Congress of the United States Washington, DC 20515

October 3, 2018

The Honorable Scott Gottlieb Commissioner U.S. Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993

Re: Docket No. FDA-2018-N-3522

Dear Commissioner Gottlieb:

We are pleased that your agency plans to take action to enforce FDA regulations defining what may be labeled a dairy product, to combat the proliferation of imitation and substitute dairy products in the marketplace that violate FDA regulations by employing standardized dairy terms on non-dairy products. We appreciate that you are following the direction provided to your agency by Congress in the recently-enacted Fiscal Year 2018 Consolidated Appropriations Act (H.R. 1625).

We are greatly concerned about the lack of enforcement of existing dairy terms that are described in 21 Code of Federal Regulations parts 131, 133, and 135, which pertain to milk and cultured milk products, cheeses, and frozen dairy desserts, respectively. These standards were written with the express purpose of promoting honesty and fair dealing in the interest of consumers by promulgating regulations that fix and establish, under their common or usual names, reasonable definitions or standards of identity for foods.

As you know, in recent years the proliferation of imitation and substitute dairy foods and beverages that are labeled with standardized dairy terms has dramatically increased. Use of the term "milk" by manufacturers of plant-based products is a clear violation of milk's standard of identity, and this type of labeling practice is extending to other plant-based versions mimicking butter, yogurt, cheese and ice cream. Moreover, dairy terms convey specific information for consumers on nutritional content and ingredient performance that dairy imitations and substitutes do not meet. Imitation and substitute dairy products do not have standardized requirements for product nutritional content, composition, and processing as do the dairy products they imitate. Most importantly, they are not sourced from cows or other lactating mammals as referenced in the standards established in the Code of Federal Regulations.

Given that dairy terms are being misappropriated by manufacturers of imitation dairy products, we are pleased that FDA now plans to take action to address this issue. As your agency moves forward, we urge you to clearly indicate that imitation products will not be considered in compliance with regulations if they simply add the name of a plant material in front of a standardized dairy term, or otherwise reference dairy terms. Modifying the word "milk" with a plant product descriptor does not result in appropriate names for non-dairy beverages, as these products do not contain milk or milk ingredients, the plant-based liquids are not permitted ingredients in milk, and they do not represent the common or usual names of these beverages.

Some manufacturers of non-standardized imitation dairy products do properly label their products without resorting to standardized dairy names. The current marketplace includes, for example, "rice beverage," or fanciful names that do not have "milk" included in the name of the beverage on the front of the package. We also note that similar standards limiting dairy terms for use on real dairy products are the rule, not the exception, around the world, and that U.S. manufacturers of plant-based foods already comply with these regulations when they export their products.

Thank you for your attention to this matter and for your willingness to act. We look forward to working with you to enforce existing dairy standards of identity.

Sincerely,

PETER WELCH

Member of Congress

JOE COURTNEY

Member of Congress

SEAN DUFFY

Member of Congress

FRED UPTON

Member of Congress

PAUL D. TONKO

Member of Congress

MIKE SIMPSON

Member of Congress

TOM REED

Member of Congress

SUZAN DELBENE

Member of Congress

COLLIN C. PETERSON

Member of Congress

BILLY LONG

Member of Congress



Member of Congress

BOB GIBBS Member of Congress

STEVE PEARCE Member of Congress

TOM MARINO Member of Congress

RICK LARSEN Member of Congress

LOU BARLETTA Member of Congress

JOHN KATKO Member of Congress

CAROL SHEA-PORTER Member of Congress

F. JAMES SENSENBRENNER,

Member of Congress

TIM WALBERG Member of Congress

KURT SCHRADER Member of Congress

THOMAS J. ROONEY Member of Congress

GUS M. BILIRAKIS Member of Congress

Member of Congress .

JOHN J. FASO

Member of Congress

RON KIND

Member of Congress

MARK POCAN
Member of Congress

CHRIS COLLINS

LLOYD SMUCKER Member of Congress

Member of Congress

TED S. YOHO, D.V.M. Member of Congress

NEAL P. DUNN M.D. Member of Congress

Thin M. Sufa

ELISE M. STEFANIK Member of Congress

ROGER MARSHALL M.D.
Member of Congress

ELIZABETH H. ESTY

Member of Congress

DAN NEWHOUSE

DAN NEWHOUSE Member of Congress

MIKE GALLAGHER Member of Congress

CLAUDIA TENNEY
Member of Congress

DENNIS A. ROSS Member of Congress

JIM RENACCI
Member of Congress

TOM EMMER
Member of Congress

DANIEL T. KILDEE
Member of Congress

Michelle hujan Binhem

MICHELLE LUJAN GRISHAM
Member of Congress



PAUL MITCHELL
Member of Congress

TOM O'HALLERAN Member of Congress

JOHN MOOLENAAR Member of Congress ANN MCLANE KUSTER

Member of Congress

GLENN 'GT' THOMPSON

Member of Congress

GLENN GROTHMAN

Member of Congress