

February 13, 2017

VIA ELECTRONIC SUBMISSION

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1030
Rockville, MD 20852

Re: Evaluation of the Beneficial Physiological Effects of Isolated or Synthetic Non-Digestible Carbohydrates; Request for Scientific Data, Information, and Comments, 81 Fed. Reg. 84595 (Nov. 23, 2016), Docket No. FDA-2016-N-3389

The Consumer Healthcare Association (“CHPA”) is the leading national trade association representing manufacturers and distributors of over-the-counter drugs and dietary supplements. Our association is committed to maintaining the highest standards in the manufacture and regulation of dietary supplements and therefore appreciates this opportunity to provide comments on the Food and Drug Administration (FDA) review of the scientific evidence associated with isolated and synthetic non-digestible carbohydrates (“Science Review”).¹

CHPA appreciates that FDA has taken the time to review the significant amount of data associated with certain isolated or synthetic carbohydrates not listed as a dietary fiber in 21 CFR 101.9(c)(6)(i) and looks forward to engaging with FDA in a cooperative, collaborative effort to clarify and improve the regulation of all dietary supplements, including those that contain non-digestible carbohydrates.

We also are encouraged by the issuance of a draft Guidance by the agency providing the types of information needed to submit in a citizen petition and the scientific review approach by the agency when determining whether an isolated or synthetic non-digestible carbohydrate has a beneficial physiological effect and could thus be classified as a dietary fiber. Information of this type is helpful to companies marketing or planning to market fiber-containing supplements and will help to improve manufacturer understanding of, and compliance with, the Nutrition and Supplement Facts Labeling Rule published in May 2016.

¹ Science Review of Isolated and Synthetic Non-Digestible Carbohydrates, Office of Nutrition and Food Labeling, Center for Food Safety and Nutrition, Food and Drug Administration, November 2016

Below we provide comments addressing the Science Review. We have also submitted comments addressing the recently-released draft Guidance.²

Provide a more in-depth overview of the reasons for not including a non-digestible carbohydrate as a dietary fiber under 21 CFR 101.9(c)(6)(i)

FDA has previously made available an in-depth review³ of the publicly available studies on several isolated or synthetic non-digestible carbohydrates that they determined provide beneficial physiological effects to human health and could thus be classified as a dietary fiber under 21 CFR 101.9(c)(6)(i). In that document, FDA provided a “Strength of the Evidence” summary for each of the five non-digestible carbohydrates meeting the criteria necessary for classification as a dietary fiber. We recommend that FDA provide a similar type summary for each of the twenty-six non-digestible carbohydrates which are being evaluated for classification as dietary fiber. Doing so would help industry to better understand the amount and types of scientific evidence required for demonstration of a beneficial physiological effect to human health. This approach could also potentially reduce the burden on FDA by decreasing the number of submitted Citizen Petitions requesting classification of an isolated or synthetic non-digestible carbohydrate as a dietary fiber.

Provide clarity on dietary ingredients identified by common name as ‘fibers’ but not classified as ‘dietary fiber’ by FDA

In the 2016 Science Review¹ of isolated or synthetic non-digestible carbohydrates, FDA identified several non-digestible carbohydrate ingredients utilizing the term “fiber” in their common name which did not possess sufficient scientific evidence to be categorized as a ‘dietary fiber’⁴ and would thus not be counted when determining dietary fiber content for the purposes of labeling. We recognize that until FDA has evidence of a physiological benefit to human health these ingredients cannot be counted as a dietary fiber.

However, it is our understanding that there are no restrictions on the use of these substances in dietary supplement products and other foods. Thus, for those ingredients which include the term ‘fiber’ in their common name but for which the agency determines do not meet the classification of dietary fiber, we ask that the agency acknowledge continued labeling of these ingredients via their common name (*e.g.*, apple *fiber*, soluble corn *fiber*) in dietary supplement products is acceptable.

Provide clarity regarding the labeling and utilization of structure/function claims for dietary ingredients not considered dietary fibers

In the May 2016, Final Rule⁵ FDA noted that structure/function claims were outside the scope of the rule. Dietary supplement labels or labeling may bear statements describing the role of a nutrient or dietary ingredient intended to affect the structure or function of the body or that

² Scientific Evaluation of the Evidence on the Beneficial Physiological Effects of Isolated or Synthetic Non-digestible Carbohydrates Submitted as a Citizen Petition (21 CFR 10.30): Guidance for Industry, November 2016

³ FDA Memorandum “Scientific Review of the Beneficial Physiological Effects on Non-digestible Carbohydrates for Meeting the FDA Definition of Dietary Fiber”, May 9, 2016

⁴ Apple fiber, bamboo fiber, corn hull fiber, cottonseed fiber, oat hull fiber, pea hull fiber (insoluble pea fiber, soluble pea fiber), potato fibers, rice bran fiber, soluble corn fiber, soy fiber, sugar beet fiber, sugar can fiber, wheat fiber.

⁵ Food Labeling: Revision of the Nutrition and Supplement Facts Labels, Fed. Reg. 81(103) p. 33854, May 27, 2016

characterize the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, if such statements are not disease claims.⁶

Currently marketed dietary supplements that contain a non-digestible carbohydrate not meeting the definition of dietary fiber can include structure/functions claims on labeling such as “dietary ingredient X helps maintain healthy digestive function” contingent upon the claim being substantiated as truthful and not misleading. In the guidance document entitled “Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r) (6) of the Federal Food, Drug, and Cosmetic Act”,⁷ the agency discusses the substantiation standard for dietary supplement claims, and the agency considers whether the substantiation standard has been met with competent and reliable scientific evidence.

We ask that the agency provide clarity on the use of structure/function claims for those non-digestible carbohydrates not classified as a dietary fiber. If certain ingredients are not classified as dietary fibers, we ask FDA to continue to acknowledge the use of structure/function claims based on these dietary ingredients provided that adequate scientific evidence exists to support the claim. As such, if one of the 26 non-digestible carbohydrates under consideration is not determined to be a dietary fiber and a company has, on file, adequate scientific evidence to substantiate a structure function claim for “supporting digestive health”, then the company (under this substantiation standard) should still be able to make a structure function claim for the dietary ingredient.

For example, a claim describing the level of antioxidant nutrients in a food (dietary supplement) is a nutrient content claim.⁸ An antioxidant nutrient content claim can only be made for nutrients with an established Recommended Daily Intake.⁹ Bioflavonoid compounds cannot be the basis of a nutrient content claim but structure/function claims of an antioxidant effect are allowed for these ingredients.

Allow additional time for compliance with the Final Rule

The Nutrition and Supplement Facts Labeling Final Rule includes numerous significant changes that impact all food and dietary supplement products marketed in the United States. These include revisions in the declaration of quantitative amounts of vitamins and minerals, added sugars and fiber.¹⁰ Impacted products may need to be reformulated and nearly all must be relabeled, a process which not only requires changes to product labeling, but also updating batch records, release specifications, supporting and intermediate documents, and in some cases methods of analysis, updating internal claim substantiation documentation, updating website and promotional materials and call-center FAQs. Most of these changes require cross-functional internal review and approval prior to implementing changes.

We are aware that the agency has received several Citizen Petitions requesting classification of certain non-digestible carbohydrates as dietary fiber. FDA has noted that they are

⁶ 21 CFR 101.93(f)

⁷ [Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403\(r\) \(6\) of the Federal Food, Drug, and Cosmetic Act](#)

⁸ 21 CFR 101.54(g)

⁹ 21 CFR 101.9

¹⁰ Questions and Answers on the Nutrition and Supplement Facts Labels Related to the Compliance Date, Added Sugars, and Declaration of Quantitative Amounts of Vitamins and Minerals: Guidance for Industry; January 2017

“committed to exploring options to address the timing issue”¹¹ associated with updating the list of dietary fibers if they are not able to update this list prior to the first compliance date for the Final Rule (July 26, 2018).

Due to the substantial undertaking the Final Rule demands, and the potential for extended agency review to affect the feasibility of industry to react in a timely fashion, CHPA requests FDA extend the initial compliance date for the Final Rule until July 26, 2019.

We appreciate the opportunity to submit these comments. Please feel free to contact me should you have any questions or require additional information.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Jay S. Sirois". The signature is written in a cursive style with a large initial "J" and "S".

Jay Sirois, Ph.D.
Senior Director, Regulatory & Scientific Affairs
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¹¹ Questions and Answers for Industry on Dietary Fiber, updated December 28, 2016
<http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm528582.htm>