Dear Mr. Kushner:

The Food and Drug Administration (FDA, we) is granting your request on behalf of IBR, Ltd. (IBR), to cease our evaluation of GRN 000748, which we filed on December 21, 2017. We received your request on April 9, 2018.

The subject of the notice is tomato fruit powder. The notice informs FDA of IBR Ltd.’s view that tomato fruit powder is GRAS, through scientific procedures, for use as a source of phytoene and phytofluene in breakfast cereals, gravies and sauces, jams and jellies, processed vegetables and vegetable juices, snack foods, soft candies, soups and soup mixes (excluding those products under the jurisdiction of the U.S. Department of Agriculture) at a level of 5 milligrams (mg) per serving of foods with an estimated aggregate intake of phytoene and phytofluene up to 10 mg/person/day.

In an email on February 8, 2018, we sent a list of questions asking for clarification on the identity and intended uses of the notified substance. Because of a recent change in the company’s business plan, IBR is unable to respond to FDA’s questions within the timeframe of our evaluation.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 000748 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan Carlson, Ph.D.
Director
Division of Biotechnology
and GRAS Notice Review
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition

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