

April 9, 2015

Division of Dockets Management Food and Drug Administration Department of Health and Human Services 5630 Fishers Lane, Room 1061 Rockville, MD 20852

VIA FACSIMILE: (301) 827-6870

CITIZEN PETITION

The undersigned, U.S. Right to Know, submits this petition under section 403 of the Federal Food, Drug and Cosmetic Act (the "Act"), 21 U.S.C. §343, to request the Commissioner of Food and Drugs to (a) issue a warning letter to the Coca-Cola Company concluding that Diet Coke is misbranded under section 403 because the use of the term "diet" is false and misleading; (b) issue a warning letter to PepsiCo Inc. concluding that Diet Pepsi is misbranded under section 403 because the use of the term "diet" is false and misleading; (c) if such violations are not corrected, take appropriate enforcement actions under the Act; and, (d) investigate the use of the term "diet," and other terms implying weight loss, in other artificially sweetened foods and beverages, to determine whether those products are misbranded under section 403 of the Act.

A: Actions Requested

We request the Commissioner of Food and Drugs to (a) issue a warning letter to The Coca-Cola Company concluding that Diet Coke is misbranded under section 343 because the use of the term "diet" is false and misleading; (b) issue a warning letter to PepsiCo concluding that Diet Pepsi is misbranded under section 343 because the use of the term "diet" is false and misleading; (c) if such violations are not corrected, take appropriate enforcement actions under the Act; and (d) investigate use of the term "diet" in other food and beverage products containing artificial sweeteners. As set forth in detail below in the Statement of Grounds, scientific evidence suggests the presence of the artificial sweeteners -- on which the "diet" claims on the labeling of Diet Coke and Diet Pepsi are based -- actually contribute to weight gain, not weight loss.

In addition, we request that the FDA conduct a sweeping investigation of products containing artificial sweeteners, to determine whether any of these products' brand names or labels are false or misleading, by representing or suggesting that they are "diet" products or that they promote weight loss.

We ask that the FDA conduct this investigation urgently, given the potential for consumer harm, in that companies are portraying products as assisting with weight loss, when in fact they may well

Exposing what the food industry doesn't want us to know

contribute to weight gain. Such weight gain increases the risk of serious diseases, such as type 2 diabetes, cardiovascular disease and some forms of cancer.

B: Statement of Grounds

i: Legal Background: Federal Law and FDA Rules Require That the Use of the Term "Diet" in a Brand Name or Label Must Not Be False or Misleading

The Act prohibits "labeling [that] is false or misleading in any particular." Any food with such labeling is deemed misbranded. The Act prohibits the "introduction or delivery for introduction into interstate commerce of any food...that is adulterated or misbranded."

Section 403 of the Act, as amended by the Nutrition Labeling and Education Act of 1990, sets out detailed requirements for health-based claims in foods. Section 343(r)(2)(D), 21 U.S.C. § 343(r)(2)(D) makes subparagraph 2 inapplicable to such a claim on the labeling of a soft drink if the brand in which the claim appears was in use before October 25, 1989; but such a claim is subject to paragraph (a), referring to section 343(a), which provides that a food is misbranded if "its labeling is false or misleading in any particular." Implementing these provisions, FDA regulations provide that companies may use the term "diet" in a brand name or label of a soft drink described in section 343(r)(2)(D) only when it is not false or misleading:

A soft drink that used the term diet as part of its brand name before October 25, 1989, and whose use of that term was in compliance with 105.66 of this chapter as that regulation appeared in the Code of Federal Regulations on that date, may continue to use that term as part of its brand name, provided that its use of the term is not false or misleading under section 403(a) of the act. Such claims are exempt from the requirements of section 403(r)(2) of the act (e.g., the disclosure statement also required by 101.13(h)). Soft drinks marketed after October 25, 1989, may use the term "diet" provided they are in compliance with the current 105.66 of this chapter and the requirements of 101.13.3

More generally, regarding the use of the term "diet" in labels, FDA regulations state:

Except as provided in paragraphs (e)(2) and (e)(3) of this section, and in § 101.13(q)(2) of this chapter for soft drinks, a food may be labeled with terms such as "diet," "dietetic," "artificially sweetened," or "sweetened with nonnutritive sweetener" only if the claim is not false and misleading, and the food is labeled "low calorie" or

¹ 21 U.S.C. § 343(a).

² 21 U.S.C. § 331(a).

³ 21 C.F.R. § 101.13(q)(2).

"reduced calorie" or bears another comparative calorie claim in compliance with part 101 of this chapter and this section.⁴

ii: Factual Background: Coca-Cola Co. and PepsiCo Inc. Employ the Term "Diet" in Diet Coke and Diet Pepsi

The Coca-Cola Co. and PepsiCo Inc. use the term "diet" both on their labels and advertisements for their products Diet Coke and Diet Pepsi. According to *Beverage Digest* and *Advertising Age*, Diet Coke was the third most popular carbonated soft drink brand in 2014, and Diet Pepsi was the seventh most popular.⁵

Dictionary definitions of the term "diet" commonly refer to weight loss. For example, the *Merriam-Webster Dictionary* defines the noun "diet" as "a regimen of eating and drinking sparingly so as to reduce one's weight." The *Oxford Dictionaries* define diet as "A special course of food to which one restricts oneself, either to lose weight or for medical reasons." The *American Heritage College Dictionary* defines diet as "To eat and drink according to a regulated system, esp. so as to lose weight or control a medical condition." The *Collins English Dictionary* defines diet as "a specific allowance or selection of food, esp prescribed to control weight or in disorders in which certain foods are contraindicated."

In the case of Diet Coke and Diet Pepsi, Coca-Cola Co. and PepsiCo Inc. use the term "diet" because of the substitution of non-caloric artificial sweeteners for caloric natural sweeteners. Diet Coke is sweetened with the artificial sweetener aspartame, 10 while Diet Pepsi contains the artificial sweeteners aspartame and acesulfame potassium. 11

According to the Calorie Control Council, the artificial sweetener aspartame is found in "more than 6,000 products including carbonated soft drinks, powdered soft drinks, chewing gum, confections, gelatins, dessert mixes, puddings and fillings, frozen desserts, yogurt, [and] tabletop sweeteners." ¹² In addition, according to a 2012 ABC News article, the artificial sweetener sucralose is used in 4,500 food and beverage products. ¹³

⁴ 21 C.F.R. § 105.66(e)(1).

⁵ E. J. Schultz, "<u>Pepsi Passes Diet Coke in Market Share as Artificial Sweeteners Fall Out of Favor</u>." *Advertising Age*, March 26, 2015.

⁶ Merriam-Webster Dictionary definition of "diet."

⁷ Oxford Dictionaries definition of "diet."

⁸ American Heritage College Dictionary. (Boston: Houghton Mifflin, 1993), third edition, p. 387.

⁹ Collins English Dictionary definition of "diet."

¹⁰ See Coca-Cola product information.

¹¹ See PepsiCo product information.

¹² Aspartame Information Center, web page on "<u>Consumer Products</u>." Calorie Control Council, accessed March 19, 2015.

¹³ Liz Neporent, "Sweet Nothings: Making Sense of Artificial Sweeteners." ABC News, June 13, 2012.

iii: Scientific Background: Many Studies Suggest that Artificial Sweeteners Contribute to Weight Gain, Not Weight Loss

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."¹⁴
- 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." 15
- 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."
- 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."

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

2008. 2009 Jan;89(1):1-14. PMID: 19056571.

Yang Q, "Gain Weight by 'Going Diet?' Artificial Sweeteners and the Neurobiology of Sugar Cravings." Yale Journal of Biology and Medicine, 2010 Jun;83(2):101-8. PMID: 20589192.
Mattes RD, Popkin BM, "Nonnutritive Sweetener Consumption in Humans: Effects on Appetite and Food Intake and Their Putative Mechanisms." American Journal of Clinical Nutrition, December 3,

 ¹⁶ Brown RJ, de Banate MA, Rother KI, "<u>Artificial Sweeteners: a Systematic Review of Metabolic Effects in Youth</u>." *International Journal of Pediatric Obesity*, 2010 Aug;5(4):305-12. PMID: 20078374.
¹⁷ Swithers SE, "<u>Artificial Sweeteners Produce the Counterintuitive Effect of Inducing Metabolic Derangements</u>." *Trends in Endocrinology and Metabolism*, July 10, 2013. 2013 Sep;24(9):431-41.
PMID: 23850261.

week – compared to those who consumed none, "was associated with almost-doubled risk" of overweight or obesity." ¹⁸

- A study of beverage consumption among children and adolescents aged 6-19 found that "BMI is positively associated with consumption of diet carbonated beverages." ¹⁹
- 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 BMI Z-score, and consumption was greater in overweight subjects and subjects who gained weight as compared to normal weight subjects at two years."²⁰
- 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."²¹

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."²²

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."²³

¹⁸ Fowler SP, Williams K, Resendez RG, Hunt KJ, Hazuda HP, Stern MP. "<u>Fueling the Obesity Epidemic? Artificially Sweetened Beverage Use and Long-Term Weight Gain</u>." *Obesity*, 2008 Aug;16(8):1894-900. PMID: 18535548.

¹⁹ Forshee RA, Storey ML, "<u>Total Beverage Consumption and Beverage Choices Among Children and Adolescents</u>." *International Journal of Food Sciences and Nutrition*. 2003 Jul;54(4):297-307. PMID: 12850891.

²⁰ Blum JW, Jacobsen DJ, Donnelly JE, "<u>Beverage Consumption Patterns in Elementary School Aged Children Across a Two-Year Period</u>." *Journal of the American College of Nutrition*, 2005 Apr;24(2):93-8. PMID: 15798075.

²¹ Berkey CS, Rockett HR, Field AE, Gillman MW, Colditz GA. "Sugar-Added Beverages and Adolescent Weight Change." *Obes Res.* 2004 May;12(5):778-88. PMID: 15166298.

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

²³ Yang Q, "Gain Weight by 'Going Diet?' Artificial Sweeteners and the Neurobiology of Sugar Cravings." *Yale Journal of Biology and Medicine*, 2010 Jun;83(2):101-8. PMID: 20589192.

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."²⁴

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 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."²⁵

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..."²⁶

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."²⁷

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

²⁴ Yang Q, "<u>Gain Weight by 'Going Diet?' Artificial Sweeteners and the Neurobiology of Sugar Cravings</u>." *Yale Journal of Biology and Medicine*, 2010 Jun;83(2):101-8. PMID: 20589192.

²⁵ Bleich SN, Wolfson JA, Vine S, Wang YC, "<u>Diet-Beverage Consumption and Caloric Intake 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.

²⁶ Fowler S, Williams K, Hazuda H, "Diet Soda Intake Is Associated with Long-Term 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.

²⁷ Suez J. et al., "<u>Artificial Sweeteners Induce Glucose Intolerance by Altering the Gut Microbiota</u>." *Nature*, September 17, 2014. 2014 Oct 9;514(7521):181-6. PMID: 25231862

from the North American Branch of the International Life Sciences Institute (ILSI)."²⁸ According to a 2010 article in *Nature*, ILSI is "largely funded by food, chemical and pharmaceutical companies."²⁹

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 loss program." The study was "fully funded by the American Beverage Association," 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..."³¹

iv: Representing That Diet Coke and Diet Pepsi Are "Diet" Products Appears to Be False, Misleading and in Violation of the Act and FDA Regulations

The Act prohibits "labeling [that] is false or misleading in any particular."³² If a claim is misleading, it may be remedied with an appropriate disclaimer; and if it is inherently misleading, the Commissioner may prohibit the claim even a disclaimer is used. *E.g., Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999); *Whitaker v. Thompson*, 248 F. Supp.2d 1 (D.D.C. 2002).

The term "diet," as employed in brand names and labels by Coca-Cola Co. and PepsiCo Inc., is a representation that inherently and necessarily implies that the products Diet Coke and Diet Pepsi assist in weight loss.

However, the preponderance of the scientific evidence available contradicts that representation. In fact, there is substantial scientific evidence that artificial sweeteners may foster weight gain. That makes the "diet" representation apparently false and misleading.

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²⁸ 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.

²⁹ Declan Butler, "Food Agency Denies Conflict-of-Interest Claim." *Nature*, October 5, 2010.

³⁰ 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.

³¹ Lesser LI, Ebbeling CB, Goozner M, Wypij D, Ludwig DS. "<u>Relationship Between Funding Source</u> and Conclusion Among Nutrition-Related Scientific Articles." *PLOS Medicine*, 2007 Jan;4(1):e5. PMID: 17214504.

³² 21 U.S.C. § 343(a).

Despite full knowledge of the relevant scientific evidence, which has been published in scientific journals and recounted in major news outlets, Coca-Cola Co. and PepsiCo Inc. continue to use the term "diet" for their Diet Coke and Diet Pepsi products.

It is easy to grasp why. Americans spend about \$60 billion each year on weight loss.³³ Any representation that a product could help consumers lose weight is potentially worth many millions of dollars in annual sales.

v: Consumer Harm from the Use of the Term "Diet" by Coca-Cola Co. and PepsiCo Inc.

Consumers appear to be harmed by the use of the term "diet" in Diet Coke and Diet Pepsi in several ways.

Consumers are using products – Diet Coke and Diet Pepsi -- that are advertised to make us think they assist in weight loss, when in fact ample scientific evidence suggests that this is not true, and the opposite may well be true. In this respect, the use of the term "diet" appears to be not only false and misleading, but perhaps fraudulent as well.

Would consumers purchase Diet Coke or Diet Pepsi if they knew that it likely will not help them lose weight, and may well make them gain weight? Perhaps some might, but almost certainly many would not.

Consumers who wish to lose weight may actually suffer physical harm from consuming Diet Coke and Diet Pepsi, in that these products may lead them to gain weight instead losing it. Extensive scientific evidence suggests that weight gain, overweight and obesity increases the risk of serious diseases, including type 2 diabetes,³⁴ cardiovascular disease³⁵ and some types

³³ Geoff Williams, "<u>The Heavy Price of Losing Weight</u>." *U.S. News & World Report*, January 2, 2013. "<u>The U.S. Weight Loss Market: 2014 Status Report & Forecast</u>." Marketdata Enterprises, February 1, 2014. Drew Harwell, "<u>Americans' New Way of Losing Weight Has Left Weight Watchers Behind."</u> *Washington Post*, October 29, 2014.

³⁴ Colditz GA, Willett WC, Rotnitzky A, Manson JE, "<u>Weight Gain as a Risk Factor for Clinical Diabetes Mellitus in Women</u>." *Annals of Internal Medicine*, 1995 Apr 1;122(7):481-6. PMID: 7872581. Koh-Banerjee P, Wang Y, Hu FB, Spiegelman D, Willett WC, Rimm EB. "<u>Changes in Body Weight and Body Fat Distribution as Risk Factors for Clinical Diabetes in US Men</u>." *American Journal of Epidemiology*, 2004 Jun 15;159(12):1150-9. PMID: 15191932

³⁵ Bogers RP et al., "Association of Overweight with Increased Risk of Coronary Heart Disease Partly Independent of Blood Pressure and Cholesterol Levels: a Meta-Analysis of 21 Cohort Studies Including More Than 300 000 Persons." Archives of Internal Medicine, 2007 Sep 10;167(16):1720-8. PMID: 17846390. Strazzullo P, D'Elia L, Cairella G, Garbagnati F, Cappuccio FP, Scalfi L, "Excess Body Weight and Incidence of Stroke: Meta-Analysis of Prospective Studies with 2 Million Participants." Stroke, 2010 May;41(5):e418-26. PMID: 20299666. McGee DL, "Body Mass Index and Mortality: a

of cancer³⁶ – and also brings economic costs,³⁷ such as decreased productivity, increased health care costs, and decreased quality of life.

Some studies propose links between artificial sweeteners and the health risks arising from the sequela of weight gain. For example, a study on older adults in the *Journal of the American Geriatrics Society* found "In a striking dose-response relationship, increasing DSI [diet soda intake] was associated with escalating abdominal obesity, a potential pathway for cardiometabolic risk in this aging population." The study also notes that "High incidences of overweight and obesity, hypertension, metabolic syndrome, diabetes mellitus, kidney dysfunction, heart attack, and hemorrhagic stroke have all recently been associated with frequent NNSI [nonnutritive sweetener intake] and DSI."38 Along the same lines, according to a review article in *Trends in Endocrinology and Metabolism*, "Recent data from humans and rodent models have provided little support for ASB [artificially sweetened beverages] in promoting weight loss or preventing negative health outcomes such as T2D [type 2 diabetes], metabolic syndrome, and cardiovascular events. Instead, a number of studies suggest people who regularly consume ASB are at increased risk compared with those that do not consume ASB; with the magnitude of the increased risks similar to those associated with SSB [sugar-sweetened beverages]."39

D: Environmental Impact

The requested actions requested do not require the preparation of an environmental assessment.⁴⁰

E: Certification

We certify that, to our best knowledge and belief, this Petition includes all information and views on which the Petition relies, and it includes representative data and information known to the petitioner that are unfavorable to the Petition.

<u>Meta-Analysis Based on Person-Level Data from Twenty-Six Observational Studies</u>." *Annals of Epidemiology*, 2005 Feb;15(2):87-97. PMID: 15652713.

³⁶ "Food, Nutrition, Physical Activity, and the Prevention of Cancer: A Global Perspective." World Cancer Research Fund/American Institute for Cancer Research. 2007.

³⁷ "Obesity Is Hurting the U.S. Economy in Surprising Ways." *Bloomberg*, March 4, 2015.

³⁸ Fowler S, Williams K, Hazuda H, "<u>Diet Soda Intake Is Associated with Long-Term Increases in Waist Circumference in a Biethnic Cohort of Older Adults: The San Antonio Longitudinal Study of Aging."</u> *Journal of the American Geriatrics Society*, March 17, 2015.

³⁹ Swithers SE, "<u>Artificial Sweeteners Produce the Counterintuitive Effect of Inducing Metabolic Derangements</u>." *Trends in Endocrinology and Metabolism*, July 10, 2013. 2013 Sep;24(9):431-41. PMID: 23850261.

⁴⁰ For details, see 21 C.F.R. § 25.30.

F: Conclusion

There is substantial scientific evidence suggesting that Coca-Cola Co. and PepsiCo Inc. are deploying false and misleading brand names and labels for their products Diet Coke and Diet Pepsi, in violation of the Act and FDA regulations.

We urge the FDA to act swiftly to protect consumers against this apparent misbranding.

Because of the potential for physical harm to consumers from this and similar misbranding, we urge the FDA to urgently investigate Coca-Cola Co., PepsiCo Inc. and all other companies who manufacture products containing artificial sweeteners while branding or labeling them "diet" or weight loss products.

Sincerely,

Gary Ruskin

Executive Director