



Martin J. Hahn
Hogan Lovells US LLP
555 Thirteenth Street, NW
Washington, DC 20004

Re: GRAS Notice No. GRN 000769

Dear Mr. Hahn:

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 000769. We received the notice that you submitted on behalf of NutriFusion LLC (NutriFusion) on March 19, 2018, and filed it on April 11, 2018. NutriFusion submitted amendments to the notice on July 24, 2018, and October 3, 2018. In the amendments, NutriFusion clarified the intended use and analytical methods, and provided additional discussions on safety studies.

The subject of the notice is ascorbic acid from edible fruits and vegetables for use as a substitute for existing commercially available forms of ascorbic acid added to foods as a nutrient. The notice informs us of NutriFusion's view that these uses of ascorbic acid from edible fruits and vegetables are GRAS through scientific procedures.

Our use of the term "ascorbic acid from edible fruits and vegetables" 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. We did not consult with ONFL regarding the appropriate common or usual name for ascorbic acid from edible fruits and vegetables.

NutriFusion provides information about the identity and composition of ascorbic acid from edible fruits and vegetables. NutriFusion describes the notified substance as a white or slightly yellow powder that contains 25 to 30% ascorbic acid that is encapsulated with food grade ingredients such as maltodextrin. Vitamin C is known as L-ascorbic acid, has a molecular weight of 176 g/mol, molecular formula of $C_6H_8O_6$, and is designated by the CAS Registry Number 50-81-7.

NutriFusion describes the manufacturing process for ascorbic acid from edible fruits and vegetables. The dried edible portions of fruits and vegetables are ground to a fine powder. The powder is extracted with water, ethanol, or supercritical CO_2 ; and then

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separated by centrifugation. The supernatant may optionally be subjected to solid phase extraction. The extract is then freeze-dried and encapsulated with food grade ingredients such as maltodextrin. All raw materials and processing aids are food-grade and the process is in compliance with current good manufacturing practices.

NutriFusion provides food grade specifications for ascorbic acid from edible fruits and vegetables. These include content of ascorbic acid (25-30%), starch (67-72%), moisture (2-5%), lead (<1.5 mg/kg), cadmium (<0.5 mg/kg), arsenic (<1 mg/kg), and limits on microorganisms. NutriFusion provides results of batch analyses to demonstrate that ascorbic acid can be manufactured to meet specifications.

NutriFusion estimates the dietary exposure to ascorbic acid from current uses. NutriFusion reports estimates of the 90th percentile dietary exposure to ascorbic acid based on data from the Institute of Medicine 2015 guidelines. Exposure to ascorbic acid for the U.S. population aged four years and older is 177 mg/person (p)/day (d) (3 mg/kg body weight (bw)/d) and for one to three years old is 165 mg/p/d (3 mg/kg bw/d). NutriFusion states that ascorbic acid from edible fruits and vegetables is intended to be substitutional for vitamin C and would not result in increased overall dietary exposure.

NutriFusion states that they undertook an independent review of recent literature on vitamin C and completed the search in July, 2018. NutriFusion states that the National Toxicology Program concluded that ascorbic acid is not carcinogenic in rats at up to ~2,500 mg/kg bw/d and in mice at up to ~7,500 mg/kg bw/d based on its 2-year carcinogenicity studies. No toxicologically relevant adverse effects were reported at these levels. NutriFusion states that based on published human studies, a no observed adverse effect level of 1,000 mg/kg bw/d can be established in humans. NutriFusion notes that ascorbic acid is listed as GRAS for use as a nutrient under 21 CFR 182.8013 (Ascorbic acid) with no limits other than cGMP.

Based on the totality of the data and information available, NutriFusion concludes that ascorbic acid from edible fruits and vegetables is GRAS for its intended use.

Standards of Identity

In the notice, NutriFusion states its intention to use ascorbic acid from edible fruits and vegetables 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.

Section 301(II) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

Section 301(II) 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(l)(1)-(4) applies. In our evaluation of NutriFusion’s notice concluding that ascorbic acid from edible fruits and vegetables is GRAS under its intended conditions of use, we did not consider whether section 301(l) or any of its exemptions apply to foods containing ascorbic acid from edible fruits and vegetables. Accordingly, our response should not be construed to be a statement that foods containing ascorbic acid from edible fruits and vegetables, if introduced or delivered for introduction into interstate commerce, would not violate section 301(l).

Conclusions

Based on the information that NutriFusion provided, as well as other information available to FDA, we have no questions at this time regarding NutriFusion’s conclusion that ascorbic acid from edible fruits and vegetables is GRAS under its intended conditions of use. This letter is not an affirmation that ascorbic acid from edible fruits and vegetables 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 000769 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Dennis M. Keefe

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Dennis M. Keefe, Ph.D.
Director
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition

Digitally signed by Dennis M. Keefe -S
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