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 001234

Dear Ms. Rihner:

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 001234. We received the notice that you submitted on behalf of Suntory Global Spirits (Suntory) on November 27, 2024, and filed it on February 7, 2025. Suntory submitted an amendment to the notice on May 1, 2025, clarifying the identity, manufacturing process, dietary exposure, and safety.

The subject of the notice is sansho (*Zanthoxylum piperitum*) pepper extract (sansho pepper extract) 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 sansho pepper extract are GRAS through scientific procedures.

Our use of the term, “sansho pepper extract,” 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 “sansho pepper extract.”

Suntory provides information on the identity and composition of sansho pepper extract, describing it as an aqueous ethanol-based solution derived from the berries of *Z. piperitum*. Suntory states that sansho pepper extract is a pale yellow liquid containing sansho pepper extractives, ethanol, and water. Suntory provides a table describing the composition of sansho pepper extract.

Suntory describes the method of manufacture for sansho pepper extract. The fresh berries are dried, mixed with grain-neutral spirit (GNS; ethanol) and water, and the slurry is steeped at room temperature for one to three days. The slurry is filtered using a 5 mm mesh screen to remove the berries, yielding the final sansho pepper extract. Suntory states that sansho pepper extract 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 sansho pepper extract that include total solids (≤65 g/100 L), total sansho pepper extractives (0.005 to 0.03 % w/v), ABV (21 to 25% w/v), and 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 to demonstrate that sansho pepper extract can be manufactured to meet these specifications. Based on accelerated stability studies, Suntory concludes that sansho pepper extract is stable for at least 6 months when stored at room temperature.

Suntory estimates the dietary exposure to sansho pepper extract 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 sansho pepper extract 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 states that the fruits, leaves, and roots of sansho peppers, which are native to Japan and Korea, have been used in culinary preparations since ancient times. Suntory discusses published *in vitro* and *in vivo* genotoxicity studies evaluating sansho pepper extract and sansho pepper essential oil. Suntory reports from these studies that sansho pepper extract is not mutagenic (negative in Ames test) nor is it clastogenic or aneugenic in human lymphocytes. Suntory discusses several published rodent studies using oral exposure to sansho pepper extract or distillate and states that no adverse effects were reported in these studies. Suntory 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 sansho pepper extract at the intended use levels in alcoholic and dealcoholized distilled spirit beverages. Suntory concludes that the dietary exposure to the chemical components in sansho pepper extract are not at levels of concern and are commonly found in plants that humans consume. Suntory states that they found no reports of allergic reactions to sansho pepper and additionally comments that sansho pepper extract does not contain proteins.

Based on the totality of evidence, Suntory concludes that sansho pepper extract is safe 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 sansho pepper extract 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 sansho pepper extract. Accordingly, our response should not be construed to be a statement that foods containing sansho pepper extract, 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 sansho pepper extract is GRAS under its intended conditions of use. This letter is not an affirmation that sansho pepper extract 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 001234 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

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Director
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