



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. 2B4792

Dear Representative Markey:

This is in reference to your petition, FAP No. 2B4792, proposing that 21 CFR 175.300 of the food additive regulations be amended to no longer provide for the use of Bisphenol A (BPA) in resinous and polymeric coatings for canned food and beverages, especially those designed or intended primarily for children under 12 years of age, 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. 2B4792, is facially deficient because it contains information that directly contradicts your claim of abandonment. In particular, the March 2012 letters from Campbell Soup Company and Hormel Foods provided with the petition clearly indicate that these companies have not abandoned the use of BPA-based epoxy coatings for canned food and beverages. Therefore, your petition is not suitable for filing because it does not contain data to demonstrate your assertion of abandonment of the uses that are the subject of this petition.

In addition, your petition references a March 2012 survey of identifiable manufacturers of canned food and beverages. In the petition you report providing copies of the survey letters to 26 manufacturers. You did not provide a rationale on how these manufacturers were identified and whether they represent a complete survey of all manufacturers both in the US and worldwide intended for sale in the U.S. Furthermore, your petition only provided the response letters from 7 of the 26 manufacturers surveyed. Moreover, in the last paragraph of Section II of the petition, you state “The Petitioner is in the process of obtaining additional data from manufacturers regarding the use of BPA in their canned food and beverage products and will submit that data to the FDA when it is available.” Thus, the petition is also not suitable for filing because it does not provide evidence to demonstrate that a reasonably significant percentage of the market has been abandoned.

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.

2B4792; rather, you may explicitly reference the information in Petition No. 2B4792 in any subsequent petition you choose to submit.

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