



William J. Rowe
President
GRAS Associates, LLC
27499 Riverview Center Blvd., Suite 212
Bonita Springs, FL 34134

Re: GRAS Notice No. GRN 000878

Dear Mr. Rowe:

The Food and Drug Administration (FDA, we) completed our evaluation of the supplement you submitted on behalf of Daepyung Co., Ltd (Daepyung) to GRN 000878. We received the supplement on February 5, 2020. The supplement provides a correction to the specifications in Appendix 1.1 of GRN 000878.

We previously responded to GRN 000878 on December 9, 2019. We stated that we had no questions at that time regarding Daepyung's conclusion that enzyme-modified steviol glycosides (EMSG) is GRAS for use as a flavor modifier in foods, excluding infant formula and products under jurisdiction of the United States Department of Agriculture (USDA).

The EMSG that is the subject of GRN 000878 is made from highly purified components of the leaves of *Stevia rebaudiana* (stevia). We note that a GRAS notice for the use of specific purified components of stevia, such as EMSG, and FDA's response do not necessarily apply to the uses of other stevia products.

Our use of the terms "EMSG," and "steviol glycosides," or "SGs" in this letter is not our recommendation of these terms 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 Center for Food Safety and Applied Nutrition. The Office of Food Additive Safety did not consult with ONFL regarding the appropriate common or usual name for "EMSG."

In the supplement, Daepyung informed FDA of corrections to the specifications for a stevia extract preparation used in the manufacture of EMSG and noted that this

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information does not alter the previous notified identity, method of manufacture, or specifications of EMSG. In GRN 000878, information was provided on a stevia leaf extract that is further processed to obtain a preparation that is $\geq 95\%$ total SGs and then subjected to an enzyme modification step to produce EMSG. In an appendix to that notice, a certificate of analysis was provided for a stevia extract preparation that included specifications for total SGs ($\geq 95\%$) and minimum rebaudioside A ($\geq 85\%$). In the supplement, Daepyeong provides corrected specifications for the stevia extract preparation that include a minimum of total SGs ($\geq 95\%$) but excludes a specification for minimum rebaudioside A. Daepyeong states that the stevia extract preparation used to produce EMSG and EMSG itself meet the specifications for SGs established by the Joint FAO/WHO Expert Committee on Food Additives. Daepyeong concludes that this correction raises no safety concerns and concludes that EMSG is GRAS for the intended use.

Standards of Identity

In the supplement, Daepyeong state its intention to use EMSG in several food categories, including foods for which standards of identity exist, located in Title 21 of the Code of Federal Regulations. We note that an ingredient that is lawfully added to food products may be used in a standardized food only if it is permitted by the applicable standard of identity.

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 its review of Daepyeong's supplement that EMSG is GRAS for the intended use, FDA did not consider whether section 301(ll) or any of its exemptions apply to foods containing EMSG. Accordingly, this response should not be construed to be a statement that foods that contain EMSG, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).


Conclusions

Based on the information Daepyeong provided, and other information available to FDA, we have no questions at this time regarding Daepyeong's conclusion that EMSG is GRAS under its intended conditions of use. This letter is not an affirmation that EMSG 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 the supplement to GRN 000878 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J.
Carlson -S

 Digitally signed by Susan J.
Carlson -S
Date: 2020.05.11 16:30:42
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