



Laura Montes Ordoñez
Biosearch, S.A.
Camino de Purchil, 66
18004 Granada, SPAIN

Re: GRAS Notice No. GRN 000820

Dear Ms. Ordoñez:

The Food and Drug Administration (FDA, we) is granting the request to cease our evaluation of GRN 000820, which we filed on December 7, 2018. We received this request on March 26, 2019.

The subject of the notice is *Lactobacillus fermentum* CECT5716 for use as an ingredient in multiple food categories at a maximum level of up to 10^{10} CFU/serving. The notice informs FDA of Biosearch, S.A.'s (Biosearch) (you, your) view that *L. fermentum* CECT5716 is GRAS, through scientific procedures.

In an email dated March 15, 2019, we informed you of significant deficiencies in the notice including: inconsistent information about allergenicity; an incomplete bibliography; regulatory and language issues; and the need for more information on the intended uses of your product. We also noted that several scientific writing conventions were not followed. Given the need for extensive changes, we recommended that Biosearch requests that we cease our evaluation of the notice. In an email dated March 26, 2019, Biosearch requested that we cease our evaluation of GRN 000802 to give the company the opportunity to revise and resubmit their notice.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 000820 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson
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Digitally signed by Susan J.
Carlson -S
Date: 2019.04.03 16:42:31
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Susan Carlson, Ph.D.
Director
Division of Biotechnology
and GRAS Notice Review
Office of Food Additive Safety
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