



Amy Mozingo
GRAS Associates, LLC
11810 Grand Park Avenue, Suite 500
North Bethesda, MD 20852

Re: GRAS Notice No. GRN 001302

Dear Ms. Mozingo:

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 001302. We received the notice that you submitted on behalf of Crush Dynamics, Inc. (Crush Dynamics) on August 12, 2025, and filed it on March 18, 2026. Crush Dynamics submitted amendments to the notice on June 16, 2026, July 30, 2026, and September 4, 2026, that provided additional information regarding the manufacturing process, analytical methods, specifications, intended uses, dietary exposure, the safety assessment approach, total polyphenol content and the safety of polyphenol dietary exposure at the proposed level.

The subject of the notice is fermented grape pomace for use as a flavoring agent and flavor enhancer in the food categories and at the maximum use levels described in Table 1 (excluding use in infant formula, infant foods, foods for young children, and products under the jurisdiction of the United States Department of Agriculture). The notice informs us of Crush Dynamics' view that these uses of fermented grape pomace are GRAS through scientific procedures.

Table 1. Intended food uses and maximum use levels of fermented grape pomace

Food Category	Maximum Use Level (g/100 g)	
	Fermented Grape Pomace (Purée)	Fermented Grape Pomace (Powder)
Candy containing chocolate	3	0.6
Condiments (excluding lemon/lime juices, vinegar, and garlic condiments)	4	0.5
Meat substitute products made from processed soy, bean, pea or legume	8	0.8
Nutritional beverages and powders	3	0.8
Sports beverages and “energy” drinks	3	0.6

Our use of the term, “fermented grape pomace” 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 Nutrition Center of Excellence. The Office of Pre-Market Additive Safety (OPMAS) did not consult with ONFL regarding the appropriate common or usual name for "fermented grape pomace."

Crush Dynamics describes fermented grape pomace as a deep red to dark purple or golden-brown purée or slurry or golden powder. Crush Dynamics states that the purée form of fermented grape pomace is produced from either white or red grapes (*Vitis vinifera*) and contains either $\leq 0.5\%$ or $\leq 0.8\%$ total polyphenols, respectively. The powder form of fermented grape pomace is produced from white grapes only and contains $\leq 5\%$ total polyphenols. White grape varieties may include Chardonnay, Gewurztraminer, Pinot Gris, Riesling, Pinot Blanc, Sauvignon Blanc, Semillon, or Viognier and red grape varieties may include Cabernet Franc, Cabernet Sauvignon, Malbec, Merlot, Pinot Noir, Syrah or Petit Verdot). Crush Dynamics states that fermented grape pomace consists of carbohydrates, dietary fiber, fat, protein, polyphenols, minerals, ash, and moisture.

Crush Dynamics describes the method of manufacture for fermented grape pomace. Destemmed white or red grapes are pressed to extract the juice, and the remaining pulp, skin, and seeds form the pomace. The resulting grape pomace undergoes a two-step fermentation process. The first fermentation is carried out using *Saccharomyces cerevisiae* along with a commercial nutrient blend. Crush Dynamics states that the yeast is not genetically engineered. The second fermentation step uses naturally cultivated *Acetobacter* (vinegar bacteria) and a commercial nutrient blend. Following fermentation, water is added to maintain a target moisture content, and the fermented grape pomace is blended, sheared, and heat-treated to produce the purée form of fermented grape pomace. The purée obtained from white grapes is then dried and milled to produce the powder form of fermented grape pomace. Crush Dynamics states that fermented grape pomace is manufactured in accordance with current good manufacturing practices and that all raw materials and processing aids are food-grade and are used in accordance with applicable U.S. regulations, are GRAS for their intended uses, or are the subject of an effective food contact notification.

Crush Dynamics provides specifications for fermented grape pomace that include total polyphenols ($\leq 0.5\%$ and $\leq 5\%$ for purée and powder, respectively, from white grape varieties, $\leq 0.8\%$ for purée from red grape varieties), moisture ($\leq 90\%$ for purée and $\leq 9\%$ for powder), residual ethanol ($\leq 0.5\%$), lead (≤ 0.05 mg/kg), arsenic (≤ 0.1 mg/kg), mercury (≤ 0.01 mg/kg), cadmium (≤ 0.01 mg/kg), and limits for microorganisms. Crush Dynamics provides results from the analyses of non-consecutive batches (five batches for the purée from white grapes, six batches for the purée from red grapes, and five batches for the powder) to demonstrate that fermented grape pomace can be manufactured to meet the specifications.

Crush Dynamics estimates the dietary exposure to fermented grape pomace from the intended uses based on food consumption data from the 2017-2020 National Health and Nutrition Examination Survey (NHANES). Crush Dynamics estimates the eaters-only dietary exposure to the purée form of fermented grape pomace to be 3.2 g/person (p)/d (0.05 mg/kg body weight (bw)/d) at the mean and 8.9 g/p/d (0.12 mg/kg bw/d) at the 90th percentile for the U.S. population aged 2 years and older. Crush Dynamics estimates the eaters-only dietary exposure to the powder form of fermented grape pomace to be 0.58 g/p/d (0.008 mg/kg bw/d) at the mean and 1.6 g/p/d (0.023 mg/kg bw/d) at the 90th percentile for the U.S. population aged 2 years and older.

Based on the maximum total polyphenol content of 0.8% for the purée form of fermented grape pomace produced from red grapes, and of 0.5% for the purée form (5% for the powder form) produced from white grapes, Crush Dynamics estimates the eaters-only 90th percentile dietary exposure to polyphenols to be 70.9 mg/p/d and 44.3 mg/p/d (81.5 mg/d for the powder form), respectively, for the U.S. population aged 2 years and older. Polyphenols are present in the diet, with background estimated dietary exposure at approximately 1656 mg/d in adults 20 years and older. Crush Dynamics states that the intended uses of the purée and powder forms of fermented grape pomace are substitutional for each other. The highest estimated 90th percentile dietary exposure to polyphenols from the intended uses of fermented grape pomace is 121.9 mg/p/d (1.46 mg/kg bw/d) for adult males that consume the powder form of fermented grape pomace. Therefore, the background dietary exposure to polyphenols from the diet is significantly greater than the expected dietary exposure from the intended uses of fermented grape pomace.

Crush Dynamics notes the long history of consumption of grapes and grape-derived food products including many that are fermented. Crush Dynamics bases its evaluation of the effects and safety of consumption of the purée and powder forms of fermented grape pomace on their total polyphenol content. Crush Dynamics reports that absorbed dietary polyphenolic compounds and their metabolites have a low potential for long-term accumulation in tissues or organs and are rapidly excreted. Based on an updated literature search through June 2026, Crush Dynamics identifies total polyphenol exposure levels encountered in studies that orally administered other types of grape-derived substances. The findings from these studies serve to determine the safe level of total polyphenols from consumption of the purée and powder forms of fermented grape pomace. Crush Dynamics concludes that dietary exposure to polyphenols from the purée and powder forms of its fermented grape pomace do not exceed the upper limit of safe human dietary exposure and thus are not at a level of concern.

Based on the totality of evidence considered, Crush Dynamics concludes that fermented grape pomace is GRAS under the intended conditions of use.

Standards of Identity

In the notice, Crush Dynamics states its intention to use fermented grape pomace 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 Requirement for a Color Additive Petition

There is no GRAS provision for color additives. In the notice, Crush Dynamics describes fermented grape pomace as a deep red to dark purple or golden-brown purée or gold powder. As such, the use of fermented grape pomace in food products may constitute a color additive use under section 201(t)(1) of the Federal Food, Drug, and Cosmetic Act (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 001302 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 Food Ingredients in OPMAS.

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 Crush Dynamics's notice concluding that fermented grape pomace 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 fermented grape pomace. Accordingly, our response should not be construed to be a statement that foods containing fermented grape pomace, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

Conclusions

Based on the information that Crush Dynamics provided, as well as other information available to FDA, we have no questions at this time regarding Crush Dynamics's conclusion that fermented grape pomace is GRAS under its intended conditions of use. This letter is not an affirmation that fermented grape pomace 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

001302 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

SUSAN J.

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Susan J. Carlson, Ph.D.

Director

Division of Food Ingredients

Office of Pre-Market Additive Safety

Office of Food Chemical Safety, Dietary
Supplements, and Innovation

Human Foods Program