Sidd Purkayastha, Ph.D.
VP, Head of Global Scientific & Regulatory Affairs
PureCircle Limited
200 W Jackson Blvd, Suite 800
Chicago, IL 60606

Re: GRAS Notice No. GRN 000607

Dear Dr. Purkayastha:

The Food and Drug Administration (FDA, we) completed our evaluation of PureCircle Limited (PureCircle)'s supplement to GRN 000607. We received the supplement on May 6, 2019. The supplement addresses intended uses and estimates of dietary exposure for enzyme-modified steviol glycosides (EMSG).

We previously responded to GRN 000607 on October 14, 2016. We stated that we had no questions at that time regarding PureCircle's conclusion that 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).

In the supplement received May 6, 2019, PureCircle informs us of its view that EMSG is GRAS, through scientific procedures, for use as a sweetener in foods, excluding infant formula and products under jurisdiction of the USDA.

The EMSG that is the subject of GRN 000607 and its supplement is made from highly purified components of the leaves of the stevia plant. 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 "enzyme-modified steviol glycosides" or "EMSG" 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 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, PureCircle states that the identity, manufacturing process and specifications for EMSG are the same as described in GRN 000607. In addition, PureCircle provides sensory data to demonstrate that EMSG exhibits sweetness when used in food at concentrations higher than the maximum levels specified in GRN 000607 and data related to the determination of the relative sweetness of EMSG to sucrose. Further, PureCircle notes the acceptable daily intake (ADI) for steviol glycosides of up to 4 mg/kg body weight (bw)/day (expressed as steviol) established by the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

In the supplement, PureCircle provides estimates of dietary exposure to EMSG based on the methodology described in Ref. 1 and a relative sweetness intensity of 100 times that of sucrose. PureCircle estimates the maximum dietary exposure in adults (expressed as steviol equivalents) to be 1.88 mg/kg bw/day and in children to be 2.08 mg/kg bw/day.

PureCircle concludes that the dietary exposure resulting from the intended use of EMSG use as a general-purpose sweetener in foods, excluding infant formula and meat and poultry products, at levels determined by current good manufacturing practices to be below the ADI established by JECFA.

Standards of Identity

In the supplement, PureCircle states 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 our evaluation of PureCircle's supplement concluding that EMSG 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 EMSG. Accordingly, our response should not be construed to be a statement that foods containing EMSG, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

Conclusions

Based on the information that PureCircle provided, as well as other information available to FDA, we have no questions at this time regarding PureCircle'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 000607 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

Digitally signed by Susan J. Carlson -S
Date: 2019.11.15 16:43:28 -05'00'

Susan Carlson, Ph.D.
Director
Division of Food Ingredients
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition

Reference

1. Renwick, A.G. 2008. The use of a sweetener substitution method to predict dietary exposures for the intense sweetener rebaudioside A. Food and Chemical Toxicology 46:S61–S69.