



Madhu G. Soni, Ph.D.
Soni & Associates, Inc.
749 46th Square
Vero Beach, FL 32968

Re: GRAS Notice No. GRN 000692

Dear Dr. Soni:

The Food and Drug Administration (FDA, we) is granting Vis Vitalis GmbH's (Vis Vitalis) request to cease our evaluation of GRN 000692, which we filed on March 6, 2017. We received the request on October 4, 2017.

The subject of the notice is quinoa sprout powder containing B-vitamins¹ (quinoa powder) for use as an ingredient in baked goods, ready-to-eat cereals, and snack foods at levels up to 100 mg/serving. The notice informs FDA of Vis Vitalis' view that the use of quinoa powder is GRAS through scientific procedures.

In a September 5, 2017, telephone conversation that included yourself and representatives from, or on behalf of, Vis Vitalis, we discussed the inclusion of folic acid as a constituent in quinoa powder and the safe upper limit (UL) of folic acid intake. Folic acid (also referred to as folacin or folate) is a food additive under 21 CFR 172.345. We also discussed that 21 CFR 104.20 discourages indiscriminate addition of nutrients to foods and addresses the inappropriateness of fortifying snack foods.

In a follow up email on September 8, 2017, we attached a copy and provided the link to a publicly available toxicology memorandum discussing the safe and tolerable ULs for folic acid consumption that are recognized by various authoritative bodies.² We also provided a Questions and Answers guidance on 21 CFR 104.20.³ This guidance specifically discusses the addition of folic acid in the voluntary fortification of foods.

On September 29, 2017, we responded to Vis Vitalis' request for clarification on how 21 CFR 172.345 is relevant to Vis Vitalis' GRAS notice. We indicated that it is not clear

¹ As part of the method of manufacture, quinoa seeds are sprouted in the presence of eight B vitamins, including folic acid.

² Reference 12 of the final rule amending the food additive regulations to provide for the safe use of folic acid in corn masa flour (81 FR 22176, April 15, 2016). Available at: www.regulations.gov (in Docket No. FDA-2012-F-0480).

³ FDA, "Guidance for Industry: Questions and Answers on FDA's Fortification Policy," (<https://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/ucm470756.htm>), 2015.


whether quinoa powder meets the identity and specifications in 21 CFR 172.345. In addition, we explained that the dietary exposure for certain population groups in the U.S. currently exceeds the Institute of Medicine's UL for folic acid. We also explained that additional food uses of folic acid (e.g., baked goods and snack foods) will likely further contribute to more population groups exceeding the UL. We noted that the safety concerns for dietary intake of folic acid that exceeds the UL were discussed in the toxicology memorandum.² We recommended that Vis Vitalis send us a request to cease our evaluation of GRN 000692.

If Vis Vitalis decides to exclude folic acid from quinoa powder, then the identity will be substantially different from that described in GRN 000692 and will require a new GRAS conclusion, which the company is strongly encouraged to share with us through the GRAS Notification Program. We also recommended that snack foods be excluded from the intended use. If Vis Vitalis intends to retain folic acid as a constituent of quinoa powder,¹ then the company will need to submit a food additive petition seeking approval for the use of quinoa powder in foods. An unapproved food additive is subject to FDA's enforcement activity.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 000692 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely, **Michael J.
Dinovi -S**

Susan Carlson, Ph.D.
Director
Division of Biotechnology
and GRAS Notice Review
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition

 Digitally signed by Michael J. Dinovi -S
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