NATURAL PRODUCTS ASSOCIATION

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January 10, 2023

Mrs. Bonnie Patten
Executive Director
TINA
P.O. Box 927
Madison, CT 06443

Dear Mrs. Patten,

The Natural Product Association took great interest in the Truth in Advertising, Inc. (TINA) and the Rudd Center's letters in December to manufacturers of energy drink products regarding your concerns about certain practices and their compliance with Federal Law. This letter is not in response to a specific letter and is not intended to be comprehensive of all the issues raised, we wanted to take the time to address some of the statements outlined in your letters and explain how energy drink products are regulated and the steps our members take to comply with applicable laws and regulations.

NPA takes truth in advertising very seriously, and our organization's educational foundation, the Natural Products Foundation's truth in advertising program, was initiated in 2008 (Program). The Foundation has referred numerous cases to both the FTC and FDA over the years for violation of the principles laid out in our Program.

As you know, the FTC and the FDA have overlapping jurisdiction to regulate the advertising and labeling of foods, including the energy drink products cited in your letters. Section 403(a) of the FDCA prohibits the "misbranding" of food, which includes labeling that "is false or misleading in any particular." Section 5 of the Federal Trade Commission Act (FTC Act) prohibits "unfair or deceptive acts or practices," and Sections 12 and 15 of the FTC Act prohibit "any false advertisement" of food products that is "misleading in a material respect." This shared jurisdiction over labeling and advertising of food products operates pursuant to a longstanding Memorandum of Understanding between the agencies. Under this agreement, the FDA exercises primary responsibility for regulating food labeling, while the FTC assumes primary responsibility for ensuring that advertising of food products is truthful and not misleading.

The FDCA—which provides authority for the FDA's consumer-protection work— requires that labels on packaged food products in interstate commerce not be false or misleading in any way. The FDA focuses on whether a product's label makes certain permissible claims (i.e. structure/function, nutrient content claims, health claims, etc.). Labeling is broadly defined as labels and other written, printed, or graphic material accompanying a product and can include brochures, flyers, infomercials, conference talks, websites, social media, etc. FDA interpretation of claims on labels is made on the overall intended use of the product based on statements and representations made.

The FDA also reviews products to see if the product is accurately representing itself as a conventional food or another food item. Per both the regulation and the statute, improperly mimicking another food is not the same as the FDA's prior "simulate conventional food" definition (i.e., "conventional food form"). The FDA has issued guidance on this topic that was released during my time

at the agency. The FDA guidance identifies a variety of factors to consider when determining whether a food product is misbranded by way of misrepresenting itself as another product. The FDA analyzes these factors in their totality to determine if products are misrepresenting themselves as another product type. This is critical to evaluating any product category and its intended use: all label information must be evaluated in its totality to render any evaluation on whether a product is misleading or not. Reliance on a single criterion like a flavor, is generally inappropriate. The totality of language used on the product labeling is usually the heaviest weighted factor in considering the intended use of the product. This seems to be the primary thrust of your letters, that, because of the use of nostalgic flavors, recognizable candy and confectionary product flavors, the products in question are inappropriately targeting minors in their marketing. This statement doesn't hold up under scrutiny and clear reading of the applicable laws and regulations.

The FDA guidance states that "The most obvious representations about a product's use are claims made for the product in its labeling and advertising. However, a product's name, packaging, serving size, recommended daily intake and other recommended conditions of use, and composition, as well as marketing practices and representations about the product outside its labeling and advertising, can also be important determinants of whether the product is represented as a conventional food."

Section 403(g) of the FDCA specifies that a food is deemed misbranded if: "If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by section 401, unless: (1) It conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard, and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavorings, and coloring) present in such food." To that point there is no standard of identity for many of the nostalgic branded food items like candies, that are mentioned in some of your letters, would not be on their own capable of misbranding the food product by misrepresenting itself.

The term "principal display panel" (PDP) means the part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale. The PDP shall be large enough to accommodate all the mandatory label information required to be placed thereon with clarity and conspicuousness and without obscuring design, vignettes, or crowding. Where packages bear alternate PDPs, information required to be placed on the PDP shall be duplicated on each PDP.

21 C.F.R. § 101.3 requires the following for food labels:

Identity labeling of food in packaged form.

(a) The principal display panel of a food in package form shall bear as one of its principal features a statement of the identity of the commodity.

(b) Such statement of identity shall be in terms of:

(1) The name now or hereafter specified in or required by any applicable Federal law or regulation; or, in the absence thereof, (2) The common or usual name of the food; or, in the absence thereof, (3) An appropriately descriptive term, or when the nature of the food is obvious, a fanciful name commonly used by the public for such food.

Notably, brand names or logos are not considered part of the statement of identity, and they should be appropriately less prominent than the food name. "Fanciful names" are acceptable when the nature of the food is obvious, and the fanciful name is commonly used and understood by the public. We are unaware of any data, pertaining to adults or children, on reasonable consumer behavior that there is

confusion regarding cobranded beverages and their flavors being mistaken for another food item. Even in the face of such data, the statement of identity clarifies without question that the products are indeed beverages. On a preliminary review of the labeling cited in your letters, the product labels are not misbranded or false or misleading consistent with the guidance provided in 21 C.F.R. § 101.18(a), as the totality of the labeling makes it clear that the products are beverages under FDA regulations. Therefore, the products in question could not be confused as candy or anything else.

While the name(s) of the flavors are also present on the PDP, that would not impart the products were candy, or candy-like, as all products are clearly identified on the PDP as containing a given number of fluid ounces. This is important, as the Reference Amounts Customarily Consumed (RACCs) per Eating Occasion established in 21 C.F.R. § 101.12(b) for a beverage are twelve (12) fluid ounces. Therefore, the product wouldn't be confused as anything other than a beverage under FDA regulations, these facts are all disclosed on the PDP of the label to the consumer in plain sight. For the flavors to be even marginally considered misleading, there would need to be either (1) in addition to the presentation of a logo, clear statements comparing it to a specific, popular, and commonly used product, not just a generic image, (i.e. chews like bubble gum) or (2) a product name used without qualifying language about the flavors and without any disclosure of the ingredients to where it could be implied that it was representing another food item. These factors or analysis of how they are misleading are absent from any discussion presented in your letters. Flavors, by themselves, are generally not compelling to mislead a consumer into believing a product is misrepresented. By way of a comparison, the FDA would not conclude that consumers would believe Champagne Cola was Champagne. Flavors commonly appear in all sorts of food and beverage products. As such there are no inconsistent uses that would render the term(s) describing the flavor as associated exclusively with one particular food or beverage product. The use of a flavor term in the product name would be evaluated in the broader context of other factors.

For something to be misrepresented as another ingestible product, there must be a comparison somewhere that would mislead a consumer into thinking a product is "representative" of another product category. For a reference point you used the graphic where the manufacturers of an e-liquid vaping product mimics TreeTop™ apple juice boxes. The misbranded product contains statements indicating it is a "juice box" and the choice, color, positioning, packaging (as a box, containing a liquid) and size of graphics closely represent a product widely understood to be a popular apple juice box. That would be an example of misleading marketing. However, that example does not translate in your letters, while some of the products contain a graphic representation of a flavor from another food type in similar form, a beverage where all labels are compliant with federal labeling law is not a gum, not a cookie, not a candy, none of the products labeled themselves as such. In addition to the labeling, disclosures about the intended use of the products neither the color, positioning, ingredient disclosure, or packaging in total is mimicking another food item. On this basis it is unclear how the products are misleading.

Additionally, it is important to note that while beverages do not usually carry directions for use or cautionary statements on labeling, many, if not all, of the products subject to your letters do carry specific statements on age/maturity of the user. Such statements clarify beyond any doubt, of the intended use of the product as an energy drink/beverage, not another food item. These also serve as an example of the corporate responsibility from companies that provide a clear statement that the products aren't to be used by children.

Most of the companies mentioned in your letters have no corporate experience in marketing candy or confectionary products to children, thus the notion that they are attempting to make their products look like an item of food they have no familiarity in marketing is without a basis in practice. This is important as the statements regarding intention to mislead consumers and appear to market a food appealing to children. What common marketing tactics or statements from the domain of marketing candies and confectionery products did these firms engage in? The letters offer no citation in that regard,

which is important because the FDA or FTC could rely on that information when assessing whether the products are misbranded. While there is co-branding, that is with legal agreements to add a flavor to the beverage product, not to co-locate products on the shelves next to each other, where there could possibly be confusion. To my knowledge no candy or any other of the concerned representations of products are co-packaged with any of the products in question.

While we certainly appreciate any group looking out for the well-being of America's youth, the notion that uniformly across all the firms who received a letter from your organization there's some sort of collective practice to deceive is what's false and misleading here. While we aren't looking to assign malicious intent to your organization's efforts, we do ask that blanket statements that would not hold up under scrutiny to cease. If there are specific issues, supported by data, like the need for font size to be larger than currently required by Federal Law on some areas of products so that they are easier to see, as that would be more beneficial to inform consumers, we're happy to explore those conversations with you, and find ways of working together for the benefit of all concerned parties. I appreciate your consideration of the matter and look forward to your response.

Thank you,

Daniel Fabricant, Ph.D.
President and CEO