



May 24, 2017

Via Facsimile (301-436-2668) & 1st Class Mail
Dr. Susan Mayne, Director Food Safety and Applied Nutrition
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Mayne:

The Center for Science in the Public Interest (“CSPI”) writes to draw your attention to the labeling of 100% juices as “NO ADDED SUGAR.” Such product labeling is ubiquitous, but violates 21 C.F.R. § 101.60(c)(2)(iv). More, it deceives consumers and undermines intentions that are productive individually and societally. We write to request respectfully that the FDA take action to enforce its regulation.

Background

Americans increasingly seek products that are lower in sugar. This trend is important given that obesity, diabetes, and cardiovascular disease have reached epidemic levels, in significant part owing to excess sugar in the American diet. Indeed, two-thirds of adults in the United States are overweight or obese, and obesity rates in children have tripled since 1980.¹ These diseases burden individuals, diminishing quality of life, and place a substantial burden on society by way of billions of dollars spent annually on associated medical and assistance costs as well as lost productivity.²

¹ Cynthia L. Ogden et al., *Prevalence of Childhood and Adult Obesity in the United States, 2011–2012*, 311 JAMA 806 (2014). The McKinsey Report provided an important perspective on this scourge: the 2.1 billion obese or overweight people in the world is two and a half times the number of malnourished people. McKinsey Glob., *Overcoming Obesity: An Initial Economic Analysis* 9 (2014) (internal citation omitted), <http://www.mckinsey.com/search?q=sugar>.

² See, e.g., McKinsey Report at 7, 10 (“Obesity has roughly the same economic impact as smoking or armed conflict”; measuring global annual cost at \$2 trillion); *id.* at 9 (reporting that, inclusive of costs relating to obesity-related disease, the toll of obesity is up to 20% of all health care costs in developed countries (exclusive of lost productivity in the workplace)). In 2013, an in-depth analysis by Credit Suisse reached similar conclusions. Extending scientific consensus to the financial mainstream, it found that “While medical research is yet to prove conclusively that

When a label indicates on the front of a package that a juice has “NO ADDED SUGAR,” often prominently, consumers predictably equate such claim with low, or at least moderate, levels of all sugars. This is especially so where the juice is named after, or predominately bears images of, non-sugary ingredients like kale. However, 100% juices often contain between 30-60 grams per 15-ounce serving, and sometimes more. At the upper end, this translates into consuming approximately 15 teaspoons of sugar per serving.³

Beyond public health, labeling 100% juices “NO ADDED SUGAR” also harms competitors in the juice market who comply with the law. These manufacturers are disadvantaged because consumers are likely to conclude, erroneously, that the juice bearing the unlawful “NO SUGAR ADDED” claim has less sugar, is healthier, and thus preferable to purchase.

For these reasons, CSPI respectfully urges the FDA to take action to enforce 21 C.F.R. § 101.60(c)(2)(iv), which prohibits the labeling of 100% juices as “NO ADDED SUGAR.”

“NO SUGAR ADDED” claims violate FDA regulations

FDA adopted 21 C.F.R. § 101.60(c)(2)(iv) largely to help consumers reduce their sugar consumption. It permits manufacturers to identify particular food (brands) that do not contain added sugar where, ordinarily, the food would contain added sugar.⁴ Jam illustrates this point. Consumers seeking healthier, lower-sugar alternatives for jam could be steered to a jam made without the typically added sugar by way of a “NO ADDED SUGAR” label claim.

sugar is the leading cause of obesity, diabetes type II and metabolic syndrome, the balance of recent medical research studies are coalescing around this conclusion. Advances in understanding the negative effects of refined carbohydrates on blood sugar regulation and cholesterol, and the metabolic impacts of fructose, are undermining the traditional view that all calories are the same.” Credit Suisse, *Sugar Consumption at a crossroads* 4 (2013), <https://publications.credit-suisse.com/tasks/render/file/index.cfm?fileid=780BF4A8-B3D1-13A0-D2514E21EFFB0479>. *See also id.* (Noting, “In the USA alone, the healthcare costs tied to diabetes type II are estimated at USD 140 billion, compared to USD 90 billion for tobacco-related healthcare costs.”).

³ Notably, while the updated Nutrition Fact Panels will indicate how many grams of added sugars there are in any given product, such notice is immediately adjacent to the total grams of sugar contained in the product such that consumers are not misled as to the total sugar content.

⁴ “In implementing the guidelines, the purpose of the ‘no added sugar’ claim is to present consumers with information that allows them to differentiate between similar foods that would normally be expected to contain added sugars.” 58 Fed. Reg. at 2327.

Specifically § 101.60(c) provides:

2) The terms "no added sugar," "without added sugar," or "no sugar added" may be used *only if*: . . .

(iv) The food that it resembles and for which it substitutes *normally contains* added sugars; and

(v) The product bears a statement that the food is not "low calorie" or "calorie reduced" (unless the food meets the requirements for a "low" or "reduced calorie" food) and that directs consumers' attention to the nutrition panel for further information on sugar and calorie content.

21 CFR § 101.60(c)(2)(iv)-(v) (emphasis added).

By definition, 100% juices do not normally contain added sugar, and as such, labeling 100% juices as "NO SUGAR ADDED" violates the regulation. One hundred percent juice must be precisely that—100% juice product from the fruit(s), exclusive of any other non-fruit juice ingredient, like added sugar.

The clear import of the plain language also aligns perfectly with other FDA regulations. For example, 21 C.F.R. § 101.30(b)(3) clarifies that beverages containing 100% juice *and other* ingredients must designate those other (non-100% juice) ingredients expressly on the label either by way of the statement of identity or by the clause "with added [sweeteners]."

If the beverage contains 100 percent juice and *also* contains *non-juice ingredients* that do not result in a diminution of the juice soluble solids or, in the case of expressed juice, in a change in the volume, when the 100 percent juice declaration appears on a panel of the label that does not also bear the ingredient statement, *it must be accompanied by the phrase "with added ____,"* the blank filled in with a term such as "ingredient(s)," "preservative," or "sweetener," as appropriate (e.g., "100% juice with added sweetener"), except that when the presence of the non-juice ingredient(s) is declared as a part of the statement of identity of the product, this phrase need not accompany the 100 percent juice declaration.

Id. (emphasis added). As such, products bearing the statement of identity "100% juice," without any qualifying "with" clause, do not normally contain added sugar and may not lawfully bear the claim "NO SUGAR ADDED."⁵

⁵ See also 58 Fed. Reg. at 2327 ("the 'no added sugar' claim is not appropriate to describe foods that do not normally contain added sugars. In such cases, proposed § 101.60(c)(3) would provide for the use of a factual statement that the food . . . contains no added sweeteners in the case of a food that contains apparent substantial inherent sugar content, e.g., fruit juices . . .").

Despite its clear illegality, many manufacturers of 100% juice products make the “NO SUGAR ADDED” claim. This misleads productively-inclined consumers, and gives these bad actors an unfair competitive advantage over other manufacturers.

Product Examples

The following are a few of the many product labels that violate 21 CFR § 101.60(c) owing to their “NO SUGAR ADDED” claims. We proffer these particular, high-profile products to illustrate the extent of the regulatory-defiant labeling in the 100% juice category.

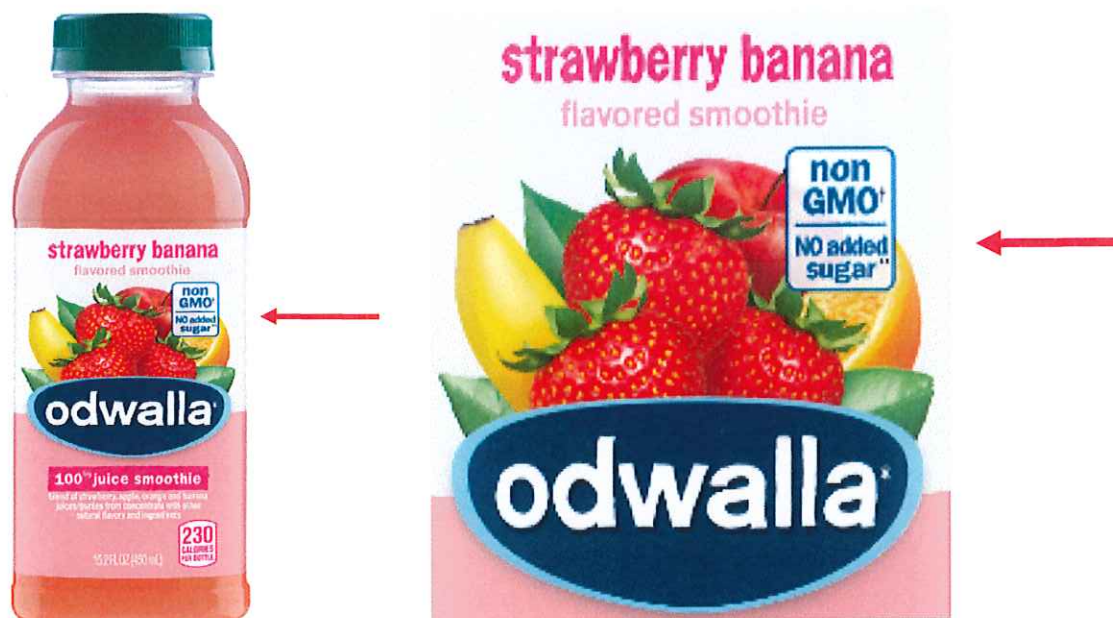
...//...

- PepsiCo's Naked Juice line, including but not limited to kale blazer and mighty mango. Naked's front of package juice labels carry the claim "NO SUGAR ADDED." Kale blazer has 34 grams of sugar per serving (approximately 8.5 teaspoons), and mighty mango has 57 grams of sugar (approximately 14.5 teaspoons) per 15-ounce serving.⁶



⁶ Quite commendably, following notification of deceptive labeling concerns, PepsiCo worked collaboratively with CSPI to reach agreement on prospective labeling changes, which forthcoming

- Coca-Cola's Odwalla 100% juice smoothie line, including but not limited to strawberry banana. Strawberry banana has 47 grams of sugar per 15-ounce serving.

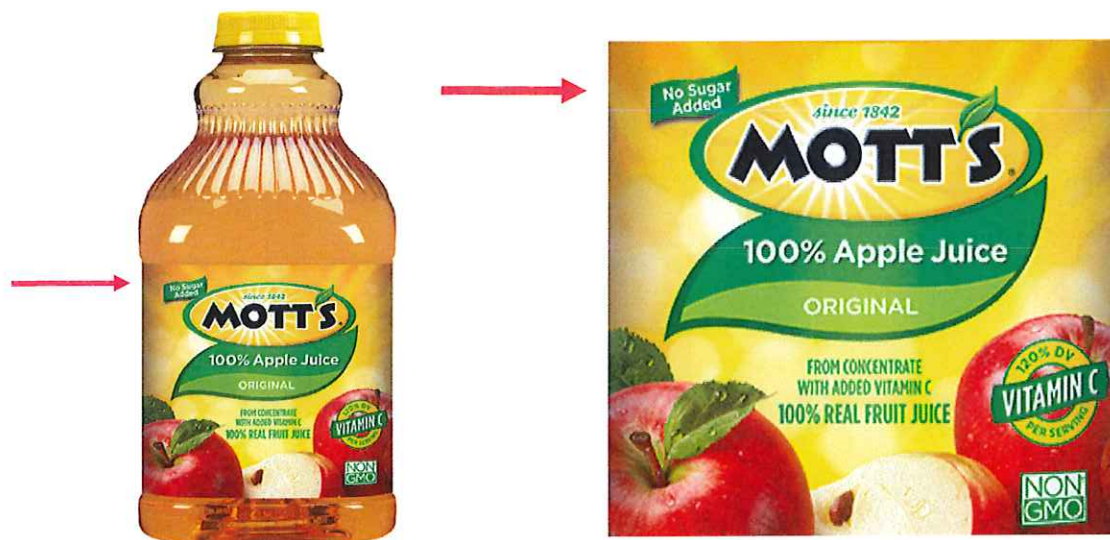


changes are not reflected in the above images. However, PepsiCo was not willing to remove the “NO SUGAR ADDED” claim from the Naked Juice line unless and until courts or the FDA enforce the requirement across the market that manufacturers comply with FDA regulations and remove the claims. *See* Naked Settlement Agreement at Par. 13a(iv)(b), attached hereto as Exh. 1.

- Nestlé's Juicy Juice 100% fruit juice line, including White Grape Juice, which has 34 grams of sugar per 8-ounce serving, or approximately 60 grams (15 teaspoons) per 15-ounce serving.



- Mott's 100% juice line, including Apple Juice, which has 28 grams of sugar per 8-ounce serving, or approximately 54 grams (approximately 13 teaspoons) per 15-ounce serving.



- Bolthouse Farms recently amended its labeling. Bolthouse previously labeled its 100% juices, "SWEETENED ONLY WITH ALL NATURAL FRUIT" (acknowledging inherent sugars). The old label is below:



Bolthouse's new label, however, adopts the same deceptive "NO SUGAR ADDED" labelling used by juice market leaders:



The FDA has clearly set forth the unavailability of the “NO SUGAR ADDED” claim for 100% juices by way of 21 C.F.R. § 101.60(c)(2)(iv). We strongly believe it is in the consumers’ best interest for the FDA to enforce its rule by way of warning letters and other legal measures, where appropriate. By moving actively, the FDA would help ensure that well-intentioned consumers are protected from deceptive labeling, and more likely to experience better health outcomes through their efforts at health-conscious shopping. So too, it will avert further violation of clear FDA regulations.

We thank you in advance for your attention to this matter.

Very truly yours,

A handwritten signature in black ink, appearing to be 'Maia Kats'.

Maia Kats, Litigation Director
Laura MacCleery, Director, Regulatory Affairs
Center for Science in the Public Interest