



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

Re: GRAS Notice No. GRN 000875

Dear Dr. Cho:

The Food and Drug Administration (FDA, we) is granting the request on behalf of BIFIDO Co., Ltd. (BIFIDO) to cease our evaluation of GRN 000875, which we filed on August 19, 2019. We received this request on October 23, 2019.

The subject of the notice is *Bifidobacterium animalis* subsp. *lactis* strain ADO11 for use as a food ingredient in non-exempt term infant formula (milk-, soy-, and whey-based); and foods (dairy products/dairy-based foods and dairy substitutes, including fermented milk including butter milk and kefir; flavored milk beverage mixes; dried milk powder; imitation milk and yogurt; powdered baby cereals and foods; meal replacement and nutritional drink mix powders; and powdered sugar substitutes) for the general population. Powdered non-exempt term infant formulas (milk-, soy-, or whey-based) will contain up to 10^8 colony forming units (CFU) of *B. lactis* ADO11 per gram of powdered formulas; and the other foods will contain up to 10^{10} CFU *B. lactis* ADO11 per serving. The notice informs FDA of BIFIDO's view that *B. lactis* ADO11 is GRAS through scientific procedures.

In an email of October 23, 2019, we informed you that our review team had identified several issues and deficiencies or inconsistencies with this notice. These issues focus on the context and text emphasizing the purported health benefit aspects of the subject of the notice, the notifier's view that the subject of the notice is a nutrient under the intended use, as well as the lack of a definitive statement that the subject of the notice is non-pathogenic and non-toxic. Additional deficiencies include: lack of clarity whether there is a wash step after the microorganism is harvested from the soy-peptone fermentation medium, lack of an English translation for certain non-English text, lack of clarity about the use of this microorganism with other microorganisms, as well as inconsistencies. We offered BIFIDO the opportunity to request that we cease our evaluation of GRN 000875, noting that they are welcome to resubmit a new notice after the issues and deficiencies/inconsistencies are addressed. In addition, we suggested that BIFIDO request a pre-submission meeting prior to the submission of a new GRAS notice.

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

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 000875 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

**Susan J.
Carlson -S**

Digitally signed by Susan J.
Carlson -S
Date: 2019.10.30 15:52:18
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Susan Carlson, Ph.D.
Director
Division of Food Ingredients
Office of Food Additive Safety
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and Applied Nutrition