U.S. FOOD & DRUG ADMINISTRATION
Human Foods Program

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

Re: GRAS Notice No. GRN 1223

Dear Ms. Rihner:

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 001223. We received the notice that you submitted on behalf of Suntory Global Spirits (Suntory) on October 4, 2024, and filed it on December 19, 2024. Suntory submitted amendments to the notice on March 14, 2025, and April 10, 2025, providing additional information about the composition, manufacturing process, analytical data, specifications, dietary exposure, and safety narrative.

The subject of the notice is sakura (*Prunus serrulata* Lindl.) flower distillate (sakura flower distillate) for use as a flavoring agent in alcoholic (≥0.5% alcohol by volume (ABV)) and dealcoholized (<0.5% ABV) distilled spirits at a level up to 40% by volume and in alcoholic and dealcoholized ready-to-drink distilled spirit-based cocktails at a level up to 10% by volume. The notice informs us of Suntory's view that these uses of sakura flower distillate are GRAS through scientific procedures.

Our use of the term, "sakura flower distillate," 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 did not consult with ONFL regarding the appropriate common or usual name for "sakura flower distillate."

Suntory provides information about the identity and composition of sakura flower distillate, describing it as an aqueous ethanol-based solution derived from the flowers of *P. serrulata* trees. Suntory states that sakura flower distillate is a colorless liquid containing sakura flower derivatives, ethanol, and water. Suntory provides a table describing the composition of sakura flower distillate.

Suntory describes the method of manufacture for sakura flower distillate. The flower petals are separated from the fresh sakura flowers followed by rinsing with water. The clean petals are mixed with grain-neutral spirit (GNS; ethanol) and water, and the slurry is steeped at room temperature for three weeks. The slurry is filtered using a 5 mm mesh screen to remove the petals, and the filtrate (i.e., sakura flower extract) is vacuum distilled to obtain the final sakura flower distillate. Suntory states that sakura flower distillate 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.

Suntory provides specifications for sakura flower distillate that include total solids (<0.6 g/100 L), total sakura flower derivatives (0.01-0.02% w/v), and ABV (30-32.5% w/v), as well as limits for lead (<0.01 mg/kg), arsenic (<0.005 mg/kg), cadmium (<0.001 mg/kg), mercury (<0.001 mg/kg), and microorganisms. Suntory provides the results from the analyses of three non-consecutive batches of sakura flower distillate to demonstrate that the ingredient can be manufactured to meet the specifications. Based on accelerated stability studies, Suntory concludes that sakura flower distillate is stable for at least six months when stored at room temperature.

Suntory estimates the dietary exposure to sakura flower distillate based on the intended uses and food consumption data from the 2017-2020 National Health and Nutrition Examination Survey (NHANES). Suntory estimates the mean and 90th percentile eaters-only dietary exposure to sakura flower distillate for the U.S. population aged 21 years and older to be 36.3 g/person (p)/d (0.42 g/kg body weight (bw)/d) and 77.8 g/p/d (0.92 g/kg bw/d), respectively.

Suntory assesses the safety of sakura flower distillate based on a review of available information from authoritative sources on the individual chemical components of the ingredient. This includes consideration of existing regulations or guidance on dietary exposure to certain chemical components or identification of established safety reference values for other chemical components to ensure the safety of the dietary exposure to sakura flower distillate at the intended use levels in alcoholic and dealcoholized distilled spirit beverages. Suntory concludes that the dietary exposure to the chemical components in sakura flower distillate are not at levels of concern and are commonly found in plants that humans consume. In further support of safety, Suntory describes the history of consumption of the flowers of the *P. serrulata* tree. For instance, they have been consumed as tea or in food items for more than 100 years in Japan.

Based on the totality of the data and information, Suntory concludes that sakura flower distillate is GRAS for its intended use.

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 Suntory's notice concluding that sakura flower distillate 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 sakura flower distillate. Accordingly, our response should not be construed to be a statement that foods containing sakura flower distillate, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

Conclusions

Based on the information that Suntory provided, as well as other information available to FDA, we have no questions at this time regarding Suntory's conclusion that sakura flower distillate is GRAS under its intended conditions of use. This letter is not an affirmation that sakura flower distillate 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 001223 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

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Date: 2025.06.03 11:37:39 -04'00'

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Director
Division of Food Ingredients
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