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May 9, 2012

Dr. Avenel Joseph
2108 Rayburn House Office Building
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Dear Dr. Joseph:

I am writing in response to your April 27, 2012 email below, which raised certain follow up questions to Perrigo's December 13, 2011 response to Rep. Markey's November 30, 2011 letter regarding BPA.

In particular, with respect to the statement that "BPA was component of the exterior coating for the non-product contact surface of the outer cap" used with plastic bottles, you asked the following questions:

1. What was the purpose of this BPA component and where is it located? For example, is it used as a component of the cap liner, in between the cap and another substance, or on the outside of the cap? Is it used as an adhesive, etc? If it's easier to provide a diagram than illustrates the placement of BPA that is fine as well.
2. Is the component of the cap referenced above in direct contact with the infant formula?
3. And one more, not mentioned on the phone----Is the new "reformulated" BPA-free coating that is discussed in the letter already being used in the sale of Perrigo infant formula? Can you provide further specifics regarding completion of your conversion to this new packaging material?

Here are Perrigo's responses to your follow up questions:

1. What was the purpose of this BPA component and where is it located? For example, is it used as a component of the cap liner, in between the cap and another substance, or on the outside of the cap? Is it used as an adhesive, etc?

The referenced plastic infant formula bottles come with a cap that is used to seal the container. One component of that cap contains BPA, the purpose of which is to provide scratch and corrosion resistance to the outer cap.

By way of further response, the caps (40mm closures) are manufactured with internal food contact coatings that do not use BPA in their formulations. While an external base coat is used that does contain BPA, this coating is covered by a vinyl top coating that does not contain BPA in its formulation. In addition, the cap has metal that acts as a functional barrier to prevent BPA from migrating from the exterior into the product.

There is also a plastic ring around the metal that does not contain BPA in its formulation.

2. Is the component of the cap referenced above in direct contact with infant formula?

No.

3. Is the new “reformulated” BPA-free coating that is discussed in the letter already being used in the sale of Perrigo infant formula? Can you provide further specifics regarding completion of your conversion to this new packaging material?

With respect to the cap used to seal the 8 oz. plastic bottles of infant formula, Perrigo is in the process of transitioning to a new (and FDA compliant) package that includes a 40 mm closure (cap) which does not have any component made with BPA . These caps are scheduled for delivery in July 2012 and will be used for commercial manufacturing shortly thereafter.

By way of further response with respect to toddler foods, Perrigo manufactures a soy liquid pediatric nutritional drink that is currently packaged in an aluminum can made with BPA. As previously noted, Perrigo had anticipated transitioning that product to a plastic bottle that is not made with BPA by then end of 2012. However, that transition will not take place because the can uses a standard epoxy-based coating on the interior that contains trace amounts of BPA at levels below the threshold limits set by the FDA in 21 CFR 175.300. This is consistent with FDA’s March 30, 2012 update, titled FDA Continues to Study BPA, in which FDA stated that “the scientific evidence at this time does not suggest that the very low levels of human exposure to BPA through the diet are unsafe.”

If you should have any questions regarding this response or need any additional information, please feel free to contact me.

Sincerely,

Joseph C. Papa

