June 26, 2023

The Honorable Robert M. Califf, M.D.
Commissioner
Food and Drug Administration.
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002.

Dear Commissioner Califf:

Earlier this year, in a discussion with you and Susan Mayne regarding the draft guidance for labeling of Plant-based Milk Alternatives, I expressed my ongoing concern about FDA's lack of action in enforcing the labeling of plant-based food products and the ensuing labeling fiasco in the marketplace that has occurred as a result of the agency's longtime failure to address the problem.

I also raised concern in that discussion that this problem would be exponentially compounded should the agency fail to address these same labeling standards as synthetic, cell-based foods emerge from laboratories and seek to enter the marketplace.

I write to you today to inform you that the labeling problems these synthetic products raise are already present – and it's imperative that FDA take action now, before this situation spins out of control. Like the plant-based labeling fiasco that's bedeviled regulators for more than four decades, we are beginning to see the presence of mislabeled synthetic food products in the marketplace masquerading as natural foods. FDA has a legal obligation to ensure that food labels are accurate, truthful and not misleading. Products are now coming into the marketplace that do not meet FDA Standards of Identity; the agency’s past failures to uniformly enforce these standards must not be repeated.

Recent marketing promotions tout that food retailer Sprouts will begin carrying a product from the brand Bored Cow described as “Animal Free Dairy Milk.” Despite it’s brazenly inappropriate label, the product is clearly not milk, as prescribed by FDA's own Standard of Identity. (See Attachment A.)

Milk is a natural, biologically produced, highly complex and nutritious food. It is the first food of all humans – indeed all mammals, providing sustenance and promoting growth. Fortunately for humans, cow's milk is similar to human milk and has helped our species grow and thrive for thousands of years.
Milk provides a unique, natural nutrient package and is a good or excellent source of 13 different nutrients which include: protein, calcium, phosphorus, vitamin A, vitamin D, riboflavin, niacin, pantothenic acid and cobalamin, iodine, potassium, selenium and zinc. The milkfat portion contains approximately **400 different fatty acids**, and milk contains **two categories** of proteins, casein and whey. Caseins include αs1-casein with Variants (A,B,C,D,E,F,G,H,I,J), αs2-casein with Variants (A,B,C,D,E), β-casein with Variants (A1, A2, A3, B,C,D,E,F,G,H1,H2,J,K,L) and κ-casein with Variants (A,B,C,E,F1,F2, G1,G2,H,I,J). The whey proteins include **8 different types**: α-lactalbumins, β-lactoglobulins, bovine serum albumin, immunoglobulins (IgG, IgM, IgA), proteose-peptones, lactoperoxidase, lactoferrin, caseinomacropeptide. In addition, milk naturally contains countless other bioactive compounds, some of which the function and contribution to nutrition are not yet fully understood.

Taken as a whole, that’s what milk is.

The synthetically produced product from Bored Cow is not milk. It is not even close.

Bored Cow's product takes water and adds what we believe to be **one unidentified, lab-engineered “whey protein”** along with a highly processed concoction of food additives, preservatives, oil, sugar and several added vitamins, and claims to have created “animal-free dairy milk.” It is baseless, preposterous and absurd to call the resulting product “milk.” It would be much more accurate to label it as a “synthetic whey beverage.” In the interest of public health, the misleading labeling charade must end before it gets out of hand. FDA must act, and must do so now.

We implore you to stop this false, misleading, and completely unlawful labeling. As we have seen in the decades-long folly of plant-based beverage labeling, an ounce of prevention is worth oceans of cure. We ask the agency to exercise its well-established authority to prevent this company and others that seek to follow from leading consumers down what will become a superhighway of misinformation, absent your willingness to enforce the law.

Dairy farmers are more than happy to compete in the marketplace, and we do not oppose the sale of synthetic, cell-based products if regulatory authorities deem them safe. But public health, safety and federal law requires that their labels be truthful and not misleading. Everyone should be held to follow the rules, regardless of whether a company is too “Bored” to do so.

Sincerely,

Jim Mulhern
President & Chief Executive Officer

cc: Dr. Donald Prater,
    Acting Director of Center for Food Safety & Applied Nutrition

Attachment
Attachment A

Bored Cow (plain): INGREDIENTS: Water, animal-free whey protein (from fermentation), sunflower oil, sugar, less than 1% of: vitamin A, vitamin B12 (cyanocobalamin), vitamin D2, riboflavin, citrus fiber, salt, dipotassium phosphate, acacia, gellan gum, mixed tocopherols (antioxidant), calcium potassium phosphate citrate, natural flavor.

Real Milk: 21 CRF § 131.110 Milk.

(a) Description. Milk is the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows. Milk that is in final package form for beverage use shall have been pasteurized or ultrapasteurized, and shall contain not less than 8 1/4 percent milk solids not fat and not less than 3 1/4 percent milkfat. Milk may have been adjusted by separating part of the milkfat therefrom, or by adding thereto cream, concentrated milk, dry whole milk, skim milk, concentrated skim milk, or nonfat dry milk. Milk may be homogenized.