

March 9, 2020

Stephen Hahn, M.D.
Commissioner of Food and Drugs
U.S. Food and Drug Administration
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*Re: Agency Information Collection Activities; Proposed Collection; Comment Request;
Focus Groups as Used by the Food and Drug Administration (All FDA-Regulated Products);
(Docket No. FDA-2019-N-6098)*

Dear Dr. Hahn:

The Academy of Nutrition and Dietetics (the “Academy”) appreciates the opportunity to submit comments to the Food and Drug Administration (FDA) at the U.S. Department of Health and Human Services (HHS) related to its open information collection, “Comment Request; Focus Groups as Used by the Food and Drug Administration (All FDA-Regulated Products) (Docket No. FDA-2019-N-6098),” published in the Federal Register on January 8, 2020. Representing over 107,000 registered dietitian nutritionists (RDNs);¹ nutrition and dietetic technicians, registered (NDTRs); and advanced-degree nutritionists, the Academy is the largest association of food and nutrition professionals in the United States and is committed to transforming health through the power of food and nutrition.

The Academy strongly supports the proposed information collection related to focus groups used by the FDA. Previous focus groups convened by the FDA have provided significant and substantive benefits to the FDA, stakeholders, and the public at-large. We agree that “[f]ocus groups [can] provide an important role in gathering information because they allow for a more in-depth understanding of consumers’ attitudes, beliefs, motivations, and feelings than do quantitative studies.”

Among the focus group information used by the FDA and its Center for Food Safety and Applied Nutrition to enact meaningful, evidence-based policies that protect and promote public health include initiatives related to fostering good nutrition and effective food safety practices. Specifically, the FSA has utilized focus group information as it updates the Nutrition Facts Label and front-of-package labeling, considers modifications to nutrient content claims and health claims, seeks to better understand consumers’ preferences for fortified foods, and undertakes various aspects of the ambitious and exciting Nutrition Innovation Strategy.

In each of the above consumer research areas and others undertaken by the FDA and CFSAN, the information collected has been necessary for the proper performance of FDA's functions and the information has had substantial practical utility for the Academy of Nutrition and Dietetics, the FDA, and the American public. We wholeheartedly support continued use of focus groups by the FDA in “developing variables and measures for

¹ The Academy approved the optional use of the credential “registered dietitian nutritionist (RDN)” by “registered dietitians (RDs)” to more accurately convey who they are and what they do as the nation’s food and nutrition experts. The RD and RDN credentials have identical meanings and legal trademark definitions.

quantitative studies, . . . better understanding consumers' attitudes and emotions in response to topics and concepts, and . . . further explor[ing] findings obtained from quantitative studies." It is helpful to use a mixed methods approach including both qualitative and quantitative methods to answer research questions; qualitative research—such as focus groups—can provide important context to quantitative findings.

As noted in the Journal of the Academy of Nutrition and Dietetics

QUAL and QUAN are combined so weaknesses in one approach can be compensated by strengths in the other. QUAN approaches assume that truth and facts are objective, whereas QUAL assume that truth and facts have subjective elements based on the perceptions and meanings assigned by people. QUAN approaches can, with experiments and probability sampling, allow deduction of cause and effect and generalization of results to larger populations, whereas QUAL allows the investigator to consider context and processes in an inductive way. QUAL data promote a richer description of phenomena such as an individual's perceptions, meanings, and overall experiences. Combining approaches leads to a more complete understanding of a phenomenon. For example, results from the Diabetes Prevention Program (DPP) demonstrated that through lifestyle change type 2 diabetes mellitus could be prevented. Suppose an investigator decides to replicate this program and test its effectiveness among inner-city Hispanic men. She collects baseline QUAN data, implements the study, and gathers QUAN outcome data. In contrast to previous studies, she finds the program to be ineffective at improving diabetes risk factors. This is clearly a QUAN approach. Had she added a QUAL component, conducting personal interviews with the participants at specific time points during the study, she could have gained significant insight about the men's experiences throughout the program and their perceptions of the implementation of the program. In this way she could attempt to understand why the program did not work.²

The Academy appreciates the opportunity to comment on the information collection related to focus groups used by the FDA. Please contact either Jeanne Blankenship at 312-899-1730 or by email at jblankenship@eatright.org or Pepin Tuma at 202-775-8277 ext. 6001 or by email at ptuma@eatright.org with any questions or requests.

Sincerely,



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² Zoellner J, Harris JE. Mixed-Methods Research in Nutrition and Dietetics. J Acad Nutr Diet. 2017;117(5):683-697. (Internal citations omitted.)