Susan Cho, Ph.D.
NutraSource, Inc.
6309 Morning Dew Ct.
Clarksville, MD 21029

Re: GRAS Notice No. GRN 000755

Dear Dr. Cho:

The Food and Drug Administration (FDA, we) is granting SamYang Corp.'s (SamYang's) request to cease our evaluation of GRN 000755, which we filed on February 14, 2018. We received the request on April 11, 2018.

The subject of the notice is D-psicose for use as a sugar substitute in sugars, and in other sugar substitutes; selected low calorie, reduced calorie, or sugar-free foods including bakery products; beverages; cereals; chewing gums; confections and frostings; frozen dairy desserts; yogurt and frozen yogurt; dressings for salads; gelatins, puddings, and fillings; hard and soft candies; jams and jellies; sweet sauces and syrups; and fat-based creams, at levels ranging from 2 to 100% (w/w). The notice informs us of SamYang's view that D-psicose is GRAS through scientific procedures.

On March 20, 2018, FDA received an amendment (the March 20th amendment) to replace five study reports on the safety of the production organism, *Microbacterium foliorum* SYG27B-MF, with data in a manuscript that was unpublished as of that date. The March 20th amendment states that one of the study reports in the notice is incorrect. On March 27, 2018, FDA received a second amendment to replace the incorrect study report with a corrected version located in an external, nonpublic shared drive. On March 28, 2018, FDA received a third amendment to withdraw the original request in the March 20th amendment to replace one of the five study reports with data in an unpublished manuscript and to replace the incorrect study report with the corrected version located in the external, non-public shared drive.

In a telephone conversation with NutraSource, Inc. on March 28, 2018, we discussed our concerns raised by these amendments. We explained that we are unable to replace parts of the notice with data or information submitted in an amendment. We further explained that the data and information in a notice, including study reports and references, must be complete and accurate prior to submitting the notice to FDA. Additionally, data and information establishing the safety of D-psicose, including the safety of the production microorganism, must be publicly available and there must be evidence that those safety data and information are generally recognized by qualified scientific experts in the field. Data and information located in an external non-public shared drive are not publicly available. We also discussed the opportunity for SamYang

to ask us to cease our evaluation of GRN 000755 and to schedule a pre-submission meeting with FDA before submitting a new notice.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 000755 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

Digitally signed by Susan J. Carlson -S
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