



Dr. Tania Martinez
Demos Global Group, Inc
8950 SW 74 Court
Miami, FL 33156

Re: GRAS Notice No. GRN 001168

Dear Dr. Martinez:

The Food and Drug Administration (FDA, we) is granting the request on behalf of Tigernut Traders, SL to cease our evaluation of GRN 001168, which we filed on April 4, 2024. We received this request on July 29, 2024.

The subject of the notice is tigernuts flour for use at levels up to 25% in baked goods, nutritional drinks and drink mixes, non-dairy smoothies, breakfast cereals, pasta, puddings, plant protein products, snack foods, and chocolates. The notice informs us of Tigernut Traders, SL's view that these uses of tigernuts flour are GRAS through scientific procedures.

In an email dated July 24, 2024, we informed you of several deficiencies in the notice that will require an extensive amount of clarification. Specifically, we note that you have used a margin of safety less than the default 100-fold margin and you have not provided a robust rationale for lowering that 100-fold safety margin. Furthermore, we found additional concerns with your safety evaluation of tigernuts flour such as studies that only employ female rats, other studies showing variations in testes weight, and endocrine effects from consuming tigernuts flour. In an email dated July 29, 2024, you requested that we cease to evaluate this notice.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 001168 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson

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Susan J. Carlson, Ph.D.
Director
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