Kurt Waananen
Blue Diamond Growers
1802 C Street
Sacramento, CA 95811

Re: GRAS Notice No. GRN 000918

Dear Mr. Waananen:

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 000918. We received Blue Diamond Growers' (Blue Diamond) notice on February 20, 2020 and filed it on June 18, 2020. Blue Diamond submitted amendments to the notice on October 7, 2020, December 17, 2020, and April 20, 2021, providing additional information regarding estimates of dietary exposure, intended use, composition, safety, and amending the specifications.

The subject of the notice is partially defatted almond flour (PDAF) for use as a source of protein at levels ranging from 5 to 10% in baked goods, ready-to-drink coffee drinks and smoothies (fruit, milk-based, non-milk based), cereal and granola bars; 25 to 80% in meal replacement (milk and non-milk) and plant-based nutritional powders, energy or protein bars, protein powders, and prepared beverages (from powder). The notice informs us of Blue Diamond's view that these uses of PDAF are GRAS through scientific procedures.

Our use of the term, "PDAF," 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 non-standardized 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 "PDAF."

Blue Diamond describes PDAF as a tan or light cream-colored fine flour that has a characteristic odor and flavor profile of sweet, fresh, natural almonds. Almonds used for PDAF are grown in accordance with Good Agricultural Practices and subjected to pasteurization.[1] Blue Diamond states that PDAF is comprised of approximately 42 to

[1] We note requirements for pasteurization of almonds are stated in 7 CFR Part 981 Almonds Grown in California; Outgoing Quality Control Requirements and in the final rule providing for a mandatory program to reduce the potential for *Salmonella* in almonds (72 FR 15021; March 30, 2007).

46% protein, 35 to 39% carbohydrates, 5% moisture, 8% fat, and 6% ash. Blue Diamond notes that PDAF is produced from unblanched (with skin) or blanched (without skin) sweet almonds through a series of mechanical processing steps, and in accordance with current Good Manufacturing Practices (cGMPs). Blue Diamond states that pasteurized almonds are crushed with a mechanical press to remove the oil. The resulting almond cake is milled to form a powdered flour that is thermally treated, packaged, and sealed in multi-wall bags prior to storage.

Blue Diamond provides the following specifications, expressed by weight percent, for PDAF from unblanched and blanched almonds: moisture (≤6%), fat (5.3-12%), protein (40.0-46.5% for unblanched; 41.5-48.7% for blanched), lead (<0.25 mg/kg), arsenic (<0.25 mg/kg), cadmium (<0.25 mg/kg), and limits for microorganisms including *Salmonella* (negative in 25 g). Blue Diamond provides results from four non-consecutive lots of PDAF from unblanched almonds and five non-consecutive lots of PDAF from blanched almonds, to demonstrate that PDAF meets the stated specifications. Blue Diamond also reports mean level for amygdalin, a cyanogenic glycoside present in almonds, to be 143 mg/kg and 70 mg/kg, based on analyses of PDAF from unblanched and blanched sweet almonds, respectively.[2] Blue Diamond provides results of stability testing to demonstrate that PDAF is stable under frozen, ambient, and accelerated storage conditions.

Blue Diamond provides an estimate of the dietary exposure to PDAF based on the intended uses and food consumption data from the National Health and Nutrition Examination Survey (NHANES, 2015-2016). Blue Diamond reports eaters-only mean and 90th percentile estimated dietary exposures to PDAF for the U.S. population ages 2 years and older to be 15 and 22 g/p/d (i.e., 221 and 388 mg/kg bw/d), respectively.

Blue Diamond discusses the safety of the intended use of PDAF as a source of protein. Blue Diamond cites publications which document a history of safe use of whole almonds in the diet. Based on the manufacturing process described above, together with the PDAF analytical and protein quality data, Blue Diamond concludes that safety of PDAF may be assessed by considering nutritional implications and the dietary exposure to constituents of PDAF such as anti-nutritional factors.

Blue Diamond notes that the protein quality of PDAF is consistent with the protein quality of whole almond varieties reported in scientific publications. Blue Diamond also notes that while almonds and PDAF lack some essential amino acids, PDAF is not intended for use as the sole source of protein in foods, concluding that nutritional insufficiencies of these amino acids are not anticipated to be a safety concern. Blue Diamond notes that PDAF will serve as an alternative to other protein sources and its uses are unlikely to increase consumer dietary intake of protein. Blue Diamond also discusses the dietary exposure to minerals resulting from the consumption of PDAF in comparison to published recommended tolerable limits of these minerals, concluding that the levels did not raise safety concerns.

[2] Amygdalin contributes to bitter taste at higher levels and can be metabolized to release hydrogen cyanide. Blue Diamond provided an upper value of 330 mg/kg for amygdalin in PDAF based on published information for the almond varieties grown in the source region.

Blue Diamond addresses the safety of anti-nutritional factors and toxins including amygdalin, phytic acid, and oxalic acids in PDAF noting that each of these substances are found naturally in almonds. Based on chronic and acute dietary exposure estimates of amygdalin from PDAF and citing chronic and acute safe levels of hydrogen cyanide proposed by the Joint FAO/WHO Expert Committee on Food Additives and the European Food Safety Authority, respectively, Blue Diamond concludes that the presence of amygdalin in PDAF would not pose any safety concerns under the conditions of intended use. Blue Diamond also concludes that the presence of phytic acid, and oxalic acids in PDAF is not expected to have a negative effect on the availability of other nutrients in foods to which PDAF is added. Blue Diamond addresses the allergenicity of PDAF, states that almonds are a type of "tree nut," a major food allergen, and that foods containing PDAF will be labeled as containing almonds.

Blue Diamond includes the report of a panel of individuals (Blue Diamond's GRAS panel). Based on its review, Blue Diamond's GRAS panel concluded that PDAF is safe under the conditions of its intended use.

Based on the totality of data and information discussed in the notice, Blue Diamond concludes that PDAF is GRAS for its intended uses.

Standards of Identity

In the notice, Blue Diamond states its intention to use PDAF in several food categories, including foods for which standards of identity exist, located in Title 21 of the CFR. 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

Under section 403(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), a food is misbranded if its labeling is false or misleading in any way. Section 403(r) of the FD&C Act lays out the statutory framework for labeling claims characterizing a nutrient level in a food or the relationship of a nutrient to a disease or health-related condition (also referred to as nutrient content claims and health claims). If products containing PDAF bear any nutrient content or health claims on the label or in labeling, such claims are subject to the applicable requirements and are under the purview of ONFL in the Center for Food Safety and Applied Nutrition. OFAS did not consult with ONFL on this issue or evaluate any information in terms of labeling claims. Questions related to food labeling should be directed to ONFL.

Allergen Labeling

The FD&C Act requires that the label of a food that is or contains an ingredient that contains a "major food allergen" declare the allergen's presence (section 403(w)). The FD&C Act defines a "major food allergen" as one of eight foods or food groups (i.e., milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, wheat, and soybeans) or a food

ingredient that contains protein derived from one of those foods. PDAF requires labeling under the FD&C Act because it contains protein derived from tree nuts.

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 our evaluation of Blue Diamond's notice concluding that PDAF is GRAS under its intended conditions of use, we did not consider whether section 301(ll) or any of its exemptions apply to foods containing PDAF. Accordingly, our response should not be construed to be a statement that foods containing PDAF, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

Conclusions

Based on the information that Blue Diamond provided, as well as other information available to FDA, we have no questions at this time regarding Blue Diamond's conclusion that PDAF is GRAS under its intended conditions of use. This letter is not an affirmation that PDAF 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 000918 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

Digitally signed by Susan J. Carlson -S
Date: 2021.07.07 17:48:20 -04'00'

Susan Carlson, Ph.D.
Director
Division of Food Ingredients
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