



Claire L. Kruger, Ph.D., D.A.B.T.
Spherix Consulting Inc., a Division of ChromaDex, Inc.
11821 Parklawn Drive, Suite 310
Rockville, MD 20852

Re: GRAS Notice No. GRN 000671

Dear Dr. Kruger:

The Food and Drug Administration (FDA, we) is granting your request, on behalf of Vitalus Nutrition Inc. (Vitalus), to cease our evaluation of GRN 000671. We received the notice, dated September 20, 2016, that you submitted on behalf of Vitalus in accordance with the agency's proposed regulation, proposed 21 CFR 170.36 (62 FR 18938; April 17, 1997; Substances Generally Recognized as Safe (GRAS); the GRAS proposal) on September 22, 2016, and filed it on October 13, 2016. We received an amendment containing additional information on the safety and the general recognition of that safety for the subject of the notice on January 13, 2017. We received the request to cease our evaluation on February 10, 2017.

FDA published the GRAS final rule on August 17, 2016 (81 FR 54960), with an effective date of October 17, 2016. As GRN 000671 was pending on the effective date of the GRAS final rule, we requested some additional information consistent with the format and requirements of the final rule. We received an amendment responding to this request on October 25, 2016.

The subject of the notice is galacto-oligosaccharides (GOS). The notice informs us of the view of Vitalus that GOS is GRAS, through scientific procedures, for use as an ingredient in nonexempt infant formulas for term infants at a maximum level of 7.2 g/L of reconstituted infant formula, and in conventional foods such as milk and milk products, frozen dairy desserts and mixes, dairy product analogs, soups, nut beverages, non-alcoholic beverages, fruit and vegetable juices, coffees and teas, bakery products, cereals, snacks, sugars and sweets, and sweet sauces at a maximum level of 11 g/serving.


U.S. Food & Drug Administration
Center for Food Safety & Applied Nutrition
5001 Campus Drive
College Park, MD 20740

In a telephone conversation on December 12, 2016, we discussed our questions about the notice. In general, our questions related to the identity of the GOS that is the subject of GRN 000671, its intended uses, GOS exposure estimates, and GOS bridging and corroborative safety studies. FDA informed Vitalus that the data and information supporting the safety of the ingredient that is the subject of GRN 000671 must be generally available and generally accepted by qualified scientific experts. Regarding the identity of GOS, FDA noted that GRN 000671 is the first notice to describe use of enzymes from *Aspergillus oryzae* and *Kluyveromyces lactis* in combination with each other to produce GOS. At this point, the data and information describing the production and identity of GOS that is needed to support the safety of the GOS that is the subject of GRN 000671, does not have general availability and acceptance. FDA noted that Vitalus compared the GOS that is the subject of GRN 000671 with other GOS ingredients currently used in food that are the subjects of previous GRAS notices. However, Vitalus did not demonstrate that the ingredient that is the subject of GRN 000671 is similar to the identities of GOS ingredients in these previous notices. FDA also noted that Vitalus references published safety studies from previous GRAS notices that contain GOS ingredients to support their safety conclusion for the GOS ingredient that is the subject of GRN 000671. However, Vitalus did not demonstrate that the effects noted in these studies of the GOS that is the subject of GRN 000671 are comparable to the effects of the GOS ingredients in previous notices. FDA also noted that Vitalus provided limited information about their corroborative, unpublished study on the GOS ingredient that is the subject of GRN 000671. Therefore, we discussed the opportunity of asking us to cease our evaluation of GRN 000671 and resubmitting a new GRAS notice. We also discussed that the resubmission should address fully all our questions and comments.

In a telephone conversation on February 9, 2017, we discussed our questions about the amendment received January 13, 2017. The amendment contained Vitalus' responses to FDA's questions and comments. FDA informed Vitalus that the data and information in their amendment generated additional questions regarding the safety and general recognition of safety of the ingredient, which is the subject of GRN 000671, for its intended uses. FDA noted that Vitalus' amendment to GRN 000671 altered the description of the chemical identity of the GOS ingredient without discussing the changes. FDA noted that Vitalus' updated exposure estimate combining all uses of the GOS ingredient that is the subject of GRN 000671 referred to the estimate provided in a previous GRN submission from another notifier, which assumes that the chemical identities of the two GOS ingredients are the same. FDA also noted that Vitalus did not take clear ownership of their GRAS conclusion. Therefore, we again discussed the opportunity of asking us to cease our evaluation of GRN 000671 and resubmitting a new GRAS notice that addresses all our concerns.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 000671 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,
Susan J.
Carlson -S



Digitally signed by Susan J. Carlson -S
DN: c=US, o=U.S. Government, ou=HHS,
ou=FDA, ou=People,
o=9.2342.19200300.100.1.1=2000419015,
cn=Susan J. Carlson -S
Date: 2017.04.11 12:39:56 -04'00'

Susan Carlson, Ph.D.
Director
Division of Biotechnology
and GRAS Notice Review
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition