

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: Scientific Evaluation of the Evidence of the Beneficial Physiological Effects of Isolated or Synthetic Non-Digestible Carbohydrates Submitted as a Citizen Petition; Draft Guidance for Industry, 81 Fed. Reg. 84516 (Nov. 23, 2016), Docket No. FDA-2016-D-3401

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) Guidance detailing the agency’s review process for evaluating data on the beneficial physiological effects of isolated or synthetic non-digestible carbohydrates.¹

CHPA is encouraged by the issuance of a draft Guidance by the agency providing the types of information needed to submit in a citizen petition and the scientific review approach by the agency when determining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.

We look 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 (some of which are classified as ‘dietary fiber’). Below we provide comments addressing the Guidance Science Review. We have also submitted comments addressing the recently-released review of non-digestible carbohydrates.²

¹ 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

² 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

Despite the absence of an established pathway for adding substances to the regulatory definition of dietary fiber, FDA has established a two-year deadline for compliance with the new labeling regulations issued in May 2016. FDA acknowledges that it will “review expeditiously any additional data it receives” regarding ingredients seeking to be classified as dietary fiber.³ FDA is currently in the process of reviewing several Citizen Petitions for non-digestible carbohydrates.⁴ However, without extending the deadline for compliance with the Final Rule, companies will have less than two years (potentially much less than this) to ensure compliance with the dietary fiber definition. The necessary changes required to conform with the Final Rule (*e.g.*, label changes, reformulation) are significant and warrant an extension of the deadline for compliance with the Final Rule to July 26, 2019.⁵

On page 13 of the Guidance, FDA notes that “The findings for a beneficial physiological effect need to be replicated.” We ask that the agency accept that one sufficiently large, well-controlled, multi-center trial demonstrating significant evidence of a beneficial physiological effect of an added non-digestible carbohydrate be sufficient to classify that ingredient as a dietary fiber, particularly if independent substantiation from other non-controlled studies exist (*e.g.*, observational studies; *in vitro* data).

Congress amended section 505(d) of the Food, Drug and Cosmetic Act in 1997⁶ explicitly to authorize FDA to find “substantial evidence” as demonstrating effectiveness without requiring data from two clinical trials.

“If the Secretary determines, based on relevant science, that data from one adequate and well-controlled clinical investigation and confirmatory evidence (obtained prior to or after such investigation) are sufficient to establish effectiveness, the Secretary may consider such data and evidence to constitute substantial evidence...”

Indeed, between 1998 and 2011 FDA approved 30 new drugs and biological products on the basis of efficacy demonstrated in a single clinical trial.⁷ Thus, in some instances, we believe it would be possible to demonstrate a beneficial physiological effect to human health of a non-digestible carbohydrate by conducting a large well-controlled trial, as described above, without the requirement for replication of the results.

We ask that the agency provide additional clarity on how they will announce that a non-digestible carbohydrate (for which a Citizen Petition has been submitted) has been “approved” as a dietary fiber before it is added to the definition through rulemaking. Given the aforementioned significant changes associated with label changes and reformulation, we request that the agency handle such situations as expeditiously as possible to minimize the financial burden on the industry.

³ Questions and Answers for Industry on Dietary Fiber, December 8, 2016; available at <http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm528582.htm>

⁴ Isomalto-oligosaccharides; Modified Wheat Starch; Soy Fiber; Inulin-type Fructans Derived from Chicory Root; Maltodextrin; Soluble Corn Fiber

⁵ CHPA has also requested an extension of the date for compliance with the Final Rule in comments submitted on the ‘Scientific Evaluation of the Beneficial Physiological Effects of Isolated or Synthetic Non-Digestible Carbohydrates’.

⁶ Food and Drug Modernization Act (FDAMA), Section 115(a)

⁷ Three of these products were approved on the basis of large trials demonstrating a reduced risk for cardiovascular events (death, myocardial infarction, stroke and embolism).

Lastly, we also ask that the agency take into account the rapidly-evolving science surrounding the microbiome when determining the need to update guidance on isolated or synthetic non-digestible carbohydrates, particularly in regards to processes not currently classified as beneficial physiological effects.⁸

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 Sirois". The signature is fluid and cursive, with the first name "Jay" and last name "Sirois" clearly distinguishable.

Jay Sirois, Ph.D.
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⁸ On page 11 of the draft guidance, FDA notes that “[f]ermentation and changes in the microbiota in the large intestine are considered to be processes, rather than beneficial physiological effects.”