

OCT 02 1998

Mr. Anthony E. Conte  
President  
Pure Tech Plastics, Inc.  
91 East Carmans Road  
East Farmingdale, New York 11735

Dear Mr. Conte:

This is in response to your letters dated September 15, 1995, and March 3, 1997, and letters dated December 18, 1995, April 17, 1996, November 11, and November 21, 1997, submitted on your behalf by Mr. John Fearncombe of Bottom Line Consulting, Inc., requesting FDA's opinion concerning the use of post-consumer recycled polyethylene terephthalate (R-PET) beverage bottles in manufacturing new PET containers for packaging low-alcoholic ( $\leq 8\%$  alcohol), aqueous, acidic, and dry foods.

**We have reviewed your data submitted to demonstrate the suitability of your recycling system to remove post-consumer contaminants from recycled PET. You have provided analytical data and diffusion modeling results to demonstrate that surrogate contaminants intentionally added to virgin PET to represent contaminated post-consumer feed material do not migrate in quantities that present regulatory concerns, when used in contact with low-alcoholic, aqueous, acidic, and dry foods at room temperature or lower.**

Based upon our review of these data and information, we agree that the dietary concentrations of possible contaminants in the post-consumer PET resulting from your proposed multi-step recycling process would be below FDA's threshold level of concern. Therefore, we conclude that the recycling process described in your September 15, 1995, March 3, 1997, December 18, 1995, April 17, 1996, November 11, and November 21, 1997, submissions, will produce PET that is acceptable for use in contact with low-alcoholic ( $\leq 8\%$  alcohol), aqueous, acidic, and dry foods at room temperature or lower, provided the PET complies with 21 CFR 177.1315, 177.1630, and other applicable regulations.

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Our conclusion applies only to post-consumer PET beverage bottles collected and processed as described in your submissions listed in this letter. If the your recycling process is modified, new data would need to be evaluated.

Although we have concluded that the intended use of recycled post-consumer PET that has been collected and processed in the manner described in your submissions is acceptable, you should be aware that we are currently developing a formal regulation on the use of post-consumer recycled plastics in contact with food. Thus, the decisions set forth in this letter may need to be modified due to future deliberations on this matter.

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

Sincerely yours,



Eugene C. Coleman  
Director,  
Division of Petition Control, HFS-215  
Center for Food Safety  
and Applied Nutrition