U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR FOOD SAFETY & APPLIED NUTRITION

October 26, 2017

Mr. Gary Ruskin
Executive Director
U.S. Right to Know
6026A Harwood Avenue
Oakland, California 94618

Docket: FDA-2015-P-1187

Dear Mr. Ruskin:

This letter responds to the petition that you submitted on behalf of U.S. Right to Know to the Food and Drug Administration (FDA or we) on April 9, 2015, concerning the use of the term "diet" to describe artificially sweetened foods and beverages. The petition requests that FDA: (1) issue a warning letter to the Coca-Cola Company concluding that Diet Coke is misbranded under section 403 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) because the term "diet" is false and misleading; (2) issue a warning letter to PepsiCo Inc. concluding that Diet Pepsi is misbranded because the use of the term "diet" is false and misleading; (3) take appropriate enforcement actions under the FD&C Act if such violations are not corrected; and (4) 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 FD&C Act (FDA-2015-P-1187 at page 1). The petition also asks us to conduct "a sweeping investigation of products containing artificial sweeteners" to determine whether any brand names or labels are false or misleading "by representing or suggesting that they are 'diet' products or that they promote weight loss" (FDA-2015-P-1187 at page 1).

We appreciate your concern about the appropriate labeling of food products. However, in accordance with 21 CFR 10.30(e)(3) and (k), and as detailed below, we are denying your petition.

Requests for FDA to initiate enforcement action and related regulatory activity are outside the scope of our citizen petition regulations (see 21 CFR 10.30(k)). A citizen petition provides a mechanism for interested persons to request that FDA issue, amend, or revoke a regulation or order, or take or refrain from taking any other form of administrative action (21 CFR 10.25(a)). However, the definition of "administrative action" does not include enforcement actions.[1]

[1] As defined, *administrative action* includes every act, including the refusal or failure to act, involved in the administration of any law by the Commissioner, except that it does not include the referral of apparent violations to U.S. attorneys for the institution of civil or criminal proceedings or an act in preparation of a referral (21 CFR 10.3(a)).

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Therefore, the requests for FDA to initiate or take enforcement actions are not proper subjects of a citizen petition.

We make decisions regarding enforcement action on a case-by-case basis, and these decisions to pursue enforcement action are within our discretion. Because the Department of Justice represents FDA in actions brought to enforce the FD&C Act and other statutes that we administer and because FDA typically refers such cases to DOJ through the local United States Attorney's Office, a decision by FDA to take enforcement action against products would be a decision related to referral of a matter to a United States Attorney for the initiation of court enforcement action.

Further, we interpret your request that we investigate other products to determine whether they are misbranded under section 403 of the FD&C Act, as a request that we publicly render an opinion on whether particular food products are in compliance with the law and take enforcement action as appropriate. Therefore, none of your requests constitute a request for an "administrative action" that can be the subject of a citizen petition, and in accordance with 21 CFR § 10.30(e)(3) and (k), we are denying your petition.

We appreciate the information you provided. This information often helps us identify problems with marketed products and possible violations of the laws and regulations that we enforce. We will evaluate the information you provided to determine whether follow-up action is needed. It is our policy to share comments about whether specific food labels meet the requirements of the FD&C Act with the firms responsible for the labeling. We take complaints seriously and share your concern about the appropriate labeling of food products so that consumers can make informed choices. However, for the reason stated earlier, we are denying your petition.

Sincerely,

Rebecca Buckner

Rebecca Buckner
Acting, Deputy Director
for Regulatory Affairs
Center for Food Safety
and Applied Nutrition