



Erik Tietig
Miracle Fruit Farm, LLC
16300 SW 184th Street
Miami, FL 33187

Re: GRAS Notice No. GRN 001027

Dear Mr. Tietig:

The Food and Drug Administration (FDA, we) is granting the request to cease our evaluation of GRN 001027, which we filed on November 1, 2021. We received this request on December 16, 2021.

The subject of the notice is miracle fruit (*Synsepalum dulcificum*) powder for use as a taste modifier at levels up to 6% in water-based beverages, carbonated beverages, fruit juices and nectars, fruit-based smoothies, fruit drinks and ades, fermented dairy products (buttermilk, acidophilus milk, kefir), yogurts, and ready-to-drink tea beverages. The notice informs us of Miracle Fruit Farm, LLC's view that this use of miracle fruit powder is GRAS through scientific procedures.

In a teleconference on December 16, 2021, we informed you that we could not continue our evaluation of GRN 001027 due to issues identified in the notice. We noted that Miracle Fruit Farm, LLC did not provide sufficient safety data and information to support the proposed use levels of the notified substance. In addition, we noted that the biochemical mechanism underlying the taste-modifying effect of the notified substance, including effects on sweet taste receptors, was not discussed in the notice.

Given the substantive nature of the issues discussed during the teleconference, we recommended that Miracle Fruit Farm, LLC request that we cease our evaluation of GRN 001027. We also offered to provide a list of the issues that we identified during our evaluation of the notice and suggested that Miracle Fruit Farm, LLC request a pre-submission meeting with us prior to the submission of a new GRAS notice for evaluation without prejudice. In an email dated December 16, 2021, you requested that we cease our evaluation of GRN 001027.

U.S. Food and Drug Administration
Center for Food Safety & Applied Nutrition
5001 Campus Drive
College Park, MD 20740
www.fda.gov

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 001027 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J.
Carlson -S

Digitally signed by
Susan J. Carlson -S
Date: 2021.12.22
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Susan Carlson, Ph.D.
Director
Division of Food Ingredients
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition