



Ricardo Carvajal
Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street, N.W.
Suite 1200
Washington, DC 20005-5929

Re: GRAS Notice No. GRN 000678

Dear Mr. Carvajal:

The Food and Drug Administration (FDA, we) is granting Wacker Chemical Corporation's request to cease our evaluation of GRN 000678, which we filed on November 28, 2016. We received the request on April 7, 2017.

The subject of the notice is alpha-cyclodextrin. The notice informs FDA of Wacker Chemical Corporation's view that alpha-cyclodextrin is GRAS, through scientific procedures, for use as an ingredient in processed and ultra-processed food, other than beverages, at levels of up to 3% (weight by weight) and in certain beverages at levels ranging from 1% to 2% (weight per volume).

In conversations on March 24 and March 30, 2017, we explained that our evaluation team had questions regarding the approach taken by Wacker Chemical Corporation to establish that the broad use of alpha-cyclodextrin (compared to the more narrowly defined uses in Wacker Chemical Corporation's 2004 GRAS notice, GRAS Notice 000155) is generally recognized as safe. We specifically noted questions about the approach to estimating the dietary exposure levels from the intended uses described in GRN 000678 and whether the published scientific literature cited in the notice supports the comparatively higher exposure estimates. We discussed the opportunity for Wacker Chemical Corporation to submit a revised GRAS notice or perhaps a supplement to GRN 000155. In an email dated April 7, 2017, Wacker Chemical Corporation asked that FDA cease to evaluate the notice so that the company can have adequate time to address the dietary exposure issues raised by the evaluation team.

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 000678 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson

-S

Susan Carlson, Ph.D.

Director

Division of Biotechnology

and GRAS Notice Review

Office of Food Additive Safety

Center for Food Safety

and Applied Nutrition

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: 2017.04.17 10:34:29 -0400