August 7, 2020

Dr. Stephen Hahn
Commissioner of Food and Drugs
U.S. Food and Drug Administration

VIA E-MAIL

Dear Dr. Hahn:

As Commissioners and Secretaries of Agriculture, we remain committed to the position that plant-based products labeled as “milk” are misleading and mislabeled. We were encouraged to hear you echo this sentiment during your Senate confirmation hearings in November 2019, affirming that you are in favor of clear, transparent and understandable labeling for the American people.

Milk is a food that has an established standard of identity defined in 21 CFR 131.110 as “the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows.” However, plant-based products continue to be branded, marketed and sold as milk, creating the misperception that those products are suitable replacements for cow’s milk. Allowing these products to be marketed under the “milk” name and benefit from its nutritional reputation not only creates confusion for consumers, but also hurts the dairy industry which is already facing a financial crisis severe enough to force a large amount of farmers and suppliers out of business.

We again call on the Food and Drug Administration to enforce its own food standards and address the issue of mislabeled plant-based products represented to be dairy milk. FDA has addressed the Standard of Identity for milk in warning letters sent in the past, but there have been no recent enforcement actions. The current trend towards enforcement discretion and inaction ironically comes at a time during which the market has exploded with more mislabeled milk substitutes.

Since 2016, there have been numerous calls for FDA to take action, including a letter to then-Commissioner Robert Califf with a request similar to ours. Similarly, language was included in the Committee Report accompanying the omnibus spending package signed into law in early 2018. That language stated:

The Committee directs the FDA to develop a standard of identity for dairy products based upon the dairy product terms described in 21 CFR 131, 133, and 135 of subchapter B of Chapter I of Title 21, Code of Federal Regulations within 180 days from the date of enactment of this Act. The FDA should issue guidance to industry on how to implement the standard of identity, including how this standard will be enforced.

Not only has Congress made this request to FDA, but the United States District Court for
the Eastern District of California has also referred this issue to FDA as it “fits squarely within the FDA’s authority, and will require the agency’s expertise in determining how to fashion labels so they adequately inform consumers.” Kelley v. WWF Operating Co., 2017 U.S. Dist. LEXIS 86971, 2017 WL 2445836.

And, even before the request from Congress, and the referral from the federal district court, this issue was on FDA’s radar. In 2008 and 2012, FDA issued warning letters to two different “soymilk” producers informing them that their product was mislabeled. In both warning letters, FDA stated:

“Your...product[s] uses the term “milk” as part of the[eir] common or usual name. Milk is a standardized food defined in 21 CFR 131.110 as the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows. Therefore, we do not consider “soy milk” to be an appropriate common or usual name because your product does not contain “milk.” We consider “soy drink” or “soy beverage,” however as acceptable common or usual names for such products.”

Consumers will continue to be unknowingly exposed to potentially nutritionally deficient substitutes if FDA continues with its inaction. If FDA has no plans to enforce existing standards of identity and labeling regulations, or comply with the directive from Congress, we ask for transparency in those decisions including the criteria and process for determining which regulations are enforced and which are not. Consumer and industry confidence is eroded by inconsistent enforcement and as we embark on the new era of food safety envisioned in the Food Safety Modernization Act, consistency becomes even more important.

We understand that enforcing standards of identity and ensuring the accuracy currently in regulations will not prevent dairy-free alternatives and real milk from co-existing in the marketplace. We are not advocating for the elimination of these foods from the marketplace. In fact, we are advocates for all agricultural products and believe in the consumer’s right to choose. However, this must be done with accuracy in labeling.

We appreciate your understanding of the importance of the issue so that American people can make appropriate decisions for their health and their nutrition. We respectfully hold you to the commitment you made during confirmation hearings to make this issue a priority, and urge you to listen and respond to the requests of industry, Congress, the federal court and the undersigned.

Sincerely,

Steven W. Troxler
Commissioner
North Carolina Department of Agriculture and Consumer Services
Andy Gipson  
Commissioner  
Mississippi Department of Agriculture and Commerce

Richard Ball  
Commissioner  
New York Department of Agriculture and Markets

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