



Marisa Rihner
Exponent
1150 Connecticut Ave., NW
Suite 1100
Washington, DC 20036

Re: GRAS Notice No. GRN 001291

Dear Ms. Rihner:

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 001291. We received the notice that you submitted on behalf of LuckyLiquor LLC (LuckyLiquor) on May 7, 2025 and filed it on January 30, 2026. LuckyLiquor submitted amendments to the notice on April 30, 2026 and May 6, 2026, including clarifications on the composition, specifications, batch analyses, and safety.

The subject of the notice is roasted wattle (*Acacia longifolia*) seeds (roasted wattle seeds), steeped in neutral spirits, for use as a flavoring agent added prior to distillation in the production of gin at a maximum use level of 815 mg/kg (0.08%). The notice informs us of LuckyLiquor's view that this use of wattle seeds is GRAS through scientific procedures.

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

LuckyLiquor provides information on the identity and composition of roasted wattle seeds. Roasted wattle seeds are the dark brown roasted seeds of *A. longifolia*, primarily composed of protein, fat, and carbohydrates, with small amounts of polyphenols. LuckyLiquor provides tables describing the composition of roasted wattle seeds, including the fatty acid, amino acid, and volatile component profile.

LuckyLiquor describes the method of manufacture for roasted wattle seeds. The seeds are separated from the pods and roasted in approximately 3 kg aliquots in open pans over a high gas flame (180 °C) for 25 minutes with stirring until the seed aril has burnt

away and the seed is smoking. The seeds are cooled and then packaged. When used in the production of gin, the roasted wattle seeds are steeped in neutral cane spirits at room temperature and then the distillation occurs at 78-80 °C. LuckyLiquor states that wattle seeds are manufactured in accordance with current good manufacturing practices and that no processing aids are used.

LuckyLiquor provides specifications for roasted wattle seeds that include carbohydrates (45-55%), crude protein (25 –35%), fat (12–17%), ash (3–4.5%), moisture (2–3%), and limits for lead (<0.01 mg/kg), arsenic (<0.05 mg/kg), cadmium (<0.1 mg/kg), mercury (<0.01 mg/kg), and microorganisms. LuckyLiquor provides the results from the analyses of three non-consecutive batches to demonstrate that roasted wattle seeds can be manufactured to meet the specifications. LuckyLiquor states that roasted wattle seeds are stable for at least 2 years when stored at 4 °C.

LuckyLiquor estimates dietary exposure to roasted wattle seeds 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 roasted wattle seeds for the U.S. population aged 21 years and older to be 60.5 mg/person (p)/d at the mean and 183 mg/p/d at the 90th percentile.¹

LuckyLiquor assesses the safety of roasted wattle seeds steeped in neutral spirits based on a review of authoritative sources on the individual chemical components of the ingredient. LuckyLiquor states that roasted wattle seeds from *A. longifolia* contain primarily carbohydrates, protein, and fat along with polyphenols. LuckyLiquor notes that there is a history of indigenous Australians consuming both raw and roasted wattle seeds. Roasted wattle seeds also contain volatile flavoring components that will be present in gin. LuckyLiquor includes considerations of existing regulations or guidance on dietary exposure to certain volatile components or identification of established safety reference values for volatile components to ensure the safety of roasted wattle seeds at the intended use level in gin. LuckyLiquor concludes that the dietary exposure to these volatile components is not at levels of concern and notes that the volatile flavoring components are naturally occurring flavor and aroma compounds found in many foods. Additional components like polyphenols, flavonoids, and acrylamide are common in edible plants and cooked foods, with dietary exposure levels below background dietary intake levels. LuckyLiquor also assessed the potential for allergenicity through major allergen database searches. LuckyLiquor concludes that the proteins present in *A. longifolia* are unlikely to cause allergic reactions in the general population.

Based on the totality of the data and information, LuckyLiquor concludes that roasted wattle seeds are GRAS through scientific procedures under the conditions of their intended use.

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>).

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 wattle seeds are GRAS under its intended conditions of use, we did not consider whether section 301(ll) or any of its exemptions apply to foods containing wattle seeds. Accordingly, our response should not be construed to be a statement that foods containing wattle seeds, 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 wattle seeds are GRAS under its intended conditions of use. This letter is not an affirmation that wattle seeds 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 001291 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,
**SUSAN J.
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CARLSON -S
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Susan J. Carlson, Ph.D.
Director
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