

April 5, 2018

VIA ELECTRONIC SUBMISSION

Division of Dockets Management (HFA-305) Food and Drug Administration Department of Health and Human Services 5630 Fishers Lane, Room 1061 Rockville, MD 20852

Re: Docket No. FDA-2017-P-6211; Citizen Petition from DSM Nutritional Products, LLC

The Council for Responsible Nutrition (CRN) respectfully submits these comments to the Food and Drug Administration (FDA) in support of the Citizen Petition submitted by DSM Nutritional Products, LLC (DSM) requesting that FDA amend 21 C.F.R. § 101.9(c)(8)(v) to allow the use of simple vitamin letter names on both the Nutrition and Supplement Facts labels and Ingredient Declaration lines for vitamins when added for nutritive value only. CRN has previously supported this prudent regulatory modification in comments to FDA² and appreciates the opportunity to provide additional comments. CRN is the leading trade association for the dietary supplement and functional food industry, representing manufacturers of dietary ingredients and of national brand name and private label dietary supplements.³

¹ Citizen Petition from DSM Nutritional Products, LLC [FDA-2017-P-6211] (Oct. 19, 2017), https://www.regulations.gov/document?D=FDA-2017-P-6211-0001.

² CRN Comments to: Review of Existing General Regulatory and Information Collection Requirements of the Food and Drug Administration. [FDA-2017-N-5093] (Feb. 5, 2018), https://www.crnusa.org/sites/default/files/pdfs/comments-pdfs/CRN%20Comments_FDA%20Regulatory%20Review_5February2018_Final.pdf.

The Council for Responsible Nutrition (CRN), founded in 1973 and based in Washington, D.C., is the leading trade association representing dietary supplement and functional food manufacturers, marketers and ingredient suppliers. CRN companies produce a large portion of the functional food ingredients and dietary supplements marketed in the United States and globally. Our member companies manufacture popular national brands as well as the store brands marketed by major supermarkets, drug stores and discount chains. These products also include those marketed through natural food stores and mainstream direct selling companies. CRN represents more than 150 companies that manufacture dietary ingredients, dietary supplements and/or functional foods, or supply services to those suppliers and manufacturers. Our member companies are expected to comply with a host of federal and state regulations governing dietary supplements and food in the areas of manufacturing, marketing, quality control and safety. Our supplier and manufacturer member companies also agree to adhere to additional voluntary guidelines as well as to CRN's Code of Ethics. Learn more about us at www.crnusa.org.

CRN is encouraged by Commissioner Scott Gottlieb's recent remarks indicating that FDA is considering what changes could make ingredient information on food packages more consumer friendly, including whether simpler alternative names for certain ingredients could be used so they are more understandable. ⁴ Commissioner Gottlieb stated that, for example, FDA could consider whether use of the name "vitamin B6" for "pyridoxine" and "vitamin B12" for "cyanocobalamin" might help consumers better understand what is in their food. CRN agrees that helping consumers identify healthful food products should be an important part of the FDA Nutrition Innovation Strategy that is currently in development.

DSM's Citizen Petition provides evidence indicating that the mixed common and usual naming conventions for vitamins, as per current regulations, is confusing to consumers and that many consumers do not understand the chemical names of vitamins and may not perceive these names as "healthy." CRN agrees that consistently calling a vitamin by the name most commonly understood by consumers (e.g., vitamin C, as opposed to ascorbic acid) would help reduce consumer confusion and would help consumers more easily recognize vitamin-fortified foods, thereby contributing to the nutrient density of their diets. As FDA has long recognized, the "achievement and maintenance of a desirable level of nutritional quality in the nation's food supply is an important public health objective." In addition, allowing the simple vitamin letter names to be displayed on both the Nutrition and Supplement Facts labels and Ingredient Declaration lines will simplify the overall label. CRN urges FDA to modify 21 C.F.R. § 101.9(c)(8)(v) to allow broader use of simple vitamin letter names as the agency moves forward with plans to promote public health through improved nutrition.

Respectfully submitted,

Anduk

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⁴ Reducing the Burden of Chronic Disease. Remarks by Scott Gottlieb, M.D. Commissioner of Food and Drugs. National Food Policy Conference. Washington, DC. March 29, 2018. https://www.fda.gov/NewsEvents/Speeches/ucm603057.htm.

⁵ Citizen Petition from DSM Nutritional Products, LLC at 4-5 (Citing a 2016 survey, conducted by the International Food and Information Council (IFIC), in which consumers were asked to rate the "healthfulness" of a list of ingredients. According to the survey, 42 percent of consumers were unaware of the term "ascorbic acid," and while 83 percent rated Vitamin C as healthy, only 21 percent rated ascorbic acid as healthy").

⁶ 21 C.F.R. § 104.20 (FDA's Statement of Purpose related to the nutritional quality guidelines for food).