Gary L. Yingling
Morgan, Lewis and Bockius, LLP
1111 Pennsylvania Ave, NW
Washington, DC 20004

Re: GRAS Notice No. GRN 000688

Dear Mr. Yingling:

The Food and Drug Administration (FDA, we) is granting your request on behalf of Taradon Laboratory (Taradon) to cease our evaluation of GRN 000688, which we filed on February 28, 2017. We received your request on July 19, 2017.

The subject of the notice is sodium thiocyanate for use as a component of a lactoperoxidase system used in dairy products, at a maximum level of 15 mg/L of milk. The lactoperoxidase system is a combination of the enzymes lactoperoxidase and glucose oxidase, glucose, sodium thiocyanate, and sucrose; it is intended for use as an antimicrobial at levels up to 300 mg/L of milk to extend the shelf life of fresh cheese, including mozzarella and cottage cheeses, frozen dairy desserts, fermented milk, flavored milk drinks, and yogurt. The notice informs us of Taradon's view that this use of sodium thiocyanate is GRAS through scientific procedures.

In a telephone conversation on April 17, 2017, we discussed issues identified during our evaluation of the notice. In particular, we discussed that the safety information needs to focus on the sodium thiocyanate, rather than on safety of the lactoperoxidase system. We recommended that the narrative presented in the notice tie the safety studies for sodium thiocyanate to its intended use in the lactoperoxidase system.

In a telephone conversation on June 28, 2017, we discussed the additional safety information and narrative on the use of sodium thiocyanate provided in amendments received on May 1, 2017, and June 12, 2017. We stated that the amended safety narrative did not sufficiently document that the substance is safe for its intended use and that the safety of the substance under its intended use is generally recognized. We noted that a published subacute toxicity study was removed from the notice by Taradon and unpublished acute and subacute studies were introduced that were designated confidential. We stated that it was not evident which generally available information was considered to demonstrate the safety of sodium thiocyanate under the conditions of its intended use. We discussed the opportunity for Taradon to ask us to cease our evaluation of GRN 000688 and to resubmit a new GRAS notice with a revised safety narrative describing the intended use of sodium thiocyanate. In addition, in a meeting of July, 17, 2017, we further discussed this opportunity.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 000688 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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Susan Carlson, Ph.D.
Director
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