DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740-3835

July 1, 2014

Martha E. Marrapese
Keller & Heckman LLP
1001 G Street, N.W.
Suite 500 West
Washington, D.C. 20001
Email: marrapese@khlaw.com

Re: Prenotification Consultation (PNC) 1398

Dear Ms. Marrapese:

This letter is in response to your submission, received on February 27, 2014 (PNC 1398), requesting on behalf of KW Plastics (KW) a non-objection letter confirming the capability of the proposed physical recycling process to produce post-consumer recycled polypropylene (PCR-PP) material (containing up to 30% post-consumer recycled low density polyethylene, PCR-LDPE) that is suitable for use at levels of up to 100% recycled content in the manufacture of disposable food service articles, such as disposable cutlery, soup containers, and hot and cold drink cups (e.g. stadium cups), i.e., Conditions of Use C through G, as described in Table 2, which can be accessed from the Internet in the Ingredients, Packaging & Labeling section under the Food topic of www.fda.gov.

We previously reviewed the same recycling process and issued a letter of no objection dated September 20, 2013, which allowed for use of PCR-PP/PCR-LDPE at levels of up to 100% recycled content in the manufacture of reusable crates or pallets for holding relatively large quantities of fresh, unwrapped produce and shelled eggs under room temperature and below, i.e. Conditions of Use E through G, provided the feedstock consists of food grade PP and LDPE that comply with 21 CFR 177.1520 (olefin polymers) and may contain adjuvants complying with the applicable authorizations.

We have reviewed the information submitted in reference to the previous submission. Because of strict source control, there is little likelihood of unacceptable contaminant levels in your recycled PP/LDPE blend. Thus, the proposed recycling process as described in the submission would be acceptable to produce recycled PP/LDPE blends that may be suitable for use at levels of up to 100% recycled content in the manufacture of disposable food service articles under the Conditions of Use C through G.

While the agency encourages the use of tight source control in the collection of products for recycling into food-contact articles, it remains the responsibility of the manufacturer to ensure that the final plastic article is free of possible chemical and microbiological contaminants. Furthermore, if any adjuvants are used in the blending of recycled resin to form the food-contact articles, those adjuvants and their levels must be appropriately regulated for the proposed use.

The use of unregulated adjuvants or the use of regulated adjuvants at levels higher than are currently authorized would require further review by FDA.

Please note that the resultant recycled material must comply with all applicable authorizations including 21 CFR § 174.5 General provisions applicable to indirect food additives. For example, in accordance with section 402(a)(3) of the Federal Food, Drug and Cosmetic Act, use of the recycled material should not impart odor or taste to food rendering it unfit for human consumption.

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

Sincerely,

Vanee Komolprasert -S

Digitally signed by Vanee Komolprasert -S
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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