



James Heimbach, Ph.D.  
JHeimbach LLC  
923 Water Street #66  
Port Royal, VA 22535

Re: GRAS Notice No. GRN 001007

Dear Dr. Heimbach,

The Food and Drug Administration (FDA, we) is granting the request on behalf of Lallemand Health Solutions (Lallemand) to cease our evaluation of GRN 001007, which we filed on July 29, 2021. We received this request on December 5, 2022.

The subject of the notice is *Bacillus subtilis* strain R0179 for use as an ingredient in baked goods and baking mixes, beverage and beverage bases, breakfast cereals, chewing gum, confections and frostings, dairy product analogs, fruit and water ices, nuts and nut products, plant protein products, processed fruits and fruit juices, and snack foods at a maximum level of  $10^9$  colony forming units (CFU)/serving. The notice informs us of Lallemand's view that these uses of *B. subtilis* R0179 are GRAS through scientific procedures.

We received amendments to this notice on November 3, 2021, December 2, 2021, January 10, 2022, February 10, 2022, and July 6, 2022. On August 31, 2022, in a teleconference with the notifier, we discussed the remaining issues identified during our evaluation of GRN 001007 and the prior amendments, including the specification limits for heavy metals and the analytical results considered to establish these limits. On September 22, 2022 and October 18, 2022 we received additional amendments to the notice responding to the issues we had identified. In an email dated November 18, 2022 we informed you that the amendments did not adequately address the issues and suggested that Lallemand consider requesting that we cease our evaluation of the notice. In an email dated December 5, 2022 you requested on behalf of Lallemand that we cease our evaluation of GRN 001007.

U.S. Food and Drug Administration  
Center for Food Safety & Applied Nutrition  
5001 Campus Drive  
College Park, MD 20740  
[www.fda.gov](http://www.fda.gov)

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 0010070 is accessible to the public at [www.fda.gov/grasnoticeinventory](http://www.fda.gov/grasnoticeinventory).

Sincerely,

**Susan J.  
Carlson -S**

Digitally signed by Susan J.  
Carlson -S  
Date: 2022.12.16 17:56:30  
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Susan Carlson, Ph.D.  
Director  
Division of Food Ingredients  
Office of Food Additive Safety  
Center for Food Safety  
and Applied Nutrition