Mary M. Murphy
Exponent, Inc.
1150 Connecticut Avenue, NW
Suite 1100
Washington, DC 20036

Re: GRAS Notice No. GRN 000947

Dear Ms. Murphy:

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 000947. We received the notice that you submitted on behalf of CABOSSE Naturals NV (CABOSSE) on June 2, 2020 and filed it on September 16, 2020. CABOSSE submitted amendments to the notice on June 21, 2021, November 29, 2021, and December 20, 2021 that provide clarifications regarding the composition, analytical methodology, specifications, storage conditions, and changes to the scope of the notice to remove 100% cacao juice.

The subjects of the notice are cacao pulp and cacao fruit juice concentrate for use as ingredients as indicated in Table 1. The notice informs us of CABOSSE's view that these uses of cacao pulp and cacao fruit juice concentrate are GRAS through scientific procedures.

**Table 1. Intended uses of cacao pulp and cacao fruit juice concentrate**

| Food category | Maximum Use Level (weight %) | |
|---|---|---|
| | Cacao Pulp | Cacao Fruit Juice Concentrate |
| Bakery products | 15 | 50 |
| Beverages | 20 | 20 |
| Candy and confections (non-chocolate) | 25 | 65 |
| Cereal bars, chips and crackers | | 15 |
| Cocoa and chocolate products | | 50 |
| Edible ices – ice cream type | | 30 |
| Edible ices - sorbet type | | 30 |
| Gelatin/fruit mousse spreads | | 30 |
| Jams, jellies, fruit syrups, and toppings | 50 | 25 |
| Nutrition bars | | 50 |
| Plant-based spreads | 20 | 25 |
| Yogurt/yogurt drinks | 25 | 10 |

Our use of the terms, "cacao pulp" and "cacao fruit juice concentrate" in this letter is not our recommendation of those terms as appropriate common or usual names 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 did not consult with ONFL regarding the appropriate common or usual name for "cacao pulp" and "cacao fruit juice concentrate."

CABOSSE provides information on the identity and composition of cacao pulp and cacao fruit juice concentrate. Cacao pulp and cacao fruit juice concentrate are derived from the fruit of the cacao plant, *Theobroma cacao* L. Cacao pulp is the semi-solid fruit flesh from the mucilaginous layer surrounding the cacao bean that is collected as part of the initial processing of the cacao bean after pod opening and prior to fermentation of the cacao bean. This pulp is further processed to obtain cacao fruit juice concentrate. CABOSSE states that cacao pulp and cacao fruit juice concentrate are composed of predominantly water and carbohydrates, accounting for 96-97% percent by weight of the products. They also contain fiber, protein (<1%), fat (<0.2%), organic acids, vitamins and minerals, polyphenols, and the purine alkaloid theobromine.

CABOSSE states that cacao pulp and cacao fruit juice concentrate are manufactured using current good manufacturing practices. The cacao beans are sorted to remove undesirable pieces of husk and placenta and then depulped. The depulped beans are removed and the pulp is collected, separated from the juice by centrifugation followed by ultrafiltration. The pulp is then cooled and pasteurized to obtain cacao pulp. To obtain cacao fruit juice concentrate, pectinases are added to the cacao pulp under controlled conditions to break down pectin and cellulose. The solution is then filtered to remove insoluble particles, subjected to centrifugation, pasteurized, filtered again, and the resulting juice is concentrated via evaporation to yield cacao fruit juice concentrate. The final products are frozen or refrigerated for transportation and storage.

CABOSSE provides specifications for cacao pulp to include: Brix (16-20), arsenic (≤ 0.05 mg/kg), mercury (≤ 0.005 mg/kg), lead (≤ 0.02 mg/kg), cadmium (≤ 0.02 mg/kg), pH (2.8 – 3.8), and limits for microorganisms. CABOSSE also provides specifications for cacao fruit juice concentrate to include: Brix (55-65), arsenic (≤ 0.05 mg/kg), mercury (≤ 0.005 mg/kg), lead (≤ 0.02 mg/kg), cadmium (≤ 0.2 mg/kg), pH (2.5 – 3.5), and limits for microorganisms. CABOSSE provides data from the analyses of three non-consecutive lots each to demonstrate that cacao pulp and cacao fruit juice concentrate can be manufactured to meet the specifications. CABOSSE indicates that the recommended storage conditions are -18 °C for up to 15 months, or 4 °C for up to 2 months for both products.

CABOSSE provides a dietary exposure estimate to cacao pulp and cacao fruit juice concentrate from their intended uses based on food consumption data from the 2013-

2016 National Health and Nutrition Examination Survey. CABOSSE states that only one cacao ingredient (pulp or fruit juice concentrate) will be used in a specific food at a given time. CABOSSE estimates dietary exposure to cacao fruit juice concentrate using the maximum intended use levels; these are the same or higher than those for cacao pulp in all categories other than in jams, jellies, fruit syrups and toppings; and yogurt/yogurt drinks. CABOSSE notes that the cacao fruit juice concentrate is 3 times more concentrated than the cacao pulp. Therefore, CABOSSE states that using the maximum intended use level of cacao fruit juice concentrate provides an upper bound dietary exposure to cacao fruit juice concentrate and cacao pulp for the intended uses in all food categories. CABOSSE estimates the mean and 90$^{th}$ percentile eaters-only dietary exposures to cacao pulp and cacao fruit juice concentrate from the intended uses to be 85 g/p/d and 176 g/p/d, respectively, for the U.S. population aged 2 years and older.

CABOSSE states that the safe human consumption of cacao pulp and cacao fruit juice concentrate is supported by the widespread safe use of chocolate and other cacao products derived from cacao pod pulp, and available safety-related data specific to key constituents of cacao pulp and cacao juice concentrate. CABOSSE concludes that the potential dietary exposure to these constituents from the intended use of cacao pulp and cacao fruit juice concentrate will be within background levels and therefore, safe. CABOSSE discusses published reproductive studies for theobromine and notes that there is no safety concern for reproductive toxicity or testicular toxicity at the highest intended exposure. CABOSSE notes that there are no reports of allergic responses to consumption of cacao pulp.

CABOSSE includes the statement of a panel of individuals (CABOSSE's GRAS panel). Based on its review, CABOSSE's GRAS panel concluded that cacao pulp and cacao fruit juice concentrate are safe under the conditions of its intended use.

Based on the available data and information, CABOSSE concludes that its cacao pulp and cacao fruit juice concentrate are GRAS under the intended conditions of use.

## Standards of Identity

In the notice, CABOSSE states its intention to use cacao pulp and cacao fruit juice concentrate 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 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 cacao pulp or cacao juice concentrate 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 the Office of Nutrition and Food Labeling (ONFL) in the Center for Food Safety and Applied Nutrition. The Office of Food Additive Safety 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.

## Section 301(ll) of the Federal Food, Drug, and Cosmetic Act (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 CABOSSE's notice concluding that cacao pulp and cacao juice concentrate are GRAS under the intended conditions of use, we did not consider whether section 301(ll) or any of its exemptions apply to foods containing cacao pulp and cacao juice concentrate. Accordingly, our response should not be construed to be a statement that foods containing cacao pulp and cacao juice concentrate, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

## Conclusions

Based on the information that CABOSSE provided, as well as other information available to FDA, we have no questions at this time regarding CABOSSE's conclusion that cacao pulp and cacao juice concentrate are GRAS under the intended conditions of use. This letter is not an affirmation that cacao pulp and cacao juice concentrate are 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 000947 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

Digitally signed by Susan J. Carlson -S
Date: 2021.12.20 15:40:51 -05'00'

Susan Carlson, Ph.D.
Director
Division of Food Ingredients
Office of Food Additive Safety
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and Applied Nutrition