DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

OCT 21 2013

Richard C. Theuer, Ph.D.
7904 Sutterton Ct.
Raleigh, NC 27615

Re: Docket No. FDA-2013-P-0472

Dear Dr. Theuer:

This refers to your citizen petition received and filed on April 19, 2013, under docket number FDA-2013-P-0472, requesting that we amend the generally recognized as safe regulations under 21 CFR 182.7255 to exclude the use of Chondrus extract (carrageenin) in infant formula.

The purpose of this response is to advise 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. However, be advised that your petition is currently under active evaluation by our staff.

We will contact you again when our review has been completed, at which time we will inform you of the actions, if any, the Agency decides are appropriate in response to your petition. In the interim, you and other interested parties may continue to submit additional supplemental materials for agency consideration to the docket number referenced above.

If you have any questions about the review of your petition, please direct them to Molly Harry by telephone at 240-402-1075 or by e-mail at Molly.Harry@fda.hhs.gov.

Sincerely,

Dennis M. Keefe, Ph.D.
Director,
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition

cc: Docket No. FDA-2013-P-0472; CTS 2013-3896
R/D: HFS-265: MHarry: 10/17/13
Review: HFS-265: MHonigfort: 10/17/13
Review: HFS-265: AZajac: 10/17/13