

Amy Mozingo, MS
GRAS Associates
11810 Grand Park Avenue Suite 500
North Bethesda, MD 20852

Re: GRAS Notice No. GRN 001227

Dear Ms. Mozingo:

The Food and Drug Administration (FDA, we) is granting the request on behalf of Korea Ginseng Corporation (KGC) that we cease our evaluation of GRN 001227. We received this request on August 7, 2025. We received KGC's notice on August 28, 2024 and filed it on February 28, 2025. KGC submitted amendments to the notice on May 6, 2025 and August 1, 2025 regarding ginsenoside content, certificates of analysis, and additional safety information.

The subject of the notice is Korean red ginseng (*Panax ginseng* C.A. Meyer) root extract (KRGE) for use as an ingredient in soups; cereal and nutrition bars; candy not containing chocolate; fruit and vegetable juices; fruit drinks, sports and "energy" drinks, soft drinks; tea; nutritional beverages and powders, smoothies and grain drinks, flavored, carbonated, fortified, and enhanced waters; and condiments at levels ranging from 100 mg to 1000 mg per serving (excluding use in infant formula, foods for young children, or in products under the jurisdiction of the United States Department of Agriculture). The notice informs us of KGC's view that these uses of KRGE are GRAS through scientific procedures.

In a meeting on July 30, 2025, we communicated with you as KGC's representative regarding additional information needed to support a GRAS conclusion. KRGE contains a number of bioactive constituents with known or suspected physiological effects. We note that infrequent side effects have been reported in the literature that include severe rash, liver damage, and severe allergic reactions. Additionally, it is not clear whether the resulting dietary exposure from the proposed use would have the physiological effects that have been reported in the literature. Further concerns we discussed included teratogenic effects noted in a mouse study of one of the components (ginsenoside Rb1), concerns related to consumption in pregnancy, limited long-term data for the developing fetus, effects on subpopulations with type-2 diabetes, interactions with herbal products and commonly consumed foods and medications. We find that the information currently available in the public domain strongly suggests that there is significant potential for adverse effects for long term consumption (more than 6 months) of KRGE, and that the safety of long-term consumption of KRGE in humans is not established.

We have ceased our evaluation of the notice at KGC's request. We remind KGC of a manufacturer's responsibility to ensure the safety and regulatory status of the substances that it markets for use in food or that it uses in food. We also remind KGC that the use of a substance in food that is not GRAS (and is not otherwise excluded from the definition of a food additive), must have pre-market approval by FDA for its use in food (21 CFR 170.30(g)). More information about the criteria for GRAS is available in our regulations (21 CFR part 170). Finally, we remind KGC of the signed statements and certification (part 1 of a GRAS notice, 21 CFR 170.225) by which KGC agrees to make all data and information regarding its GRAS conclusion available to FDA upon request.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 001227 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

**Susan J.
Carlson -S**

Digitally signed by Susan
J. Carlson -S
Date: 2025.08.21 16:53:41
-04'00'

Susan J. Carlson, Ph.D.
Director
Division of Food Ingredients
Office of Pre-Market Additive Safety
Office of Food Chemical Safety, Dietary
Supplements, and Innovation
Human Foods Program