Jim Lassiter
Rejimus, Inc.
600 W Santa Ana Blvd, Suite 1100
Santa Ana, CA 92701

Re: GRAS Notice No. GRN 001138

Dear Mr. Lassiter:

The Food and Drug Administration (FDA, we) is granting the request on behalf of Hangzhou Viablife Biotech Co, Ltd. (Hangzhou Viablife Biotech) to cease our evaluation of GRN 001138, which we filed on June 27, 2023. We received this request on September 21, 2023.

The subject of the notice is hydroxytyrosol intended for use as an antioxidant at levels of 5 mg per serving in ready-to-drink beverages (sports drinks, "energy" drinks, nutritional drinks and shakes, fruit-flavored drinks and flavored waters); and at levels of 10 mg per serving in fats and oils (butter, margarine, oil and shortening, salad dressing, mayonnaise and mayonnaise-type sandwich spreads), and fruit and vegetable juices. The notice informs us of Hangzhou Viablife Biotech's (you, your) view that these uses of hydroxytyrosol are GRAS through scientific procedures.

In an email dated September 18, 2023, we informed you that we identified several deficiencies during our review of your notice. We noted that many of these issues were previously discussed with you during a pre-submission meeting held on November 27, 2022. Specifically, we noted concerns about the approach used to estimate the cumulative dietary exposure for hydroxytyrosol and the flawed interpretation of publicly available information cited in support of the GRAS conclusion. Given the substantive nature of the identified deficiencies, we recommended in our September 18th email that you request that we cease our evaluation of GRN 001138. We also offered to provide a list of the deficiencies we identified during our evaluation of the notice in a separate correspondence to you. On September 21, 2023, we received an email requesting that we cease our evaluation of GRN 001138.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 001138 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

Digitally signed by Susan J. Carlson -S
Date: 2023.09.28 13:37:38 -04'00'

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