

Richard C Theuer
[REDACTED]

July 30, 2014

Re: Citizen Petition – Carrageenan - Docket No. FDA-2013-P-0472

2014 AUG -1 P 1:49

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Dear Sirs:

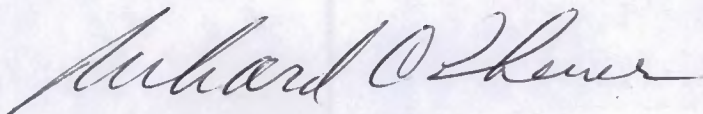
On April 18, 2013, I submitted a citizen petition under 21 CFR 10.30, requesting that 21CFR 182.7255 of the GRAS regulations be amended to prohibit the use of Chondrus extract (carrageenin) in infant formula. (Carrageenin is an alternate name for carrageenan.)

The basis of my petition was the 68th report of the Joint FAO/WHO Expert Committee on Food Additives (JECFA 2007; pp. 32-37, 205), wherein the Joint Expert Committee was of the view that it is inadvisable to use carrageenan or processed Eucheuma seaweed in infant formula intended for infants up to and including 12 months of age.

In June of this year, at its 79th meeting, JECFA reevaluated the safety of carrageenan in infant formula and formula for special medical purposes intended for infants, based on newly-available data. The new studies were specifically conducted to address the safety of the use of carrageenan in infant formula, and allayed JECFA's concerns from the 68th meeting about potential effects on the immature gut. Based on these new safety studies, JECFA concluded¹ that the use of carrageenan in infant formula or formula for special medical purposes at concentrations up to 1000 milligrams per liter (mg/L)² is not of concern.

Since the aim of my petition was to make the FDA regulation consistent with the JECFA position and that condition now exists, I withdraw my petition.

Sincerely,

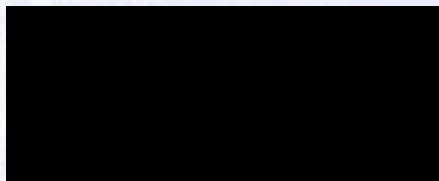


Richard C Theuer, Ph.D.

¹ The summary of the 79th JECFA meeting was published online on July 2, 2014, at http://www.fao.org/fileadmin/user_upload/agns/news_events/JECFA%2079%20Summary%20Version%20Final.pdf

² The current Codex Alimentarius maximum level for carrageenan in infant formula.

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