National Milk Producers Federation

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Laurie Lenkel, R. Ph., J.D.
Director, Office of the Ombudsman
FDA Office of the Commissioner
10903 New Hampshire Avenue
Bldg. 32, Room 4213
Silver Spring, MD 20993

Dear Dr. Lenkel:

Last year on October 29, the National Milk Products Federation (NMPF) sent you a request for assistance with FDA-CFSAN's continuing lack of enforcement with respect to plant-based dairy imitators unlawfully utilizing standardized dairy terminology on products that contain no dairy ingredients. NMPF has repeatedly asked FDA-CFSAN to enforce its own rules including the filing of a Citizen Petition on Feb. 21, 2019. The petition asks FDA to take enforcement and regulatory actions to stop the continued proliferation and marketing of unlawfully labeled, nutritionally inferior non-dairy substitutes for standardized dairy foods. To date, FDA has taken no action in response to that petition.

On October 30, 2020, you acknowledged the receipt of our correspondence and stated that you would review the matter and be in contact with the "group" shortly. By group, we assume you meant FDA-CFSAN. Our concern continues to grow regarding the agency's lack of initiative on enforcement to the extent that we feel compelled to once again request feedback from your office. We had hoped that in your office's charge to help mitigate unresolved issues between FDA and outside stakeholder organizations that some information on the matter would be forthcoming. However, the months-long silence from your office has left us in limbo.

We understand that FDA-CFSAN plans to issue guidance next year on the "Labeling of Plant-based Milk Alternatives; Draft Guidance for Industry." We caution FDA that re-writing an existing rule with guidance would be a violation of the Administrative Procedures Act (APA). The APA requires regulatory changes to be made using notice and comment rulemaking which a guidance cannot overrule. In addition, some federal courts are no longer bowing to an agency's use of enforcement discretion when such discretion is broad and long-term and amounts to a de-facto re-write of existing rules which would violate the APA.

The matter is now even more confusing with the issuance of FDA's final rule amending the yogurt standard of identity on June 11, 2021. In that rule, FDA strongly stresses the importance of standards of identity and the role they play. For example, FDA touts that

the rule "modernizes the yogurt standard to allow for technological advances while preserving the basic nature and essential characteristics of yogurt and promotes honesty and fair dealing in the interest of consumers." Further, FDA insists that yogurt must meet the minimum milkfat requirement and that "allowing fat from non-dairy ingredients to count towards the minimum fat level deviates from the basic nature and essential characteristics of yogurt as other types of fats or oils contribute to variances in taste, texture, color or aroma of yogurt." In a similar determination, FDA declined to allow the use of ultrafiltered milk (UF) as a basic dairy ingredient in yogurt because that would "not be consistent with the basic nature of yogurt because UF milk removes not only water, but lactose, minerals, and water-soluble vitamins resulting in a compositionally different ingredient." FDA explains that the use of UF milk as a basic dairy ingredient affects the essential characteristics of yogurt, which is a fermented product from milk and that lactose which is substantially reduced in UF milk would have otherwise served as a substrate for that fermentation process.

Finally, and most importantly, in response to Comment 10, FDA shared the following:

> When "yogurt" is used as part of the name of products such as frozen yogurt, yogurt-coated cereal, and dried yogurt powder, we generally expect that yogurt, or a substance derived from yogurt (i.e., yogurt powder) is used as an ingredient in their manufacture. The ingredient must be or derived from yogurt that complies with §131.200. For example, we expect that an ingredient in a yogurt drink is yogurt made in accordance with §131.200, which is combined with other ingredients to produce a drink product.

NMPF is at a complete loss as to how FDA can properly assert the way its long-term existing rules involving standards of identity work and the importance of preserving the basic nature and essential characteristics of a standardized food to promote honesty and fair dealing in the interest of consumers and yet, continue to turn a blind eye to the deliberate unlawful labeling practices perpetrated by plant-based food companies. In our opinion, there is clearly no way under this rule that a plant-based product can bear the name "yogurt" in any context unless the ingredients are yogurt or are derived from yogurt. What holds for yogurt is true for all other plant-based dairy imitators that do not contain dairy ingredients or ingredients derived from dairy.

For years, NMPF has provided FDA with numerous examples of unlawfully marketed products, established that there is consumer confusion in the marketplace with respect to the nutritional inferiority of plant-based dairy imitators, and established that there is harm to human health as a result of that confusion. Through the filing of our Citizen Petition, we have also provided FDA with a roadmap on how to proceed with suitable enforcement action using existing regulations. And yet we still have received no reply of substance to our promptings.

In closing, we reiterate that allowing unlawfully labeled plant-based imitation dairy foods to proliferate poses an immediate and growing risk to public health. As such, it is a clear dereliction of the FDA's duty to enforce federal law and agency regulations. For these reasons, and others that are more fully explained in the NMPF Citizen Petition, nine months after our initial request to you, we once again ask the FDA's Office of the Ombudsman to intervene to break the bureaucratic logjam that is adversely affecting consumers. Doing so would fit squarely within the Office's own mission to ensure even-handed application of FDA policy and procedures.

We eagerly await the resolution of this problem which has spanned decades.

Sincerely,

James Mulhern
President & CEO