DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

October 7, 2010

Joan Sylvain Baughan
Keller & Heckman
1001 G Street, NW
Washington, DC 20001

Re: Prenotification Consultation (PNC) 953

Dear Ms. Baughan:

This letter is in response to your submission, received on July 27, 2010 (PNC 953), requesting on behalf of EREMA GmbH (EREMA) an opinion letter from FDA confirming the capability of EREMA's secondary recycling process to produce post-consumer recycled polyethylene terephthalate (PCR-PET) materials that are suitable for use at levels up to 100% recycled content in the manufacture of PET containers for contact with all food types under Conditions of Use A (high temperature heat-sterilized) and B (boiling water sterilized), as described in Table 2, which can be accessed from the Internet in the Ingredients and Packaging section under the Food topic of www.fda.gov.

We have previously reviewed the same recycling process and issued letters of no objection dated November 17, 2000, June 7, 2001, February 10, 2003, December 30, 2003, October 28, 2009, and January 14, 2010, which allowed for expanded use of PCR-PET at levels up to 100% recycled content in the manufacture of containers for contact with all food types under Conditions of Use C through H, and J, when the feedstock consists of post-consumer food and/or non-food containers, excluding industrial PET containers.

We have reviewed the information you referenced in the previous submissions, including migration data and migration modeling, which were submitted to demonstrate the capability of EREMA's secondary recycling process to remove potential contaminants from PCR-PET. Based on our review of these data, we have determined that EREMA's secondary recycling process, as described in the subject submission, would be effective in reducing potential contaminants from PCR-PET materials to levels that result in dietary concentrations not to exceed 0.5 ppb, FDA's threshold of regulatory concern. This determination covers the use of PCR-PET derived from the feedstock that consists of post-consumer food and non-food PET containers (excluding industrial PET containers), and the PCR-PET complies with the existing applicable authorizations.

We have concluded that EREMA's secondary recycling process, as described in the subject submission, would produce PCR-PET materials that are suitable for use at levels up to 100% recycled content in the manufacture of articles for contact with all food types under Conditions of Use A through H and J, as described in Table 2, which can be accessed from the Internet in the Ingredients and Packaging section under the Food topic of www.fda.gov. If EREMA's recycling process is modified, new data may need to be evaluated.

The resultant PCR-PET materials 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 PCR-PET materials should not impart odor or taste to food rendering it unfit for human consumption.

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

Sincerely,

Vanee Komolprasert

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