



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

Re: GRAS Notice No. GRN 000787

Dear Dr. Soni:

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 000787. We received the notice you submitted on behalf of Vis Vitalis GmbH (Vis Vitalis) on May 31, 2018, and filed it on June 26, 2018.

The subject of the notice is quinoa sprout powder containing seven B vitamins¹ (quinoa powder) for use as an ingredient in baked goods and ready-to-eat cereals at levels up to 150 mg/serving. The notice informs us of Vis Vitalis' view that this use of quinoa powder is GRAS through scientific procedures.

Our use of "quinoa powder" in this letter is not our recommendation of that term as an appropriate common or usual name for declaring the substance in accordance with FDA's labeling requirements. Under 21 CFR 101.4 each ingredient must be declared by its common or usual name. In addition, 21 CFR 102.5 outlines general principles to use when establishing common or usual names for nonstandardized foods. Issues associated with labeling and the common or usual name of a food ingredient are under the purview of the Office of Nutrition and Food Labeling (ONFL) in the Center for Food Safety and Applied Nutrition. The Office of Food Additive Safety (OFAS) did not consult with ONFL regarding the appropriate common or usual name for "quinoa powder."

Vis Vitalis provides information about the identity and composition of quinoa powder. Vis Vitalis describes quinoa powder as an off white to yellow powder that is produced from germinated and sprouted seeds of quinoa (*Chenopodium quinoa* Willd.). Vis Vitalis states that quinoa powder contains seven B vitamins within specified limits and provides data to demonstrate that quinoa powder contains 68.5% carbohydrates (including 4.5% fiber and 3.1% sugars), 13.5% protein, and 7.1% total fat.

¹ Vis Vitalis states that the B-vitamins in quinoa powder includes thiamin (vitamin B1), riboflavin (vitamin B2), niacin (vitamin B3), pantothenic acid (vitamin B5), pyridoxine (vitamin B6), biotin (vitamin B7), and cobalamin (B12), and excludes added folic acid (vitamin B9).

Vis Vitalis describes the manufacturing method for quinoa powder, and states that all materials used are food grade, and that quinoa powder is produced in accordance with current good manufacturing practices. Quinoa seeds are washed, dried, and then soaked in water that contains the seven B vitamins. After germination reaches the desired stage of growth, the resulting quinoa sprouts are washed, dried, milled, ground, and sterilized.

Vis Vitalis provides specifications for quinoa powder that include minimum and maximum levels of the following B vitamins: thiamin (150-270 mg/100g), riboflavin (170-306 mg/100g), niacin (2000-3600 mg/100g), pantothenic acid (1000-1800 mg/100g), pyridoxine (200-360 mg/100g), biotin (30-54 mg/100g), and cobalamin (0.6-1.08 mg/100g). Specifications for quinoa powder also include limits for moisture ($\leq 8\%$), lead (< 1 mg/kg), arsenic (< 1 mg/kg), mercury (< 0.1 mg/kg), and cadmium (< 1 mg/kg), as well as limits on microorganisms. Vis Vitalis provides the results of three batch analyses to demonstrate that quinoa powder can be made to meet specifications.

Vis Vitalis estimates the dietary exposure to quinoa powder based on its intended use and food consumption data from the U.S. Department of Agriculture’s Continuing Survey of Food Intakes by Individuals. Vis Vitalis estimates the mean and 90th percentile exposures to quinoa powder to be 327.27 and 605.46 mg/person/day, respectively. Vis Vitalis estimates the dietary exposures to B vitamins (see Table 1) based on the estimated 90th percentile exposure to quinoa powder and the maximum specified levels of each B vitamin in quinoa powder.

Table 1
Estimated 90th percentile dietary exposure to B vitamins
from the intended uses of quinoa powder

B Vitamin	90 th Percentile dietary exposure (mg/person/day)
B1 as thiamin	1.63
B2 as riboflavin	1.85
B3 as niacin	21.78
B5 as pantothenic acid	10.89
B6 as pyridoxine	2.18
B7 as biotin	0.327
B12 as cobalamin	0.0065

Vis Vitalis states that quinoa had been widely consumed as food in different parts of South America before the introduction of wheat and barley. Vis Vitalis discusses published studies to support the safety of quinoa powder. Vis Vitalis discusses several published animal studies in mice, rats, broiler chickens, and piglets, in which quinoa was administered through diet. The endpoints measured included weight gain, serum biochemistry including lipid profile, and markers of antioxidant activity. Vis Vitalis reports that no adverse effects were observed in the animal studies. Vis Vitalis discusses published studies in human and notes that although these studies were designed to

assess health benefits, they still demonstrate the safety and tolerability of quinoa preparations. The endpoints measured included serum lipid profile and gastrointestinal morphology parameters in celiac patients. Vis Vitalis notes that no adverse effects were reported in the human studies, including in celiac patients. Vis Vitalis further notes that a comprehensive search of the published literature did not uncover any reports of adverse effects associated with quinoa, quinoa sprout food products, or quinoa powder consumption.

Vis Vitalis also discusses the safety of consumption of different B vitamins since the sprouting was conducted in the presence of seven B vitamins. Vis Vitalis reports that quinoa seeds are known to contain saponins and phytic acid that may exert negative effects on the bioavailability of dietary nutrients. However, Vis Vitalis notes that its starting material is food grade quinoa, which is further processed. Processing and germination of quinoa seeds lowers the saponins and phytic acid content. Vis Vitalis states that the B vitamins present in the sprouting medium are water soluble and that excess B vitamins are excreted in the urine. Therefore, Vis Vitalis concludes that the processing and germination of the quinoa seeds along with very low exposure to potential saponin or phytic acid content is not expected to cause any adverse effects. Based on the totality of evidence, Vis Vitalis concludes that quinoa powder is well tolerated and safe to consume under the conditions of its intended use.

Vis Vitalis includes the statement of a panel of individuals (Vis Vitalis' GRAS panel). Based on its review, Vis Vitalis' GRAS panel concludes that quinoa powder is safe under the conditions of its intended use.

Based on the data and information described above, Vis Vitalis concludes that quinoa powder is GRAS for its intended use in food.

Standards of Identity

In the notice, Vis Vitalis states its intention to use quinoa powder in several food categories, including foods for which standards of identity exist, located in Title 21 of the Code of Federal Regulations. We note that an ingredient that is lawfully added to food products may be used in a standardized food only if it is permitted by the applicable standard of identity.

Potential Labeling Issues

In describing the use of quinoa powder, Vis Vitalis raises a potential issue under the labeling provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Under section 403(a) of the FD&C Act, a food is misbranded if its labeling is false or misleading in any particular. Section 403(r) of the FD&C Act lays out the statutory framework for the use of labeling claims that characterize the level of a nutrient in a food or that characterize the relationship of a nutrient to a disease or health-related condition. If products that contain quinoa powder bear any claims on the label or in labeling, such claims are the purview of ONFL. OFAS neither consulted with ONFL on this labeling

issue nor evaluated the information in your notice to determine whether it would support any claims made about quinoa powder on the label or in labeling.

Potential Requirement for a Color Additive Petition

There is no GRAS provision for color additives. In the notice, Vis Vitalis describes quinoa powder as a white- to yellow-colored powder. As such, the use of quinoa powder in food products may constitute a color additive use under section 201(t)(1) of the FD&C Act and FDA's implementing regulations in 21 CFR Part 70. Under section 201(t)(1) and 21 CFR 70.3(f), a color additive is a material that is a dye, pigment, or other substance made by a synthetic process or similar artifice, or is extracted, isolated, or otherwise derived from a vegetable, animal, mineral, or other source. Under 21 CFR 70.3(g), a material that otherwise meets the definition of a color additive can be exempt from that definition if it is used (or is intended to be used) solely for a purpose or purposes other than coloring. Our response to GRN 000787 is not an approval for use as a color additive nor is it a finding of the Secretary of the Department of Health and Human Services within the meaning of section 721(b)(4) of the FD&C Act. Questions about color additives should be directed to the Division of Petition Review in OFAS.

Section 301(ll) of the FD&C Act

Section 301(ll) of the FD&C Act prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FD&C Act, a biological product licensed under section 351 of the Public Health Service Act, or a drug or a biological product for which substantial clinical investigations have been instituted and their existence made public, unless one of the exemptions in section 301(ll)(1)-(4) applies. In its review of Vis Vitalis' notice that quinoa powder is GRAS for the intended use, FDA did not consider whether section 301(ll) or any of its exemptions apply to foods containing quinoa powder. Accordingly, this response should not be construed to be a statement that foods that contain quinoa powder, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

Conclusions

Based on the information that Vis Vitalis provided, as well as other information available to FDA, we have no questions at this time regarding Vis Vitalis' conclusion that quinoa powder is GRAS under its intended conditions of use. This letter is not an affirmation that quinoa powder is GRAS under 21 CFR 170.35. Unless noted above, our review did not address other provisions of the FD&C Act. Food ingredient manufacturers and food producers are responsible for ensuring that marketed products are safe and compliant with all applicable legal and regulatory requirements.

In accordance with 21 CFR 170.275(b)(2), the text of this letter responding to GRN 000787 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Michael A.

Adams -S


Dennis M. Keefe, Ph.D.

Director

Office of Food Additive Safety

Center for Food Safety

and Applied Nutrition

 Digitally signed by Michael A.
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