



Clinton Colley
Jade Tiger Abalone
366 The Esplanade, Indented Head
Victoria, 3223
AUSTRALIA

Re: GRAS Notice No. GRN 001044

Dear Mr. Colley,

The Food and Drug Administration (FDA, we) is granting the request on behalf of Jade Tiger Abalone to cease our evaluation of GRN 001044, which we filed on March 22, 2022. We received this request on May 16, 2022.

The subject of the notice is calcium disodium ethylenediaminetetraacetic acid (EDTA) for use as a color retention agent at up to 250 mg/kg in the brine for canned abalone. This notice informs us of Jade Tiger Abalone's view that this use of calcium disodium EDTA is GRAS through scientific procedures.

In a teleconference on May 16, 2022, we informed you that we identified issues during our evaluation of GRN 001044. We noted that Jade Tiger Abalone did not provide sufficient data regarding safety, including information about pivotal studies and dietary exposure.

Given the substantive nature of these issues, we recommended that Jade Tiger Abalone request that we cease our evaluation of the notice. We also offered to provide a list of the issues that we identified during our evaluation of the notice and suggested that Jade Tiger Abalone request a pre-submission meeting with us prior to the submission of a new GRAS notice for this substance. In an email dated May 16, 2022, you requested that we cease our evaluation of GRN 001044.

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

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 001044 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

**Susan J.
Carlson -S**

Digitally signed by Susan
J. Carlson -S
Date: 2022.05.25
16:53:48 -04'00'

Susan Carlson, Ph.D.
Director
Division of Food Ingredients
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition