Nicoleta Pasecinic
Pen & Tec Consulting S.L.U.
Pl. Ausias March 1, 4th floor 01
08195 Sant Cugat del Vallès
Barcelona, SPAIN

Re: GRAS Notice No. GRN 000912

Dear Ms. Pasecinic:

The Food and Drug Administration (FDA, we) is granting your request on behalf of c-LEcta GmbH to cease the evaluation of GRN 000912, which we filed on April 9, 2020. We received this request on August 18, 2020.

The subject of the notice is trehalose, produced by enzymatic conversion of sucrose, for use as an ingredient in baked goods, alcoholic and non-alcoholic beverages, breakfast cereals, cheeses, chewing gum, coffee and tea, condiments, confections, dairy analogs, egg products, fats, fish products, frozen dairy desserts, ices, gelatins, puddings, grain products and pastas, gravies, sauces, hard and soft candy, spices, herbs, seeds, flavorings, jams and jellies, meat and poultry products, milk products, nut products, processed fruits and vegetables, juices, snack foods, and soups. Trehalose is intended for use at levels up to 5% by weight in foods in general, and at up to 2% by weight in meat and poultry products. The notice informs FDA of c-LEcta GmbH's view that trehalose is GRAS through scientific procedures. We received an amendment to the notice on July 16, 2020, responding in part to our questions and modifying several of the use levels in the listed foods.

In a telephone conversation on August 13, 2020, we explained that the July 16, 202o, amendment did not address the following:

- Provide an updated, comprehensive dietary exposure assessment that incorporated current and proposed uses of trehalose.
- Clarify the use levels and whether they were substitutional for current uses of trehalose. In the amendment to the notice, c-LEcta GmbH stated that the intended uses are substitutional for the uses in GRN 000045[1], however, this is inconsistent with statements elsewhere in the notice that the intended use is self-limiting due to organoleptic effects and, for several food categories, the use levels are inconsistent with those listed in GRN 000045 or otherwise in accordance with current good manufacturing practices.

[1] GRN 000045 describes the use of trehalose. FDA evaluated this notice and responded in a letter dated October 5, 2000, stating that we had no questions at that time regarding the notifier's GRAS conclusion.

- Provide data to support the safety of trehalose for the estimated dietary exposure of 85 grams/person/day.
- Provide sufficient information to support the safety of the enzyme preparations used in the production of trehalose. These enzymes had not previously been evaluated by FDA, and information provided in the notice was incomplete.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 000912 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

Digitally signed by Susan J. Carlson -S
Date: 2020.10.01 17:45:35 -04'00'

Susan Carlson, Ph.D.
Director
Division of Food Ingredients
Office of Food Additive Safety
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cc: Melvin Carter, Ph.D.
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