



Martin J. Hahn
Hogan Lovells US LLP
Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004

Re: GRAS Notice No. GRN 000696

Dear Mr. Hahn:

The Food and Drug Administration (FDA, we) is granting Hogan Lovells US LLP's (Hogan Lovells) request to cease our evaluation of GRN 000696, which we filed on April 14, 2017. We received your request on September 6, 2017.

The subject of the notice is dolomite for use as a substitute for calcium and magnesium salts in purified bottled water beverage at maximum levels of 90.16 mg/L calcium ions and 55 mg/L magnesium ions. The notice informs us of Hogan Lovells' view that dolomite is GRAS, through scientific procedures.

In a telephone conversation on August 24, 2017, we talked with Hogan Lovells about issues we identified during our review of GRN 000696. We explained that FDA had outstanding questions regarding the identity, composition, and safety of dolomite. We explained that the amendments we received from Hogan Lovells on July 28, 2017, and August 3, 2017, did not fully address our questions. The amendments included information on the source of the dolomite and batch analyses results, which were labeled "confidential." We explained that information that is relevant to safety cannot be confidential. We also discussed the opportunity for Hogan Lovells to ask us to cease our evaluation of GRN 000696 and to re-submit a new GRAS notice addressing the questions we shared with them.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 000696 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson Digitally signed by Susan J. Carlson S
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ou=People, o=9.2342.19200300.100.1.1-2000419015,
cn=Susan J. Carlson S
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