



April 19, 2012

The Honorable Edward J. Markey  
House of Representatives  
2108 Rayburn House Office Building  
Washington, DC 20515-2107

Re: Food Additive Petition (FAP) No. 2B4791

Dear Representative Markey:

This is in reference to your petition, FAP No. 2B 4791, proposing that 21 CFR 175.300, 177.1580 and 177.1585, of the food additive regulations be amended to no longer provide for the use of Bisphenol A (BPA)-based polycarbonate (PC) resins and epoxy resins in infant formula packaging and baby/toddler food packaging because these uses have been abandoned. We are not filing this petition for the reasons discussed below.

Under 21 CFR 171.130, a petitioner may propose that FDA amend a food additive regulation if the petitioner can demonstrate that there are "old uses abandoned" for the relevant food additive. Such abandonment must be complete for any intended uses in the U.S. market. A petition must include data to demonstrate its assertion that the specific uses mentioned in the petition have been abandoned, as required by 21 CFR 171.130(b). A petition that requests that a food additive regulation be amended to no longer provide for a certain use because that use has been abandoned, but that includes data indicating that such use has not been completely abandoned, is facially deficient. Your petition, FAP No. 2B 4791, is facially deficient because it contains information that directly contradicts your claim of abandonment. In particular, a December 2011 letter from Perrigo provided with the petition indicates that, while Perrigo has made a decision to transition its liquid infant formula products away from BPA-based packaging materials and its toddler food products away from aluminum can liners and other packaging materials containing BPA, the packaging of some of these products still contains BPA, and Perrigo does not expect to complete the transition until the end of 2012. Therefore, your petition is not suitable for filing because it does not contain data to demonstrate your assertion of abandonment of BPA-based PC and epoxy resins for either infant formula or baby/toddler packaging.

We will retain this petition in our inventory of inactive petitions, and we will not take any further action on your current proposal. You may submit a new petition that contains all of the requested information, whenever it becomes available. Should you do so, you need not resubmit the information in Petition No. 2B4791; rather, you may explicitly reference the information in Petition No. 2B4791 in any subsequent petition you choose to submit.

In regards to this petition, we offer the following specific guidance on submitting a new petition. If you obtain new data to demonstrate that Perrigo has completed its transition away from BPA-based packaging materials used with its liquid infant formula and do not become aware of any other infant formula manufacturer that uses BPA-based materials in its infant formula packaging, then a petition that requests

to amend the food additive regulation under 21 CFR 175.300 to no longer provide for the use of BPA-based epoxy resins in infant formula packaging would be considered to be suitable for filing.

In a similar fashion, if you obtain data to demonstrate that Perrigo has completed its transition away from the use of aluminum can liners and other packaging materials containing BPA with its toddler food products, and do not become aware of any other baby or toddler food manufacturer that uses BPA-based materials in the packaging for these products, then a petition that requests to amend the food additive regulations to no longer provide for the use of BPA-based materials in the packaging of baby and toddler food would be considered to be suitable for filing.

If you have any questions concerning this matter, please do not hesitate to contact us.

Sincerely,

A handwritten signature in black ink that reads "Vanee Komolprasert". The signature is written in a cursive, flowing style.

Vanee Komolprasert, Ph.D., P.E.  
Consumer Safety Officer  
Division of Food Contact Notifications, HFS-275  
Office of Food Additive Safety  
Center for Food Safety  
and Applied Nutrition