Andrey Nikiforov
Toxicology Regulatory Services (TRS)
154 Hansen Road, Suite 201
Charlottesville, VA 22911

Re: GRAS Notice No. GRN 000874

Dear Dr. Nikiforov:

The Food and Drug Administration (FDA, we) is granting the request on behalf of Cargill, Incorporated (Cargill) to cease our evaluation of GRN 000874, which we filed on August 27, 2019. We received the request on March 18, 2020.

The subject of the notice is corn protein. The notice informs FDA of Cargill's view that corn protein is GRAS, through scientific procedures, for use as a source of protein and for functional uses such as thickening; water absorption; fat/oil absorption; solid fat emulsification and gelation in: bakery products; cooked pasta (from fresh or dry); ready-to-eat (RTE) cereals; meat analogs and vegetarian food products; snack foods; nutrition bars; mixed dishes with sauce; nut butters (excluding full-fat peanut butter); dairy analog products; cream-based sauces; protein and nutritional powders; ready-to-drink (RTD) protein beverages; non-dairy beverages; and batter/breading/coating for frying at levels ranging from 0.08% to 40%.

On November 26, 2019, we sent a list of questions regarding the manufacturing process, composition, specification, exposure estimate, and safety information of the corn protein. In an email dated January 10, 2020, Cargill provided an amendment with additional information, which included a clarification that hydrogen peroxide is used in the manufacturing process for the purpose of diminishing the levels of sulfur dioxide in the corn protein. In a follow-up email dated February 19, 2020, we informed Cargill that hydrogen peroxide is not authorized for this use in accordance with requirements under 21 CFR 182.1366(c) and 21 CFR 184.1(b)(2).

In a phone conversation with Cargill on March 10, 2020, we advised Cargill to consider requesting that we cease our evaluation of the notice and to request a pre-submission meeting with FDA should they choose to resubmit a revised GRAS notice.

In an email dated March 18, 2020, Cargill requested that we cease to evaluate GRN 000874 so that the company could change its manufacturing process and submit a

revised GRAS notice. Given this request, we ceased to evaluate Cargill's GRAS notice, effective March 18, 2020.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 000874 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

Digitally signed by Susan J. Carlson -S
Date: 2020.04.29 17:04:57 -04'00'

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