U.S. FOOD & DRUG ADMINISTRATION
Human Foods Program

Marisa O. Rihner
Exponent, Inc.
1150 Connecticut Avenue, NW
Suite 1100
Washington, DC 20036

Re: GRAS Notice No. GRN 001321

Dear Ms. Rihner:

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 001321. We received the notice that you submitted on behalf of LuckyLiquor LLC (LuckyLiquor) on January 22, 2026, and filed it on April 9, 2026. LuckyLiquor submitted amendments to the notice on July 7, 2026, and August 3, 2026, clarifying the analytical data, composition, manufacturing process, specifications, and safety narrative.

The subject of the notice is a powder prepared from the dried leaves and stems of the Geraldton waxflower (*Chamelaucium uncinatum*) (Geraldton waxflower), that is steeped in neutral spirits, for use as a flavoring agent added prior to distillation in the production of gin at a maximum level of 0.078 g/L (0.0078% by volume). The notice informs us of LuckyLiquor's view that this use of Geraldton waxflower is GRAS through scientific procedures.

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

LuckyLiquor provides information on the identity and composition of Geraldton waxflower describing it as a light green, fine powder derived from the dried leaves and stems of *C. uncinatum*. LuckyLiquor states that Geraldton waxflower is primarily composed of fiber, carbohydrates, fat, and protein, with small amounts of polyphenols. LuckyLiquor provides tables describing the composition of Geraldton waxflower, including the fatty acid, amino acid, and volatile component profile.

LuckyLiquor describes the method of manufacture for Geraldton waxflower. The leaves and stems from *C. uncinatum* are hydrated in water, milled, and then lyophilized. The dried material is further milled into a homogenous fine powder and then packaged. When used in the production of gin, the Geraldton waxflower is steeped in neutral cane spirits at room temperature and then distilled at 78-80˚C. LuckyLiquor states that Geraldton waxflower is manufactured using food-grade raw materials in accordance with good manufacturing practices and that no processing aids are used.

LuckyLiquor provides specifications for Geraldton waxflower that include fiber (50-60%), carbohydrates (18-28%), crude protein (5.5-7%), fat (7-9%), ash (4-7%), moisture (4-6%), and limits for lead (< 0.1 mg/kg), arsenic (< 0.05 mg/kg), cadmium (< 0.1 mg/kg), mercury (< 0.05 mg/kg), and microorganisms. LuckyLiquor provides the results from the analyses of five non-consecutive batches to demonstrate that Geraldton waxflower can be manufactured to meet the specifications. LuckyLiquor states that Geraldton waxflower is stable for at least 3 years when stored at room temperature in the dark.

LuckyLiquor estimates dietary exposure to Geraldton waxflower based on the intended use and food consumption data from the 2017-March 2020 National Health and Nutrition Examination Survey (NHANES). LuckyLiquor estimates the eaters-only dietary exposure to Geraldton waxflower for the U.S. population aged 21 years and older to be 5.9 mg/person (p)/d (0.07 mg/kg body weight (bw)/d) at the mean and 18 mg/p/d (0.20 mg/kg bw/d) at the 90th percentile.[1]

LuckyLiquor assesses the safety of Geraldton waxflower steeped in neutral spirits for use in the production of gin based on a review of the available toxicological data and information from a search of publicly available literature, including authoritative risk assessment sources on the individual chemical constituents of the ingredient. LuckyLiquor states that Geraldton waxflower contains primarily carbohydrates, protein, and fat along with polyphenols and flavonoids. Geraldton waxflower also contains volatile flavoring components that will be present in gin. LuckyLiquor includes considerations of existing regulations or guidance on dietary exposure to certain volatile components. LuckyLiquor further utilizes other tools of safety assessment such as identification of established safety reference values for other chemical components through read-across or threshold of toxicological concern approaches to ensure the safety of Geraldton waxflower at the intended use level in gin. LuckyLiquor concludes that the dietary exposure to these chemical components is not at levels of concern and notes that the volatile flavoring components are naturally occurring flavor and aroma compounds already found in many foods. LuckyLiquor states that additional components like polyphenols and flavonoids are common in edible plants, with dietary exposure levels below levels of concern. LuckyLiquor notes that the species and cultivar

[1] LuckyLiquor notes that although the eaters-only 90th percentile dietary exposure is statistically unreliable due to the sample size, it is approximately three times higher than the eaters-only mean dietary exposure, and therefore conservative compared to the "pseudo-90th percentile" dietary exposure estimated by doubling the mean dietary exposure as described in FDA's "Guidance for Industry: Estimating Dietary Intake of Substances in Food" (https://www.fda.gov/regulatory-information/search-fda-guidancedocuments/guidance-industry-estimating-dietary-intake-substances-food).

of waxflower used to produce Geraldton waxflower is not expected to cause non-nutritive physiological effects in consumers from the intended uses. LuckyLiquor also assesses the potential for allergenicity through major allergen database searches. LuckyLiquor concludes that the proteins present in Geraldton waxflower are unlikely to cause allergic reactions in the general population. LuckyLiquor acknowledges a 2026 Record of Views formed by the Advisory Committee on Novel Foods of Food Standards Australia New Zealand (FSANZ), where FSANZ classified Geraldton waxflower as a non-traditional, non-novel food, and identified no safety concerns with its limited intended use in gin distillation.

Based on the totality of the data and information, LuckyLiquor concludes that Geraldton waxflower is GRAS through scientific procedures under the conditions of its intended use.

Potential Requirement for a Color Additive Petition

There is no GRAS provision for color additives. In the notice, LuckyLiquor describes Geraldton waxflower as a light green powder. As such, the use of Geraldton waxflower in food products may constitute a color additive use under section 201(t)(1) of the Federal Food, Drug & 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 001321 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 LuckyLiquor's notice concluding that Geraldton waxflower 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 Geraldton waxflower. Accordingly, our response should not be construed to be a statement that foods containing Geraldton waxflower, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

Conclusions

Based on the information that LuckyLiquor provided, as well as other information available to FDA, we have no questions at this time regarding LuckyLiquor's conclusion that Geraldton waxflower is GRAS under its intended conditions of use. This letter is not an affirmation that Geraldton waxflower 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 001321 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

SUSAN J. CARLSON -S

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Susan J. Carlson, Ph.D.
Director
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