

Dietary Fiber status of Gum Acacia

Rouen, September 13th, 2018

On May 27, 2016, FDA published a definition of “dietary fiber” and created a pre-approval system for various isolated and synthetic non-digestible carbohydrates (“NDCs”).¹ For all food labeled on or after January 1, 2020, the isolated or synthetic NDCs must be determined by FDA to have a physiological effect that is beneficial to human health before they can be counted as dietary fiber for nutrition labeling purposes. These effects include lowering blood glucose and cholesterol levels, reduced calorie intake, and increasing the frequency of bowel movements, among others.

In February 2017, Keller and Heckman LLP submitted comments to FDA on behalf of Nexira and other gum acacia manufacturers ². The comments demonstrated the beneficial physiological effects of gum acacia on energy intake, blood glucose levels, and bowel function/laxation, and supported the conclusion that gum acacia is a non-digestible carbohydrate that met the definition of a dietary fiber.

Nexira, with representatives of the gum acacia industry met with FDA on August 8, 2018 to discuss the fiber status of gum acacia. During the meeting, we sought feedback on the blood glucose attenuation and energy intake studies presented in FDA’s November 2016 Scientific Review³ and in the February 2017 comments to FDA. Based on the discussion with FDA, we have decided to conduct additional studies to strengthen the body of evidence supporting the beneficial physiological effects of gum acacia on blood glucose attenuation and energy intake. After completion of the additional studies, we intend to submit a Citizen Petition to FDA in the Spring of 2019 to request that gum acacia be recognized as a dietary fiber for nutrition labeling and claims on foods and beverages marketed in the United States. We are hopeful to receive a positive response from FDA by the Summer of 2019. Assuming we receive approval as a dietary fiber, we expect FDA will exercise enforcement discretion for the declaration of gum acacia as dietary fiber, pending completion of a rulemaking revising the regulations, as they have with other substances.

Frequently Asked Questions (FAQ)

1. What is gum acacia’s current dietary fiber status?

Gum acacia can be counted as dietary fiber when using the current/older nutrition labeling regulation and associated format. It should be noted that gum acacia, also known as gum arabic, is the only food ingredient that had been recognized as dietary fiber by FDA in a food

¹ 81 Fed. Reg. 33742 (May 27, 2016); see also revised 21 CFR § 101.9(c)(6)(i).

² Comments to FDA regarding Gum Acacia, Docket No. FDA-2016-N-3389-0443, posted February 17, 2017.

³ FDA Scientific Review of Isolated and Synthetic Non-Digestible Carbohydrates, November 2016.

additive regulation. See 21 CFR § 172.780 and 21 CFR § 184.1330. The manufacturers of gum acacia have now met with FDA and will be submitting a Citizen Petition with additional data that demonstrates gum acacia's beneficial physiological effect on human health. The gum acacia manufacturers intend to submit the Citizen Petition in the Spring of 2019. The manufacturers are hopeful to receive approval as a dietary fiber in the Summer of 2019; however, we are unable to make assumptions on behalf of FDA.

2. What is the timeframe for gum acacia to get approved as a dietary fiber by FDA?

The additional gum acacia studies are to commence imminently. Following the conclusion of these studies, we will submit a Citizen Petition to FDA to request that gum acacia be recognized as a dietary fiber. We estimate the Citizen Petition will be submitted Spring 2019. While the timeframe for FDA's response cannot be guaranteed, we are hopeful to receive a positive response to our Citizen Petition in Summer 2019.

3. Can I use gum acacia as a dietary fiber until January 1, 2020?

Yes. The compliance date for the Nutrition and Supplement Facts label final rule is January 1, 2020 and gum acacia may be used as a dietary fiber until then as long as the products bear nutrition labeling pursuant to the current/older version of 21 CFR § 101.9. Products that are labeled on or after January 1, 2020 must bear a label that meets the new nutrition labeling requirements at 21 CFR § 101.9, which will include the new definition for "dietary fiber" and require FDA to recognize gum acacia as dietary fiber. However, products labeled before January 1, 2020 do not need to be in compliance with the new labeling requirements. We note that manufacturers with less than \$10 million in annual food sales have an extra year to comply—until January 1, 2021.

Once the compliance date has passed, a manufacturer may not include gum acacia in the declaration of "dietary fiber," unless gum acacia achieves approval as a dietary fiber. Gum acacia may continue to be used as an approved food additive after the compliance date and would be included in the declaration for total carbohydrate.

4. What is the caloric value of gum acacia?

As per the Nutrition and Supplement Facts label final rule (81 Fed. Reg. 33867 (May 27, 2016)), the caloric value of soluble non-digestible carbohydrates, for those that both do and do not meet the definition of "dietary fiber," is 2 kcal/gram.⁴

Nexira teams remain available for any question,

4 21 CFR §101.9(c)(1)(i)(C), as revised.