William J. Rowe
GRAS Associates, LLC
11810 Grand Park Ave.
Suite 500
North Bethesda, MD 20852

Re: GRAS Notice No. GRN 000976

Dear Mr. Rowe:

The Food and Drug Administration (FDA, we) is granting your request on behalf of Bloomage Biotechnology Corp., Ltd. (Bloomage) to cease our evaluation of GRN 000976, which we filed on January 22, 2021. We received this request on April 30, 2021.

The subject of the notice is sodium hyaluronate for use as an ingredient in fruit drinks/ades, carbonated soft drinks, candy, milk drinks, yogurt, and ready-to-eat cereals at levels ranging from 40-60 mg/serving.[1] The notice informs us of Bloomage's view that this use of sodium hyaluronate is GRAS through scientific procedures.

In a teleconference on April 23, 2021, we informed you that we could not continue our evaluation due to issues identified during our review of the GRAS notice. During the teleconference, we discussed several issues that require clarification and additional information. We discussed the lack of identity and information regarding the description of the production strain. Additionally, we noted issues with the specifications and dietary exposure estimate, including that the dietary exposure estimate was conducted using food consumption data from the 1994-1996 Continuing Survey of Food Intake by Individuals and that there are more recent food consumption data available. Finally, we noted that Bloomage did not adequately consider how the molecular weight of sodium hyaluronate potentially impacts its biological effects and also did not address published literature indicating that sodium hyaluronate could have drug-like effects following oral ingestion. Given the substantive nature of the issues discussed during the teleconference, we recommended that Bloomage request that we cease our evaluation of the notice. In an email and letter dated April 30, 2021, you requested on behalf of Bloomage that we cease our evaluation of GRN 000976.

[1] Bloomage states that sodium hyaluronate is not intended for use in infant formula, in foods formulated for infants, or in any products under the jurisdiction of the United States Department of Agriculture.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 000976 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

Digitally signed by Susan J. Carlson -S
Date: 2021.05.24 17:39:16 -04'00'

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