

Docket No. FDA-2021-N-0336

BEFORE

THE UNITED STATES OF AMERICA

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

COMMENTS OF THE

AMERICAN HERBAL PRODUCTS ASSOCIATION

ON THE

**INFORMATION COLLECTION ACTIVITIES, PROPOSED COLLECTION and
COMMENT REQUEST regarding QUANTITATIVE RESEARCH ON A
VOLUNTARY SYMBOL DEPICTING THE NUTRIENT CONTENT CLAIM
“HEALTHY” ON PACKAGED FOODS**

July 6, 2021

Prefatory remarks

The American Herbal Products Association (AHPA) is the national trade association and voice of the herbal products industry. AHPA members include domestic and foreign companies doing business as growers, importers, processors, manufacturers, and marketers of herbs and herbal products. AHPA serves its members by promoting the responsible commerce of products that contain herbs, including conventional human foods, dietary supplements, health and beauty products, animal products, and other products.

On May 7, 2021, the Food and Drug Administration (FDA or the Agency) issued a Federal Register notice (the May 7 Notice)¹ announcing an opportunity for public comment on research FDA proposes to conduct; such research would test different voluntary front of package symbols to convey the “healthy” nutrient content claim for food. This research would include one experimental study (Study 1) and two web-based panels.

The May 7 Notice follows prior Agency activity concerning “healthy” claims, including a September 28, 2016, notice² (the September 28, 2016, Notice) inviting comments on the term “healthy” as a nutrient content claim in the context of food labeling. AHPA submitted timely comments responding to the September 28, 2016, Notice³, and observed therein that the *Scientific Report of the 2015 Dietary Guidelines Advisory Committee* (the 2015 DGAC Report) stated that “emphasis should be placed on expanding industry efforts to reduce the sodium content of foods and helping consumers understand how to flavor unsalted foods with spices and herbs.” AHPA’s comments also observed the 2015 DGAC Report’s recommendation that “added sugars should be reduced in the diet and not replaced with low-calorie sweeteners, but rather with healthy options, such as water in place of sugar-sweetened beverages.” The associated *Dietary Guidelines for Americans 2015-2020* encouraged similar substitutive use of herbs, spices, and unsweetened beverages to encourage “healthy dietary patterns that are low in saturated fat, added sugars, and sodium.”

¹ 86 Fed. Reg. 24,629 (May 7, 2021).

² 81 Fed. Reg. 66,527 (September 28, 2016).

³ Comments of the American Herbal Products Association on FDA’s Request for Comments on Use of the Term “Healthy” in Labeling of Human Food Products (April 26, 2017).

AHPA’s comments responding to the September 28, 2016, Notice therefore suggested, consistent with the recommendations of the 2015 DGAC Report, that “healthy options to reduce sodium intake could allow herb and spice blends or prepared foods that substitute herbs and spices for salt to bear a claim such as ‘a healthy alternative to salt.’” AHPA’s comments further suggested that “companies that market teas would be motivated to provide healthier options if regulations allowed a ‘healthy’ claim, such as ‘unsweetened tea is part of a healthy diet.’” AHPA notes that the 2020-2025 version of the *Guidelines* includes highly similar recommendations for the use of herbs, spices, and unsweetened beverages to support “healthy dietary patterns.”

Many AHPA members manufacture and market conventional foods and dietary supplements that may qualify for use of the term “healthy” as a nutrient content claim. These comments are submitted on behalf of AHPA and its members to address ways to enhance the quality, utility, and clarity of the information to be collected.

Study 1 should include a broad range of product packaging

The May 7 Notice states that Study 1 would be a controlled, randomized experimental 15-minute web-based questionnaire, which, among other things, would test consumer impressions of symbols placed on three types of mock food products. The May 7 Notice provides as examples of “a breakfast cereal, a frozen meal, and a canned soup.” Such a narrow set of product package types may prove insufficient to capture consumer impressions of a front of package symbol that consumers may encounter on a wide variety of products.

Products meeting the “healthy” nutrient content claim criteria, such as teas, spices, and herbal products, may be sold in small packages that differ from those proposed by the Agency for Study 1. Package space constraints may also affect consumer perceptions of an accompanying explanation or URL, symbol elements that are proposed for evaluation in Study 1. AHPA encourages FDA to consider specific testing of draft “healthy” symbols on packages meeting the definition of “small” at 21 C.F.R. 101.9(j)(13).⁴ For the same reason, AHPA further requests that FDA expand the set of product package conditions in Study 1 to capture how consumers may respond to the proposed symbol in a wider range of package formats, including, for example, retail

⁴ While the exemption provided by the small package definition is available only to products that bear no nutrition claims, manufacturers of such products may elect to forego this exemption to include a “healthy” front of package symbol. AHPA further notes many herbal product packages have a smaller area available for labeling than a canned soup.

packaged spices and retail packaged tea products. Addressing a wider range of products in this first study will ensure FDA has consumer data of sufficient utility to apply in later research and in final rule development. If the second and third studies described in the May 7 Notice also involve displaying the draft symbols on consumer packaging, the above recommendation also applies to these studies.

Summary

AHPA greatly appreciates the opportunity to present comments on how best to research the application of a “healthy” symbol. AHPA staff and counsel will make themselves available at any mutually convenient time to further address any of the topics addressed herein. Please feel free to contact us if clarification or additional discussion is needed on the issues raised in these comments.

Respectfully submitted,



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