



Georgia C. Ravitz  
Naomi J. Halpern  
Wilson Sonsini Goodrich & Rosati  
1700 K Street NW, 5<sup>th</sup> Floor  
Washington, DC 20006-3817

Re: Docket No. FDA-2022-P-3225

Dear Ms. Ravitz and Ms. Halpern:

This responds to your citizen petition dated December 14, 2022, requesting that the Food and Drug Administration (FDA or we):

amend its [Generally Recognized as Safe] GRAS regulations at 21 CFR §§ 184.1610 and 184.1724 describing the circumstances under which potassium and sodium alginate are deemed to be GRAS, to permit the use of these ingredients at levels above 0.01% and 1.0%, respectively, as thickeners, firming agents or texturizers in plant-based shellfish-alternative food products for human consumption, provided such use meets all of the following criteria: (1) the alginates are derived from brown seaweed, (2) combined alginate levels in a given product do not exceed 5%, (3) the alginate ingredients do not contain the heavy metals arsenic and lead at levels exceeding 1 [milligram per kilogram] mg/kg or cadmium and mercury at levels exceeding 0.2 mg/kg and (4) the ingredients otherwise conform to, or exceed, current specifications established by the Food Chemicals Codex (USP, 2014) and the Joint (Food and Agriculture Organization) FAO/ (World Health Organization) WHO Expert Committee on Food Additives (JECFA, 1997).

Your citizen petition also requested that, “pending revision of the GRAS regulations in the manner requested (or a decision to decline to do so), FDA exercise enforcement discretion with respect to the use of potassium alginate and sodium alginate in a manner that conforms with the requested amendments.”

We are advising you, in accordance with 21 CFR 10.30(e)(2), that we have not reached a decision on your petition within the first 180 days due to competing agency priorities.

U.S. Food and Drug Administration  
Center for Food Safety & Applied Nutrition  
5001 Campus Drive  
College Park, MD 20740  
[www.fda.gov](http://www.fda.gov)

We will contact you when our review is complete, at which time we will inform you of the actions, if any, we decide are appropriate in response to your petition.

Sincerely,

Kristi Muldoon-Jacobs, Ph.D.  
Director, Acting  
Office of Food Additive Safety  
Center for Food Safety  
and Applied Nutrition