



April 22, 2020

Randy and Karen Sowers
South Mountain Creamery, LLC
c/o Justin Pearson
Institute for Justice
2 South Biscayne Boulevard
Suite 3180
Miami, FL 33131

Via Email to jpearson@ij.org

Dear Mr. and Mrs. Sowers:

As you know, I wrote to you on July 10, 2018 to notify you of the United States Food and Drug Administration's (FDA) position regarding South Mountain Creamery, LLC's (SMC) desire to distribute milk from which the fat has been removed and to which vitamins A and D have not been added. A copy of that letter is attached.

As previously explained, 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 those vitamins. Furthermore, the agency does not intend to take action 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 provided that its label discloses the absence of those vitamins.

The agency prepared the above options based on our understanding that SMC wishes to use the limited space available on its bottle caps to identify the absence of vitamins A and D because SMC distributes its various milk products using the same reusable bottles. As such, the above-described options are not intended to be an exhaustive list of labeling options for non-fortified non-fat, or skim, milk, and we remain open to discussing other labeling options with SMC (or any other entity that wants to distribute non-fortified non-fat, or skim, milk) if necessary.

We understand that, through your attorney, you have expressed concern about two additional issues. First, you have asked whether FDA would seek to hold SMC liable retroactively for violations of the Federal

Food, Drug, and Cosmetic Act should FDA change the position set forth in my July 10, 2018 letter. As an initial matter, prior to sending you that letter, its contents were discussed extensively with and reviewed by the leadership of the Office of Compliance, the Office of Nutrition and Food Labeling, and the Office of Regulations and Policy, among others. We have no plan to change the position set forth in the July 10, 2018 letter. And even if FDA were to change this position (which it has no plan to do), FDA's Regulatory Procedures Manual generally provides that, absent a danger to health or intentional violations, FDA endeavors to give firms an opportunity to voluntarily take corrective action before initiating enforcement action, and we would do so in this context.

Second, you asked whether FDA expects State authorities to enforce federal labeling regulations regarding SMC's distribution of non-fat non-fortified milk that is neither labeled as "imitation" (based on the absence of vitamins A and D) nor fortified with vitamins A and D. We do not.

Sincerely,

/S/

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