



Salvatore J. D'Angelo  
Niacet Corporation  
400 47<sup>th</sup> Street  
Niagara Falls, NY 14304

Re: GRAS Notice No. GRN 000712

Dear Mr. D'Angelo:

The Food and Drug Administration (FDA, we) is granting Niacet Corporation (Niacet)'s request to cease our evaluation of GRN 000712, which we filed on August 28, 2017. We received your request on January 11, 2018.

The subject of the notice is calcium acetate for use as a firming agent, flavor enhancer, nutrient supplement, pH control agent, processing aid, sequestrant, stabilizer, thickener, and texturizer with no limitations other than current good manufacturing practices.<sup>1</sup> The notice informs us of Niacet's view that these uses of calcium acetate are GRAS through scientific procedures.

In a phone conversation with Niacet on November 16, 2017, we discussed issues related to the manufacturing and exposure sections of the notice, as well as issues with the evidence of general recognition of safety presented in the notice. In a follow-up email dated November 28, 2017, we sent Niacet questions related to these issues, as well as questions regarding the organization of the notice. In an email dated December 12, 2017, Niacet provided an amendment with additional information, including a revised safety narrative. In an email dated January 10, 2018, we informed Niacet that the information in their amendment did not fully address our questions. We noted that the remaining issues included the following:

- Heavy metal analyses were not provided. FDA requested at least 3 non-consecutive batch analyses of heavy metals showing conformance to specifications.
- The responses to our questions contained many typographical errors, such as incorrect CFR references and inconsistent citation formatting making the data and information difficult to follow.
- Niacet's revised safety narrative did not adequately incorporate into the notice data and information from prior notices in support of safety and general recognition of safety.

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<sup>1</sup> Niacet states that calcium acetate is not intended for use in products under the U.S. Department of Agriculture's jurisdiction.

We advised Niacet to consider requesting that we cease our evaluation of the notice and to request a pre-submission meeting with FDA should they choose to resubmit a revised GRAS notice.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 000712 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  
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Susan J. Carlson, Ph.D.  
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