

July 1, 2015

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RE: Coca-Cola's Apparently Illegal Claims That Its Artificially Sweetened Sodas Prevent or Treat Obesity

Dear Dr. Mayne:

This letter is a formal request that the Food and Drug Administration (FDA) stop The Coca-Cola Company from claiming that its artificially sweetened beverages prevent, mitigate or treat obesity. We urge the FDA to (a) issue a warning letter to the Coca-Cola Company concluding that it is illegally employing "disease claims" to market its artificially sweetened beverages; and, (b) if such violations are not corrected, take appropriate enforcement actions under the Federal Food, Drug and Cosmetic Act (the Act).

The Coca-Cola Company manufactures artificially sweetened beverages, including Diet Coke, Coca-Cola Zero, Coca-Cola Cherry Zero, Coca-Cola Vanilla Zero, Diet Barq's Beer, Fanta Orange Zero, Mello Yello Zero, Sprite Zero, Fresca, Pibb Zero, Seagram's Diet Ginger Ale and Tab.¹ These beverages are sweetened either with aspartame, acesulfame potassium or calcium saccharin.

On at least eight occasions, the Coca-Cola Company has claimed that its artificially sweetened beverages prevent, mitigate or treat obesity. Under FDA regulations, these appear to be "disease claims," or claims to "diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases."² Under the FDA regulatory framework, The Coca-Cola Company's claims appear to render its artificial sweetened beverages as drugs.

Even worse, while the Coca-Cola Company has repeatedly claimed that its artificially sweetened beverages prevent or treat obesity, these claims appear to be false. Scientific evidence suggests that artificial sweeteners likely do not bring weight loss, and may well cause weight gain.

¹ The Coca-Cola Company <u>products and ingredients list</u>.

² 21 U.S.C. § 343(r)(6).

A: Coca-Cola Appears to Be Making Illegal "Disease Claims" for Its Artificially Sweetened Products

During the last three years, on at least eight occasions, the Coca-Cola Company has suggested that its artificially sweetened beverages prevent, mitigate or treat obesity. These statements appear to violate federal law and FDA rules prohibiting food companies from making "disease claims" for their products.

1: Coca-Cola's Announcement of "Global Commitments to Help Fight Obesity"

In the Coca-Cola Company's news release, titled "Coca-Cola Announces Global Commitments to Help Fight Obesity," the leading "commitment" in its effort to "fight obesity" is to "Offer low- or no- calorie beverage options in every market." The news release prominently features a photograph of a woman drinking from a bottle of artificially sweetened Coke Zero.³

The Coca-Cola Company's statement that artificially sweetened beverages are a key part of its effort to "fight obesity" appears to violate FDA rules, because it triggers provision 21 C.F.R. § 101.93(g)(2)(i), since it implies that artificially sweetened beverages have an effect on a specific disease, obesity.

This news release also appears to violate FDA rules, because it triggers provision 21 C.F.R. § 101.93(g)(2)(iv)(E), since the Coca-Cola Company's "Commitments to Help Fight Obesity" prominently features a photograph displaying the consumption of artificially sweetened Coke Zero. The photo implies that consuming artificially sweetened Coke Zero is a legitimate way to "fight obesity."

2: Coca-Cola's Infographic on Its "Global Commitments to Help Fight Obesity"

The Coca-Cola Company released an infographic titled "Illustrating Coca-Cola's Global Commitments to Help Fight Obesity." Near the top of the infographic, the company states that it "commits to: Offer low- or no- calorie beverage options in every market."⁴

The Coca-Cola Company's statement that artificially sweetened beverages are a key part of its effort to "fight obesity" appears to be in violation of FDA rules, because it triggers provision 21 C.F.R. § 101.93(g)(2)(i), since it implies that artificially sweetened beverages have an effect on a specific disease, obesity.

³ "<u>Coca-Cola Announces Global Commitments to Help Fight Obesity</u>." The Coca-Cola Company news release, May 8, 2013.

⁴ "Infographic: Illustrating Coca-Cola's Global Commitments to Help Fight Obesity." The Coca-Cola Company.

3: Coca-Cola's "Position on Obesity"

In the Coca-Cola Company's "Position on Obesity," the company notes that it "announced four global commitments to bring people together to help find workable solutions to address obesity," and that its lead "commitment" was to "Offer low- or no-calorie beverage options in every market."⁵

The Coca-Cola Company's statement that artificially sweetened beverages are a "workable solution" to "address obesity" appears to be in violation of FDA rules, because it triggers provision 21 C.F.R. § 101.93(g)(2)(i), since it implies that artificially sweetened beverages have an effect on a specific disease, obesity.

4: Coca-Cola's "Company Policy on Nutrition Labeling and Nutrition Information"

"The Coca-Cola Company Policy on Nutrition Labeling and Nutrition Information" states that, "On May 8, 2013, The Coca-Cola Company announced four global commitments to help find workable solutions to address obesity." The company's leading "commitment" is to "Offer low- or no-calorie beverage options in every market."⁶

The Coca-Cola Company's statement that artificially sweetened beverages are a "workable solution" to "address obesity" appears to violate FDA rules, because it triggers provision 21 C.F.R. § 101.93(g)(2)(i), since it implies that artificially sweetened beverages have an effect on a specific disease, obesity.

5: Coca-Cola's "Commitment to Well-Being"

The Coca-Cola Company's "Commitment to Well-Being" states that, "In May 2013, Muhtar Kent, our Chairman and Chief Executive Officer, announced four worldwide business commitments, which galvanized our global system to help promote consumer and community well-being and help address obesity..." The leading "commitment" to "help address obesity" was to "Offer low- or no-calorie beverage options in every market."⁷ Also, this "commitment" to "help address obesity" prominently features a photograph of a woman drinking from a bottle of artificially sweetened Coke Zero.

The Coca-Cola Company's statement that artificially sweetened beverages are a key part of its effort to "help address obesity" appears to violate FDA rules, because it triggers

⁵ "<u>Our Position on Obesity</u>." The Coca-Cola Company, December 2013.

⁶ "<u>The Coca-Cola Company Policy on Nutrition Labeling and Nutrition Information</u>." The Coca-Cola Company, August 22, 2014.

⁷ "<u>Our Commitment to Well-Being</u>." The Coca-Cola Company, September 22, 2014.

provision 21 C.F.R. § 101.93(g)(2)(i), since it implies that artificially sweetened beverages have an effect on a specific disease, obesity.

The Coca-Cola Company's statement also appears to violate FDA rules, because it triggers provision 21 C.F.R. § 101.93(g)(2)(iv)(E), since Coca-Cola's effort to "help address obesity" prominently features the consumption of artificially sweetened Coke Zero. The photo implies that consuming artificially sweetened Coke Zero is a legitimate way to "help address obesity."

6: Coca-Cola's "2013/14 Sustainability Report

The Coca-Cola Company's "2013/14 Sustainability Report" stated that its top two "2013 Highlights" were that it "Announced four global business commitments to promote wellbeing and to help address obesity..." and that it "Introduced more than 400 new beverage products, 100 of which are reduced-, low or no-calorie."

Also, in the section titled "Our Progress," the Coca-Cola Company's report notes that "In May 2013, Muhtar Kent, our Chairman and Chief Executive Officer, announced four worldwide business commitments, which galvanized our global system to help promote consumer and community well-being and help address obesity..." and that its leading "commitment" is to "Offer low- or no-calorie beverage options in every market."⁸

Both of these statements in the Coca-Cola Company's "Sustainability Report" appear to violate FDA rules, because they trigger provision 21 C.F.R. § 101.93(g)(2)(i), since they imply that artificially sweetened beverages have an effect on a specific disease, obesity.

7: Coca-Cola's 2013 TV Ad on Obesity

In January 2013, the Coca-Cola Company released a TV advertisement to explain the company's stance on "beating obesity." The company explains that, "as the nation's leading beverage company, we can play an important role." It continues that, "we now offer over 180 low and no calorie choices, and most of our full calorie beverages now have low or no calorie versions."

Regarding schools, the ad states that, "our industry has voluntarily changed its offerings to primarily waters, juices and low and no calorie options..." The advertisement features pictures of many artificially sweetened sodas and beverages manufactured by the Coca-Cola Company.⁹

The Coca-Cola Company's implication that artificially sweetened beverages are part of its effort to "play an important role" in "beating obesity" appears to be in violation of FDA

⁸ <u>Coca-Cola 2013/14 Sustainability Report</u>. The Coca-Cola Company.

⁹ "<u>Coca-Cola's New Ad: Obesity 'Concerns All of Us' – Video</u>." *Guardian*, January 15, 2013.

rules, because it triggers provision 21 C.F.R. § 101.93(g)(2)(i), since it implies that artificially sweetened beverages have an effect on a specific disease, obesity.

The Coca-Cola Company's statement also appears to be in violation of FDA rules, because it triggers provision 21 C.F.R. § 101.93(g)(2)(iv)(E), since the Coca-Cola Company's effort to "play an important role" in "beating obesity" features pictures of many of the Coca-Cola Company's artificially sweetened sodas and beverages.

8: Coca-Cola's Statement on "Public Policy Engagement"

On its web page on "Public Policy Engagement," the Coca-Cola Company states that, "By partnering with families, whole communities, industry, government, health care experts and other concerned citizens and organizations around the world, we believe we can help to provide a positive contribution to help address obesity." The company explains that it has made four "current global commitments to well-being," and the first one is "Offering low or no-calorie beverage options in all of our markets."¹⁰

The Coca-Cola Company's statement that artificially sweetened beverages are part of its effort to "help address obesity" appears to violate FDA rules, because it triggers provision 21 C.F.R. § 101.93(g)(2)(i), since it implies that artificially sweetened beverages have an effect on a specific disease, obesity.

In summary, these eight Coca-Cola Company claims listed above appear to meet FDA's definition of a "disease claim" to prevent, mitigate or treat obesity.

B: Federal Law and FDA Rules Prohibit Food Companies from Making "Disease Claims"

Federal law prohibits food companies from making "disease claims," or claims to "diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases."¹¹

FDA regulations state that:

FDA will find that a statement about a product claims to diagnose, mitigate, treat, cure, or prevent disease (other than a classical nutrient deficiency disease) under 21 U.S.C. 343(r)(6) if it meets one or more of the criteria listed below.... In determining whether a statement is a disease claim under these criteria, FDA will consider the context in which the claim is presented.

¹⁰ "<u>Public Policy Engagement</u>." The Coca-Cola Company.

¹¹ 21 U.S.C. § 343(r)(6).

A statement claims to diagnose, mitigate, treat, cure, or prevent disease if it claims, explicitly or implicitly, that the product:

(i) Has an effect on a specific disease or class of diseases;....

(iv) Has an effect on a disease or diseases through one or more of the following factors:....

(E) Use of pictures, vignettes, symbols, or other means;....

(x) Otherwise suggests an effect on a disease or diseases.¹²

In addition, an FDA guidance document explains that:

A statement is a disease claim if it mentions a specific disease or class of diseases. For example, a claim that a product is "protective against the development of cancer" or "reduces the pain and stiffness associated with arthritis" would be a disease claim.

A statement also is a disease claim if it implies that it has an effect on a specific disease or class of diseases by using descriptions of the disease state. Examples of implied disease claims are "relieves crushing chest pain (angina)," "improves joint mobility and reduces inflammation (rheumatoid arthritis)," or "relief of bronchospasm (asthma)."¹³

C: Coca-Cola's Statements on Obesity Do Not Qualify for "Health Claim" Status

FDA guidance provides that:

Disease claims require prior approval by FDA and may be made only for products that are approved drug products or for foods under separate legal provisions that apply to claims called "health claims."¹⁴

According to FDA guidance, "Health claims describe a relationship between a food substance (a food, food component, or dietary supplement ingredient), and reduced risk of a disease or health-related condition."¹⁵

¹² 21 C.F.R. § 101.93(g).

¹³ "<u>Guidance for Industry: Structure/Function Claims, Small Entity Compliance Guide</u>." U.S. Food and Drug Administration, January 9, 2002. See also 65 FR 1000.

¹⁴ "<u>Guidance for Industry: Structure/Function Claims, Small Entity Compliance Guide</u>." U.S. Food and Drug Administration, January 9, 2002.

¹⁵ "<u>Label Claims for Conventional Foods and Dietary Supplements</u>." U.S. Food and Drug Administration, December 2013.

The Coca-Cola Company's statements are ineligible for "health claim" status. The principal reason why is that "health claims" must based on scientific evidence. A growing body of scientific evidence suggests that artificial sweeteners do not bring weight loss, and may well cause weight gain. The company's claims are also ineligible for "health claim" status because they are too strong – the company's claims propose that artificially sweetened beverages ameliorate obesity, not merely reduce the risk of it.

D: Obesity is Widely Recognized as a Disease

Obesity is widely understood to be a disease. For example, in 2000, the FDA stated in the Federal Register that, "obesity is a disease."¹⁶ In 2013, the American Medical Association officially recognized obesity as a disease.¹⁷

E: Coca-Cola Is Promoting Its Artificially Sweetened Sodas as Drugs

As you know, FDA determines whether to regulate any specific product as a based on the product's intended use. If a product is labeled, advertised or promoted in a manner consistent with it being a "drug," FDA will regulate it as a "drug." FDA regulations state that intended use refers:

to the objective intent of the persons legally responsible for the labeling of drugs. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives.¹⁸

The Coca-Cola Company is promoting its artificially sweetened beverages for a disease that causes them to be classified as drugs under section 201(g)(1)(B) of the Act. The claims on the Coca-Cola Company's website and elsewhere establish that these beverages are drugs because they are "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease..."¹⁹

¹⁶ 65 F.R. 1000.

¹⁷ Andrew Pollack, "<u>A.M.A. Recognizes Obesity as a Disease</u>." *New York Times*, June 18, 2013. "<u>AMA Adopts New Policies on Second Day of Voting at Annual Meeting</u>." American Medical Association news release, June 18, 2013.

¹⁸ 21 C.F.R. § 201.128.

¹⁹ 21 U.S.C § 321(g)(1)(B).

The Coca-Cola Company may argue that its statements are properly classified as a "structure/function claims,"²⁰ in that the claims are to have an effect on a structure or function of the human body. This classification is incorrect, because the Coca-Cola Company is referencing a specific disease – obesity – in the above eight statements. The Coca-Cola's Company's claims appear to be illegal, because they imply that its artificially sweetened beverages are "intended for [the] cure, mitigation, treatment, or prevention of [the] disease"²¹ of obesity.

F: Coca-Cola's "Disease Claims" for Its Artificially Sweetened Beverages Are False

There is a strong appearance that the Coca-Cola Company has – on at least eight occasions - made "disease claims" on behalf of its artificially sweetened beverages.

Aside from the apparent illegality of the Coca-Cola Company's "disease claims" on behalf of its artificially sweetened beverages, what makes these claims galling is that they are likely false.

Four reviews of the scientific literature on artificial sweeteners suggest that they do not contribute to weight loss, and instead link them to weight gain.

- A 2010 Yale Journal of Biology and Medicine review of the literature on artificial sweeteners concludes that, "research studies suggest that artificial sweeteners may contribute to weight gain."²²
- A 2009 American Journal of Clinical Nutrition review article finds that the "addition of NNS [nonnutritive sweeteners] to diets poses no benefit for weight loss or reduced weight gain without energy restriction. There are long-standing and recent concerns that inclusion of NNS in the diet promotes energy intake and contributes to obesity."²³

²⁰ 21 C.F.R. § 101.93(f).

²¹ 21 U.S.C § 321(g)(1)(B).

²² Yang Q, "<u>Gain Weight by 'Going Diet?' Artificial Sweeteners and the Neurobiology of</u> <u>Sugar Cravings</u>." *Yale Journal of Biology and Medicine*, 2010 Jun;83(2):101-8. PMID: 20589192.

²³ Mattes RD, Popkin BM, "<u>Nonnutritive Sweetener Consumption in Humans: Effects on</u> <u>Appetite and Food Intake and Their Putative Mechanisms</u>." *American Journal of Clinical Nutrition*, December 3, 2008. 2009 Jan;89(1):1-14. PMID: 19056571.

- A 2010 *International Journal of Pediatric Obesity* review article states that "Data from large, epidemiologic studies support the existence of an association between artificially-sweetened beverage consumption and weight gain in children."²⁴
- A 2013 *Trends in Endocrinology and Metabolism* review article finds "accumulating evidence suggests that frequent consumers of these sugar substitutes may also be at increased risk of excessive weight gain, metabolic syndrome, type 2 diabetes, and cardiovascular disease," and that "frequent consumption of high-intensity sweeteners may have the counterintuitive effect of inducing metabolic derangements."²⁵

Epidemiological evidence suggests that artificial sweeteners are implicated in weight gain. For example:

- The San Antonio Heart Study "observed a classic, positive dose-response relationship between AS [artificially sweetened] beverage consumption and long-term weight gain." Furthermore, it found that consuming more than 21 artificially sweetened beverages per week compared to those who consumed none, "was associated with almost-doubled risk" of overweight or obesity."²⁶
- A study of beverage consumption among children and adolescents aged 6-19 found that "BMI is positively associated with consumption of diet carbonated beverages."²⁷
- A two-year study of 164 children found that "Increases in diet soda consumption were significantly greater for overweight and subjects who gained weight as compared to normal weight subjects. Baseline BMI Z-score and year 2 diet soda consumption predicted 83.1% of the variance in year 2 BMI Z-score." It also found that "Diet soda consumption was the only type of beverage associated with year 2

 ²⁴ Brown RJ, de Banate MA, Rother KI, "<u>Artificial Sweeteners: a Systematic Review of</u> <u>Metabolic Effects in Youth</u>." *International Journal of Pediatric Obesity*, 2010 Aug;5(4):305-12. PMID: 20078374.

²⁵ Swithers SE, "<u>Artificial Sweeteners Produce the Counterintuitive Effect of Inducing</u> <u>Metabolic Derangements</u>." *Trends in Endocrinology and Metabolism*, July 10, 2013. 2013 Sep;24(9):431-41. PMID: 23850261.

²⁶ Fowler SP, Williams K, Resendez RG, Hunt KJ, Hazuda HP, Stern MP. "<u>Fueling the Obesity</u> <u>Epidemic? Artificially Sweetened Beverage Use and Long-Term Weight Gain</u>." *Obesity*, 2008 Aug;16(8):1894-900. PMID: 18535548.

²⁷ Forshee RA, Storey ML, "<u>Total Beverage Consumption and Beverage Choices Among</u> <u>Children and Adolescents</u>." *International Journal of Food Sciences and Nutrition*. 2003 Jul;54(4):297-307. PMID: 12850891.

BMI Z-score, and consumption was greater in overweight subjects and subjects who gained weight as compared to normal weight subjects at two years."²⁸

• The U.S. Growing Up Today study of more than 10,000 children aged 9-14 found that, for boys, intakes of diet soda "were significantly associated with weight gains."²⁹

Other types of studies similarly suggest that artificial sweeteners do not contribute to weight loss. For example, interventional studies do not support the notion that artificial sweeteners produce weight loss. According to the *Yale Journal of Biology and Medicine* review of the scientific literature, "consensus from interventional studies suggests that artificial sweeteners do not help reduce weight when used alone."³⁰

Some studies also suggest that artificial sweeteners increase appetite, which may promote weight gain. For example, the *Yale Journal of Biology and Medicine* review found that "Preload experiments generally have found that sweet taste, whether delivered by sugar or artificial sweeteners, enhanced human appetite."³¹

Studies based on rodents suggest that consumption of artificial sweeteners can lead to consuming extra food. According to the *Yale Journal of Biology and Medicine* review, "Inconsistent coupling between sweet taste and caloric content can lead to compensatory overeating and positive energy balance." In addition, according to the same article, "artificial sweeteners, precisely because they are sweet, encourage sugar craving and sugar dependence."³²

A 2014 study in the *American Journal of Public Health* found that "Overweight and obese adults in the United States drink more diet beverages than healthy-weight adults, consume significantly more calories from solid food—at both meals and snacks—than overweight

²⁸ Blum JW, Jacobsen DJ, Donnelly JE, "<u>Beverage Consumption Patterns in Elementary</u> <u>School Aged Children Across a Two-Year Period</u>." *Journal of the American College of Nutrition*, 2005 Apr;24(2):93-8. PMID: 15798075.

²⁹ Berkey CS, Rockett HR, Field AE, Gillman MW, Colditz GA. "<u>Sugar-Added Beverages and</u> <u>Adolescent Weight Change</u>."*Obes Res.* 2004 May;12(5):778-88. PMID: 15166298.

³⁰ Yang Q, "<u>Gain Weight by 'Going Diet?' Artificial Sweeteners and the Neurobiology of</u> <u>Sugar Cravings</u>." *Yale Journal of Biology and Medicine*, 2010 Jun;83(2):101-8. PMID: 20589192.

³¹ Yang Q, "<u>Gain Weight by 'Going Diet?' Artificial Sweeteners and the Neurobiology of</u> <u>Sugar Cravings</u>." *Yale Journal of Biology and Medicine*, 2010 Jun;83(2):101-8. PMID: 20589192.

³² Yang Q, "<u>Gain Weight by 'Going Diet?' Artificial Sweeteners and the Neurobiology of</u> <u>Sugar Cravings</u>." *Yale Journal of Biology and Medicine*, 2010 Jun;83(2):101-8. PMID: 20589192.

and obese adults who drink SSBs [sugar-sweetened beverages], and consume a comparable amount of total calories as overweight and obese adults who drink SSBs."³³

A 2015 study of older adults in the *Journal of the American Geriatrics Society* found "In a striking dose-response relationship," that "increasing DSI [diet soda intake] was associated with escalating abdominal obesity..."³⁴

An important 2014 study published in *Nature* found that "consumption of commonly used NAS [non-caloric artificial sweetener] formulations drives the development of glucose intolerance through induction of compositional and functional alterations to the intestinal microbiota....our results link NAS consumption, dysbiosis and metabolic abnormalities....Our findings suggest that NAS may have directly contributed to enhancing the exact epidemic that they themselves were intended to fight."³⁵

However, not all recent studies find a link between artificial sweeteners and weight gain. Two industry-funded studies did not.

A 2014 *American Journal of Clinical Nutrition* meta-analysis concluded that "Findings from observational studies showed no association between LCS [low-calorie sweetener] intake and body weight or fat mass and a small positive association with BMI [body mass index]; however, data from RCTs [randomized controlled trials], which provide the highest quality of evidence for examining the potentially causal effects of LCS intake, indicate that substituting LCS options for their regular-calorie versions results in a modest weight loss and may be a useful dietary tool to improve compliance with weight loss or weight maintenance plans." The authors "received funding to conduct this research from the North American Branch of the International Life Sciences Institute (ILSI)."³⁶ According to a 2010 article in *Nature*, ILSI is "largely funded by food, chemical and pharmaceutical companies."³⁷

A 2014 study in the journal *Obesity* tested water against artificially sweetened beverages for a 12-week weight loss program, finding that "water is not superior to NNS [non-nutritive sweetened] beverages for weight loss during a comprehensive behavioral weight

³³ Bleich SN, Wolfson JA, Vine S, Wang YC, "<u>Diet-Beverage Consumption and Caloric Intake</u> <u>Among US Adults, Overall and by Body Weight</u>." *American Journal of Public Health*, January 16, 2014. 2014 Mar;104(3):e72-8. PMID: 24432876.

 ³⁴ Fowler S, Williams K, Hazuda H, <u>"Diet Soda Intake Is Associated with Long-Term</u> Increases in Waist Circumference in a Biethnic Cohort of Older Adults: The San Antonio Longitudinal Study of Aging." Journal of the American Geriatrics Society, March 17, 2015.
³⁵ Suez J. et al., <u>"Artificial Sweeteners Induce Glucose Intolerance by Altering the Gut</u> Microbiota." Nature, September 17, 2014. 2014 Oct 9;514(7521):181-6. PMID: 25231862
³⁶ Miller PE, Perez V, <u>"Low-Calorie Sweeteners and Body Weight and Composition: a Meta-Analysis of Randomized Controlled Trials and Prospective Cohort Studies.</u>" American Journal of Clinical Nutrition, June 18, 2014. 2014 Sep;100(3):765-77. PMID: 24944060.
³⁷ Declan Butler, <u>"Food Agency Denies Conflict-of-Interest Claim.</u>" Nature, October 5, 2010.

loss program." The study was "fully funded by the American Beverage Association,"³⁸ which is the main lobbying group for the soda industry.

There is strong evidence that industry-funded studies in biomedical research are less trustworthy than those funded independently. A 2007 *PLOS Medicine* study on industry support for biomedical research found that "Industry funding of nutrition-related scientific articles may bias conclusions in favor of sponsors' products, with potentially significant implications for public health....scientific articles about commonly consumed beverages funded entirely by industry were approximately four to eight times more likely to be favorable to the financial interests of the sponsors than articles without industry-related funding. Of particular interest, none of the interventional studies with all industry support had an unfavorable conclusion...."³⁹

G: Conclusion

This letter demonstrates that the Coca-Cola Company is marketing its artificially sweetened beverages in a manner consistent with classifying them as drugs, because it promotes them as preventing, mitigating or treating obesity.

We urge the FDA to issue a warning letter to the Coca-Cola Company to cease and desist from making illegal "disease claims" that its artificially sweetened beverages prevent, mitigate or treat obesity. If the Coca-Cola Company does not stop making these disease claims, we urge the FDA take appropriate enforcement actions under the Act.

The FDA should take enforcement action in this matter because these "disease claims" appear to be not only illegal, but also false.

Sincerely,

Gary Ruskin Co-Director

 ³⁸ Peters JC et al., "<u>The Effects of Water and Non-Nutritive Sweetened Beverages on Weight Loss During a 12-Week Weight Loss Treatment Program</u>." *Obesity*, 2014 Jun;22(6):1415-21.
PMID: 24862170.

³⁹ Lesser LI, Ebbeling CB, Goozner M, Wypij D, Ludwig DS. "<u>Relationship Between Funding</u> <u>Source and Conclusion Among Nutrition-Related Scientific Articles</u>." *PLOS Medicine*, 2007 Jan;4(1):e5. PMID: 17214504.