DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

AUG 10 1999

Ralph Simmons
Keller and Heckman
1001 G. St., N.W.
Suite 500 West
Washington, DC 20001

Dear Mr. Simmons:

This letter responds to your submission of March 11, 1997, and the additional information you provided on June 16, 1998, and February 26, 1999, requesting confirmation regarding the suitability of methods, developed by Phoenix Technologies, L.P. (PT), for the secondary recycling of polyethylene terephthalate (PET) into food-contact articles intended for use in contact with dry (no surface fat or oil), aqueous, acidic, and low-alcohol (≤15%) foods at room temperature and below.

The submission of June 16, 1998, states that the source of the feedstock will be PET containers previously used for food and non-food applications obtained from deposit and curbside recycling programs (i.e., would not include industrial PET containers that had previously held chemicals).

We have reviewed the information submitted to demonstrate the capability of the process to remove potential contaminants from post-consumer recycled PET (PCR-PET). We have also considered the letters that you provided to us on June 16, 1998, and the statements made by Shell and Eastman Chemical to us during a video conference in October 1997 to support PT's claim that all PET containers produced in the U.S. for food and non-food uses comply with 21 CFR 177.1630 or 177.1315.

Based on our review of these data, we conclude that the levels of exposure to possible contaminants resulting from the proposed use of PCR-PET that was subjected to the process described in your submissions would be below FDA's threshold of regulatory concern. Therefore, we conclude that this recycling process will produce PCR-PET that is acceptable for use in contact with dry (no surface fat or oil), aqueous, acidic, and low-alcohol (≤15%) foods at room temperature and below, provided the PCR-PET complies with §177.1630. Our conclusion applies only to post-consumer PET containers obtained from deposit and curbside recycling programs and processed by the method described in the above submissions. If your recycling process is modified, new data would need to be evaluated.

Although we have concluded that the intended use of PCR-PET that has been collected and processed by the ; method described in your submissions is acceptable, you should be aware that we are currently developing a formal policy 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.

As requested by during a telephone conversation with us in March 1999, we are providing you with a copy of the model we used to estimate the sorption of surrogate contaminants into plastic.

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

Sincerely,

/S/

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