Jason Ryder, Ph.D.
Joywell Foods, Inc.
202 Cousteau Place, Suite 210
Davis, CA 95618

Re: GRAS Notice No. GRN 000994

Dear Dr. Ryder:

The Food and Drug Administration (FDA, we) is granting the request to cease our evaluation of GRN 000994, which we filed on May 27, 2021. We received this request on September 27, 2021.

The subject of the notice is miracle fruit (*Synsepalum dulcificum*), in pulp, powder, or protein forms, for use as a taste modifier at levels up to 5 g pulp/serving, 0.7 g powder/serving, and 0.005 g protein/serving, in cheesecake; alcoholic beverages; water-based beverages; non-dairy meal replacement beverages and protein drinks; chewing gum; ready-to-drink coffees and teas; milk-based beverages and yogurt; dairy product analogs; frozen dairy desserts and mixes; fruit and water ices; snack bars; meal-replacement bars; granola; fruit juices, nectars, drinks, ades, and smoothies; vegetable juices; and soft candy. The notice informs us of Joywell Foods, Inc.'s view that this use of miracle fruit, in pulp, powder, or protein forms, is GRAS through scientific procedures.

In a teleconference on September 22, 2021, we informed you that we could not continue our evaluation of GRN 000994 due to issues identified during our evaluation of the notice. During the teleconference, we noted that Joywell Foods did not provide sufficient safety data and information to support the proposed use levels of the notified substances. In addition, we noted that the biochemical mechanism underlying the taste-modifying effect of the notified substances was not discussed in the notice. Finally, we noted that Joywell Foods did not adequately address whether the notified substances have the potential to adversely affect the sweet taste receptors. In a follow-up email dated October 6, 2021, we provided you with a complete list of the issues that we identified during our evaluation.

Given the substantive nature of the issues discussed during the teleconference, we discussed the opportunity for Joywell Foods, Inc. to request that we cease our evaluation of the notice. We also recommended that you request a pre-submission meeting with us to discuss the issues before resubmitting the notice for evaluation without prejudice. In a letter dated September 27, 2021, you requested that we cease our evaluation of GRN 000994.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 000994 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

Digitally signed by Susan J. Carlson -S
Date: 2021.10.26 15:00:29 -04'00'

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