



Jana Dammeier, Ph.D.
Chemische Fabrik Budenheim KG
Rheinstrasse 27
55257 Budenheim
GERMANY

Re: GRAS Notice No. GRN 000718

Dear Dr. Dammeier:

The Food and Drug Administration (FDA, we) is granting Chemische Fabrik Budenheim KG's (Chemische Fabrik) request to cease our evaluation of GRN 000718, which we filed on August 3, 2017. We received your request on September 22, 2017.

The subject of the notice is calcium acid pyrophosphate (CAP) for use as a leavening agent, stabilizer, dough strengthener, texturizer, and acidifier in self-rising flours, noodles (Asian), batters and breadings, breads (baguettes and rolls; bread crumbs), processed cereals, bagels, tortillas, fine bakery wares, vegetable masses (spring rolls), and popcorn at levels between 0.3 and 1.3% in accordance with current good manufacturing practice.¹ The notice informs us of Chemische Fabrik's view that CAP is GRAS through scientific procedures.

In an email dated September 14, 2017, we informed Chemische Fabrik that we could not evaluate the safety of the intended use of CAP due to missing data and information in the notice, including the following: chemical composition data, batch analysis data showing conformance with provided specifications, dietary exposure calculations, discussion regarding calcium and phosphorus exposures and potential adverse effects resulting from those exposures, and discussion on the general recognition of safety of the use of CAP. Additionally, we recommended that Chemische Fabrik request that we cease our evaluation of the notice. In an email dated September 22, 2017, Chemische Fabrik requested that we cease our evaluation of GRN 000718 so that the company can revise and resubmit their notice.

¹ Chemische Fabrik states that CAP is not intended for use in meat and poultry products under U.S. Department of Agriculture jurisdiction.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 000718 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
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA,
ou=People,
c 9.2342.19200300.100.1.1=2000419015,
cn=Susan J. Carlson -S
Date: 2017.10.17 11:34:45 -0400

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