Barbara Boedenauer
The Executive Consulting, Inc.
410 Peachtree Pkwy 400. Suite 4245
Cumming, GA 30041

Re: GRAS Notice No. GRN 000889

Dear Ms. Boedenauer:

The Food and Drug Administration (FDA, we) is granting the request on behalf of TLL The Longevity Labs GmbH (TLL) to cease our evaluation of GRN 000889, which we filed on January 8, 2020. We received the request on March 16, 2020.

The subject of the notice is spermidine rich wheat germ extract. The notice informs FDA of TLL's view that spermidine rich wheat germ extract is GRAS, through scientific procedures, for use as an ingredient in food bars and yogurt at levels up to 2.7 grams per serving.

In a phone call and in a follow-up email dated March 2, 2020, we informed you that we could not continue our evaluation due to the deficiencies we identified in the notice. In a teleconference with you and TLL held on March 12, 2020, we discussed the following points that require clarification and additional information: insufficient information about the manufacturing process for the notified ingredient; insufficient information about the specifications for the notified ingredient; insufficient analytical data demonstrating that the manufacturing process results in an ingredient that meets the stated specifications; inappropriate food category selections and outdated food consumption data used to estimate the exposure to the notified ingredient; incorrect estimation of the overall mean and 90th percentile exposures to the notified ingredient; and given the deficiencies described above, uncertainty about how the safety data and narrative support the safety of the intended use of the notified ingredient. In a follow-up email dated March 13, 2020, we provided you with a list of these deficiencies. Given the substantive nature of these deficiencies, we recommended that you request that we cease our evaluation of the notice. We further recommended that you address the deficiencies and request a pre-submission meeting with us before resubmitting the notice for evaluation without prejudice. In an email dated March 16, 2020, you requested that we cease our evaluation of GRN 000889.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 000889 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

Digitally signed by Susan J. Carlson -S
Date: 2020.03.20 09:55:47 -04'00'

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