



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

Re: GRAS Notice No. GRN 001149

Dear Mr. Rowe:

The Food and Drug Administration (FDA, we) is granting the request on behalf of Cypress Systems, Inc. (Cypress) to cease our evaluation of GRN 001149, which we filed on September 29, 2023. We received this request on November 30, 2023.

The subject of the notice is high-selenium *Saccharomyces cerevisiae* yeast (high-selenium yeast) for use as a nutrient in non-exempt infant formula for term infants at levels ranging from 2.0 – 7.0 µg selenium/100 kcal infant formula, intended to comply with use levels of selenium established in 21 CFR 107.100(a). The notice informs us of Cypress's view that this use of high-selenium yeast is GRAS through scientific procedures.

In an email dated November 27, 2023, we informed you that we had concerns that the notice's safety narrative lacked sufficient data and information to support the safety of high-selenium yeast for its intended use in non-exempt infant formula, and we recommended that Cypress request that we cease our evaluation of the notice. We also offered to provide additional written feedback on the identified deficiencies and to meet with you to further discuss the deficiencies. In an email dated November 30, 2023, you requested that we cease to evaluate the notice.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 001149 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J.
Carlson -S

Digitally signed by
Susan J. Carlson -S
Date: 2023.12.12
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Susan Carlson, Ph.D.
Director
Division of Food Ingredients
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