Tom Ellsworth
Marvel Technologies USA, LLC
8161 TN-100
Bellevue, TN 37221

Re: GRAS Notice No. GRN 000723

Dear Mr. Ellsworth:

The Food and Drug Administration (FDA, we) is granting your request to cease our evaluation of GRN 000723, which we filed on September 8, 2017. We received your request on December 12, 2017.

The subject of the notice is benzalkonium chloride. The notice informs FDA of Marvel Technologies USA, LLC's (you, your) view that benzalkonium chloride is GRAS, through scientific procedures, for use in an antimicrobial wash for lettuce and carrots at a level of approximately 50 mg/L.

In an email on December 12, 2017, we described the notice's deficiencies, explained that they were too extensive to resolve within a reasonable timeframe, and suggested that you request that we cease to evaluate the notice. In an email response on December 12, 2017, you asked us to cease to evaluate the notice. We give some examples of the deficiencies below:

- The notice did not comply with the organization described in 21 CFR 170.220, contained many typographical errors, lacked logical formatting, and contained illogical, incomplete sentences. Sources were not adequately cited, and signatures from the GRAS panel appeared to be misrepresented.

- The notice provided an insufficient description of the source and method of manufacture for benzalkonium chloride, and its concentration in the notified preparation was inconsistent. It was not clear if estimates of the level of benzalkonium chloride present in food and the resulting dietary exposure were representative of actual conditions of use.

- The review of scientific literature was not comprehensive. Adverse findings in scientific literature were not adequately discussed. The notice lacked a sufficiently detailed discussion of the fate of benzalkonium chloride following oral exposure.

U.S. Food & Drug Administration
Center for Food Safety & Applied Nutrition
5001 Campus Drive
College Park, MD 20740

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 000723 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

Digitally signed by Susan J. Carlson -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2000419015, cn=Susan J. Carlson -S
Date: 2017.12.18 16:50:29 -05'00'

Susan J. Carlson, Ph.D.
Director
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