DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Admi
Washington DC 202

DEC - 6 1991

Mr. E. N. Nowak
Section Head, Toxicology and
Regulatory Compliance
The Goodyear Tire & Rubber Company
142 Goodyear Blvd.
Akron, OH 44305-0001

Re: Food Additive Master File 472

Dear Mr. Nowak:

This responds to your submissions of April 17, September 6, and September 19, 1991, concerning the use of post-consumer polyethylene terephthalate (PET) to produce reconstituted PET for re-use in the manufacture of food packaging. In this letter "reconstituted" means that PET has been depolymerized to its oligomers and re-polymerized in the to reform PET resin.

We have reviewed the data that you have provided on the isolation and purification process to produce reconstituted PET from depolymerized PET bottles. In particular, you have provided analytical data, including gas chromatographic data, demonstrating that reconstituted PET is of suitable purity and that marker contaminants representing polar volatile, non-polar volatile, polar non-volatile, and non-polar non-volatile compounds, purposefully added to the post-consumer PET feed material, are adequately removed during your multi-step process. Also, we agree that the barrier properties of PET make it unlikely that heavy metals would penetrate this resin, and that if any are present in the resin, they would not readily migrate out; therefore, we do not believe that heavy metals would be a food additive concern for PET in your recycling process. Consequently, for PET, contamination with a heavy metal to demonstrate removal by your recycling process is not necessary. However, we request that you provide us with a copy of your data on metal contamination of recycled resins obtained by X-ray fluorescence for our information.

Based upon our review of these data, we believe that your multi-step process is extremely efficient at reducing potential organic contaminants and that PET produced by this

process will be of suitable purity for use in the production of PET packaging intended for contact with food, in accordance with 21 CFR 174.5. Therefore, we do not object to the use of PET reconstituted by this process for use in the manufacture of PET packaging for food contact, provided that its use in making such articles is in compliance with 21 CFR 174.5 and 177.1630.

Further, PET articles present a special case, because they are relatively free of adjuvants, such as antioxidants, that are typically present in other types of plastic food-contact articles. Because of the absence of such adjuvants, their fate during your reprocessing of post-consumer PET bottles need not be considered. This would not be the case, however, with other plastics approved for food-contact use.

We emphasize that the data you submitted and we reviewed, and the opinion set forth in this letter address only the use of reconstituted PET from your process. Thus, this opinion does not apply to the reuse of PET or other food-contact polymers, or the reconstitution of PET by other processes.

We further emphasize that we are issuing this letter addressing your process because, based on the data that you have submitted, we believe that the use of reconstituted PET, produced by this process from depolymerized post-consumer PET, to manufacture food-contact articles is within the purview of existing regulations (21 CFR 174.5 and 177.1630).

We trust this letter responds fully to your request on this matter. If you have any further questions, please do not hesitate to contact our Indirect Additives Branch at 202-472-5690.

Sincerely yours,

/S/

Alan M. Rulis, Ph.D.
Director
Division of Food and Color Additives
Center for Food Safety
and Applied Nutrition