



July 10, 2018

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 Hard Copy

Dear Mr. and Mrs. Sowers:

I write 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.

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.

The agency has 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 necessarily 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.

I also want to let you know that, based on a search of our records, we have not identified 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.

Sincerely,

/S/

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

cc: Russell C. Redding  
Secretary, Pennsylvania Department of Agriculture