

February 9, 2012

Mr. William Correll
Acting Director
Office of Compliance
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

Dear Mr. Correll:

The Public Health Advocacy Institute is writing to request that the FDA investigate The Coca-Cola Company's use of health claims in the form of heart symbols and "third party" references to the National Heart Lung and Blood Institute's "The Heart Truth" campaign on the labels of its Diet Coke food product. The health claims suggest a relationship between Diet Coke consumption and reduced risk for heart disease. Such a claim is not specifically provided for in Subpart E of the FDA's Food Labeling regulations as required by 21 CFR 101.14(e).

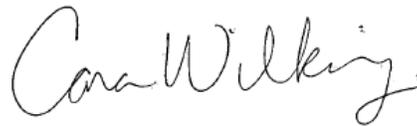
Beginning in February of 2010, The Coca-Cola Company released Diet Coke cans labeled with a large red heart symbol and the "third party" reference in the form of "The Heart Truth" Red Dress logo. Taken together, the large red heart symbol and the NHLBI's Red Dress logo imply a relationship between consuming a specific food, Diet Coke, and reduced risk for cardiovascular disease. The cans pictured below represent the cans in circulation in 2012 (left), 2011 (center) and 2010 (right).



The FDA defines health claims to include “any claim made on the label or in labeling of a food...that expressly or by implication, including ‘third party’ references, written statements (e.g., a brand name including a term such as ‘heart’), symbols (e.g., a heart symbol), or vignettes, characterizes the relationship of any substance to a disease or health-related condition. “ 21 CFR § 101.14 (a)(1). In its April 2008 “Guidance for Industry: A Food Labeling Guide,” the FDA stated “ health claims characterize a relationship between a substance (specific food component or a specific food) and a disease (e.g., lung cancer or heart disease) or health-related condition (e.g., high blood pressure), and are supported by scientific evidence (see 21 CFR 101.1472).” FDA, Guidance for Industry: A Food Labeling Guide (April 2008), <http://www.fda.gov> (emphasis added). The use of the heart symbol, the phrase “The Heart Truth” and the reference to a national health organization implies that Diet Coke consumption is beneficial to heart health. This claim is not supported by scientific evidence and is not otherwise allowed under FDA regulations.

This type of misbranding is especially damaging to the public because it unequivocally links the product to a desired health outcome through multiple uses of the word “heart” and the use of a heart symbol—expressly the type of claim the FDA sought to protect the public from in 21 CFR 101.14. We ask that you immediately investigate the Coca-Cola Company’s unlawful use of this health claim, issue the appropriate warning letter and take enforcement action as necessary.

Sincerely,

A handwritten signature in cursive script that reads "Cara Wilking".

Cara Wilking, J.D.
Staff Attorney