



July 2, 2020

Catherine Adams Hutt, PhD, RD, CFS
RdR Solutions, President
4568 Elm Bottom Circle
Aubrey, TX 76227

Re: Docket Number FDA-2019-P-4669

Dear Dr. Hutt:

This responds to your citizen petition dated September 4, 2019, on behalf of Fiber Research International, requesting that the Food and Drug Administration (FDA or we) include

a highly purified form of glucomannan with not less than 95% purity as determined by high performance lipid chromatography (HPLC), including that sold under the trade name Propol or PropolMannan, a polysaccharide isolated from the roots of *Amorphophallus konjac*,

as a dietary fiber in the definition found in 21 CFR 101.9. See Citizen Petition from Catherine Adams Hutt, RdR Solutions, submitted to the Division of Dockets Management, Food and Drug Administration, dated September 4, 2019 (Petition), at page 1.

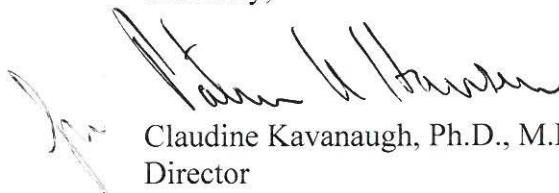
On January 10, 2020, we announced our intention to propose that “glucomannan” be added to the list of non-digestible carbohydrates that meet the definition of dietary fiber in 21 CFR § 101.9(c)(6)(i), regardless of source.¹ After reviewing the scientific evidence for our evaluation and response to The Food Lawyers’ citizen petition,² we determined that the strength of the scientific evidence shows that glucomannan has a physiological effect that is beneficial to human health.

¹ See Petition Response Letter from FDA CFSAN to George Salas, The Food Lawyers, dated January 10, 2020, available at <https://www.regulations.gov/contentStreamer?documentId=FDA-2018-P-0877-0010&attachmentNumber=1&contentType=pdf>.

² See Citizen Petition from George Salas, The Food Lawyers, submitted to the Division of Dockets Management, Food and Drug Administration, dated February 24, 2018, available at <https://www.regulations.gov/contentStreamer?documentId=FDA-2018-P-0877-0001&attachmentNumber=1&contentType=pdf>.

Because we intend to propose that “glucomannan,”³ which includes the purified glucomannan that is the subject of your petition, be added to the list of non-digestible carbohydrates that meet the definition of dietary fiber in 21 CFR § 101.9(c)(6)(i), we find it unnecessary to act on your specific request. We intend to exercise enforcement discretion for declaring glucomannan in the amount of dietary fiber declared on Nutrition and Supplement Facts labels until we can complete a rulemaking regarding amending our regulations in 21 CFR § 101.9(c)(6)(i) to include additional dietary fibers in the list of non-digestible carbohydrates that meet our definition of dietary fiber.

Sincerely,

A handwritten signature in dark ink, appearing to read 'Claudine Kavanaugh', is written over a horizontal line.

Claudine Kavanaugh, Ph.D., M.P.H., R.D.
Director
Office of Nutrition
and Food Labeling
Center for Food Safety
and Applied Nutrition

³ “Glucomannan” is the non-digestible carbohydrate contained in both konjac flour and purified konjac glucomannan. The level of purity (i.e., “a highly purified form of glucomannan with not less than 95% purity as determined by high performance liquid chromatography (HPLC)”) is not relevant to the identification of the isolated or synthetic non-digestible carbohydrate (i.e., glucomannan). This approach is consistent with our final guidance, which “addresses the scientific evaluation of synthetic non-digestible carbohydrates and isolated non-digestible carbohydrate ingredients that are produced as a result of processing of foods and other sources, to the extent that the ingredients in and of themselves have a specific chemical structure (carbohydrate composition and non-digestible bond linkages)” (see Guidance for Industry: 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), p. 5, available at

<https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM528533.pdf>).