. Mayne, Ph.D. hereby declares as follows:

1. I am the Director of the United States Food and Drug Administration's (FDA) Center for Food Safety and Applied Nutrition (CFSAN). I have held this position since January 2015.

2. I received a B.A. in chemistry from the University of Colorado, and a Ph.D. in nutritional sciences, with minors in biochemistry and toxicology, from Cornell University.

3. Immediately prior to joining FDA, I served as the C.-E.A. Winslow Professor and Chair of the Department of Chronic Disease Epidemiology at the Yale School of Public Health, and Associate Director of the Yale Cancer Center.

4. CFSAN, in conjunction with FDA's field staff, is responsible for promoting and protecting the public health by ensuring that the nation's food supply is safe, sanitary, wholesome, and honestly labeled, and that cosmetic products are safe and properly labeled.

5. CFSAN is comprised of 13 different offices. Among them are the Office of Compliance, the Office of Nutrition and Food Labeling, and the Office of Regulations and Policy. The Office of Compliance plays a critical role in any decision to pursue enforcement action for a violation of the Federal Food, Drug, and Cosmetic Act related to food. In addition, if a food were alleged to be misbranded based on nonconformance with a standard of identity or a vitamin fortification issue, the Office of Nutrition and Food Labeling would be consulted as part of CFSAN's determination about whether to pursue enforcement action.

6. As the Director of CFSAN, I lead the Center's development and implementation of programs and policies related to the composition, quality, safety, and labeling of foods, food and color additives, and cosmetics. All of CFSAN's offices (with the exception of the Office of Dietary Supplement Programs) report to me, directly or indirectly.

7. It is not unusual for firms whose products are regulated by CFSAN to contact the Center with questions concerning problems they have or believe they may have with compliance with FDA regulations or statutory requirements. We

make every effort to engage in dialogue with these stakeholders to understand their concerns and where possible resolve their issues in a manner that is not contrary to our public health mission. We are particularly sensitive to the special concerns of small businesses regulated by CFSAN.

8. I am familiar with the lawsuit that has been filed against FDA by South Mountain Creamery, LLC (SMC), and I have reviewed the Complaint for Declaratory and Injunctive Relief (Complaint). I previously caused agency staff to search for information in agency records about FDA's interactions with SMC and/or its owners related to the subject of the pending lawsuit. This included a request to FDA's Baltimore District Office, which during the relevant time period, oversaw the geographic area where SMC is located, and FDA's Office of Legislation.

9. I previously submitted two declarations in this litigation. The first was dated August 22, 2018, and filed in support of the Federal Defendants' Motion to Dismiss. ECF No. 28-1. A supplemental declaration was filed October 16, 2018, and was intended to supplement and update my August 2018 declaration after additional records relating to interactions between SMC and FDA were discovered while staff in FDA's Office of Legislation were cleaning out the office of a former FDA employee. ECF No. 31-1.

10. Agency records identify the following contacts between SMC and FDA:

a. Tony Brusco, SMC's General Manager, sent a letter to FDA dated September 27, 2001, in which he requested "an alternate means of compliance under Appendix O in the Grade 'A' Pasteurized Milk Ordinance." Robert Hennes, a Milk Safety Team Supervisor in CFSAN's Office of Field Programs, responded to Mr. Brusco in a letter dated November 2, 2001. Mr. Hennes stated in part, "vitamins A and D are required to be added back to the skim and 2% reduced fat milks to a level that is in the original standardized food, whole milk." These letters are part of a fax that a staff member in FDA's Office of Legislation received from the office of Representative Roscoe G. Bartlett (then a U.S. Representative for Maryland's 6th congressional district) on November 19, 2002. A copy of this fax is attached as Exhibit B to ECF 31-2.

b. An internal FDA email suggests that, in April 2002, FDA's Milk Safety Team visited SMC's farm and plant, among others in the surrounding area, for a standardization exercise within the Milk Safety Team. The visit was not related to the issues in this lawsuit and, to date, we have not been able to locate any records documenting this standardization exercise.

c. On December 19, 2002, representatives of FDA and the State of Maryland met with Representative Bartlett and SMC to discuss SMC's concern

about the vitamin requirements of milk. We have been unable to locate any memorandum memorializing the discussions at the meeting. An FDA employee's personal rough notes taken during the December 19, 2002, meeting are attached as Exhibit C to ECF 31-2.

d. On August 9, 2010, CFSAN wrote to SMC to grant the firm an alternative means of compliance related to certain nutrition labeling requirements for its reusable milk bottles. That letter responded to an April 20, 2010 letter from SMC. (FDA has not been able to locate SMC's incoming letter.) SMC's letter apparently requested an exemption from certain nutrition labeling requirements for its milk in glass bottles because SMC does not use specific bottles for specific products and therefore printing the nutrition information on the bottles was not feasible. FDA's August 9, 2010 letter granted SMC an alternative means of compliance. Although FDA's letter discussed the labeling of milk generally, it did not discuss the issues in SMC's lawsuit. Specifically, the issue of vitamin fortification of non-fat milk does not appear to have been raised in SMC's letter and was not addressed in FDA's responsive letter.

e. On September 17, 2012, FDA investigators visited SMC as part of an inspection assignment to conduct environmental swabbing for *Listeria monocytogenes* at soft cheese manufacturers. After determining that SMC did not manufacture the cheese sold at SMC's retail location, the investigators

discontinued the inspection. This inspection attempt was narrowly focused, and the summary does not reflect any discussion with SMC regarding fortification or labeling of non-fat milk.

f. In 2015, pursuant to a contract with FDA, the Maryland Department of Agriculture conducted an inspection of Sowers Farm, 8303 Bolivar Road, Middletown MD, which was completed on April 15, 2015. The inspection was conducted after a slaughtered dairy cow that originated at the farm tested positive for penicillin at a level above the established tolerance. The records of the inspection reflect that the inspection focused solely on issues related to the tissue residue. The fortification and labeling of SMC's milk products are not mentioned in the inspection records.

g. FDA performed a check rating inspection of SMC's milk plant on October 26, 2016. The records of the check rating inspection do not mention any discussion with SMC regarding sale of non-fortified non-fat milk.

11. Based on this information, I do not believe SMC has contacted FDA to discuss fortification of its non-fat milk or labeling of non-fortified non-fat milk since 2002.

12. On March 20, 2017, the U.S. Court of the Appeals for the Eleventh Circuit issued its decision in *Ocheesee Creamery LLC v. Putnam*, 851 F.3d 1228 (11th Cir. 2017). In that case, Ocheesee Creamery alleged that the State of Florida

had violated its First Amendment rights by prohibiting it from using the words "skim milk" to describe its non-fortified non-fat, or skim, milk product. Although the case pertained to Florida, not federal, law, CFSAN was aware of the decision and would have considered it in making any decision regarding the sale and labeling of non-fortified non-fat milk, including if we had been contacted by SMC prior to filing this lawsuit. Indeed, CFSAN considered the *Ocheesee* decision in preparing the July 10, 2018 letter to SMC discussed below.

13. On July 10, 2018, I sent a letter to SMC notifying it of the agency's position regarding SMC's desire to distribute non-fortified non-fat milk. The letter reads in part:

> FDA *does not object* to the distribution of non-fat, or skim, milk without added vitamins A or D based on the absence of those vitamins if the product is prominently labeled to notify consumers that the product does not contain vitamins A and D in one of the following ways: (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'; or (d) 'Non-fat milk, 0% DV vitamins A&D.' The agency *does not intend to take any action to require* non-fat or skim milk without added vitamins A or D to be labeled as 'imitation' based on the absence of added vitamins *or to require* such non-fat or skim milk to comply with 21 C.F.R. § 130.10(b) with respect to fortification with vitamins A and D.

*See* Ex. 2, Letter from Mayne to SMC (July 10, 2018) (emphasis added). A copy of this letter is attached as Exhibit 2 to the Federal Defendants' renewed motion to dismiss. The letter also noted that the four labeling options listed were not

intended as an exhaustive list of labeling options. Finally, I reiterate that after FDA searched its records, it did "not identify a single instance where FDA sought to take enforcement action against any entity for misbranding food based on the distribution of non-fat or skim milk to which vitamins A or D had not been added." *Id.*

14. Prior to issuance, the contents of my July 10, 2018 letter were discussed extensively with and reviewed by leadership in the Office of Compliance, the Office of Nutrition and Food Labeling, and the Office of Regulations and Policy, among others.

15. If SMC had engaged with FDA, as suggested by the Pennsylvania Department of Agriculture in its December 20, 2017 letter, before filing this lawsuit, CFSAN would have taken the same position set forth in the July 10, 2018 letter -- namely, that FDA *does not object* to the distribution of non-fat, or skim, milk without added vitamins A or D based on the absence of those vitamins if the product is prominently labeled to notify consumers that the product does not contain vitamins A and D, and that FDA *does not intend to take any action to require* non-fat, or skim, milk without added vitamins A or D to be labeled as "imitation" based on the absence of added vitamins *or to require* such non-fat, or skim, milk to comply with 21 C.F.R. § 130.10(b) with respect to fortification with vitamins A and D.

16. The Complaint alleges that selling skim milk "without complying with the challenged regulations and laws *could result in* substantial fines," "incarceration of up to one year per offense for [SMC's] owners," and/or "seizure and condemnation of skim milk being shipped across state lines." Compl., ECF No. 1, ¶¶ 87-89 (emphasis added). I disagree. As noted above, CFSAN's Office of Compliance plays a critical role in any decision to pursue enforcement action for a violation of the FDCA related to food, and if a food were alleged to be misbranded based on nonconformance with a standard of identity or a vitamin fortification issue, CFSAN's Office of Nutrition and Food Labeling would be consulted as part of CFSAN's determination about whether to pursue enforcement action. CFSAN's Office of Compliance and its Office of Nutrition and Food Labeling, which I oversee, have no intention of initiating or supporting a referral of any enforcement action (civil or criminal) to the U.S. Department of Justice for conduct that is consistent with my July 10, 2018 letter.

17. CFSAN has no plan to change the position set forth in the July 10, 2018 letter. Indeed, CFSAN would take the same position stated in the July 10, 2018 letter, if approached by another entity that wishes to distribute non-fat, or skim, milk that is not fortified with Vitamins A and D.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

April 29 2019

Susan T. Mayne, Ph.D.
Director
Center for Food Safety and Applied Nutrition
Food and Drug Administration