Kevin O'Connor, Ph.D.
Nova Mentis Ltd.
Nova UCD
Belfield Innovation Park
Dublin 4
IRELAND

Re: GRAS Notice No. GRN 000837

Dear Dr. O'Connor:

The Food and Drug Administration (FDA, we) is granting the request to cease our evaluation of GRN 000837, which we filed on March 7, 2019. We received this request on June 4, 2019.

The subject of the notice is hydroxytyrosol produced in *Escherichia coli* BL21 (DE3) #145 strain. The notice informs FDA of Nova Mentis Ltd.'s view that hydroxytyrosol is GRAS, through scientific procedures, for use as an antioxidant in a variety of foods at a use level of 5 to 10 mg of hydroxytyrosol per serving of food.

In response to our questions seeking clarification on some of the toxicological studies discussed in the narrative and about the data and information used to estimate the dietary exposure of hydroxytyrosol, Nova Mentis Ltd. provided an amendment received on May 23, 2019, that included a revised notice that had been edited and reformatted. In an email sent to you on June 3, 2019, and in a follow-up phone call on June 4, 2019, we recommended that Nova Mentis Ltd. request that we cease our evaluation of GRN 000837 so that Nova Mentis Ltd. can resubmit the revised dossier as a new notice. In an email dated June 4, 2019, you requested that we cease our evaluation of GRN 000837.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 000837 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S Digitally signed by Susan J. Carlson -S
Date: 2019.06.05 14:40:06 -04'00'

Susan Carlson, Ph.D.
Director
Division of Food Ingredients
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