

OCT 14 1992

Mr. Ralph A. Simmons  
Keller and Heckman  
1001 G Street, NW  
Suite 500 West  
Washington, DC 20001

Re: Food Additive Master File No. 515

Dear Mr. Simmons:

This is in response to your submission of May 15, 1992, on behalf of E. I. duPont de Nemours & Co., concerning the use of post-consumer polyethylene terephthalate (PET) to produce regenerated ethylene glycol (EG) and dimethyl terephthalate (DMT) for further use as components in the manufacture of PET for food packaging. In this letter "regenerated" means that EG and DMT are chemically recovered from PET that has been depolymerized to its constituent monomers.

We have reviewed the data that you have provided on the duPont isolation and purification process to produce regenerated EG and DMT from depolymerized post-consumer PET. In particular, you have provided analytical data including gas chromatographic, atomic absorption spectroscopic, and spectrophotometric data demonstrating that regenerated EG and DMT are of suitable purity and that marker contaminants purposefully added to the reaction mixture are removed during duPont's multi-step process. Based upon our review of these data, we believe that the efficiency of duPont's multi-step process in reducing potential contaminants is sufficient to produce EG and DMT of suitable purity for use in the production of PET intended for use in contact with food, in accordance with 21 CFR 174.5. Therefore, the use of EG and DMT regenerated by this process as components in the manufacture of PET food-contact articles would not require a food additive petition to the Food and Drug Administration, provided that their use in making such articles is in compliance with 21 CFR 177.1315 and 177.1630.

We emphasize that the data you submitted and we reviewed, and the opinion set forth in this letter address only the use of regenerated EG and DMT from duPont's process. Thus, this opinion does not authorize or approve the reuse of PET or other food-contact polymers, to regenerate EG and DMT by other processes.

We further emphasize that we are issuing this letter addressing the duPont process because, based on the data that you have submitted, we believe that the use of regenerated EG and DMT produced by this process from depolymerized post-consumer PET to manufacture PET food-contact articles is within the purview of existing regulations (21 CFR 174.5, 177.1315, 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 202-254-9511.

Sincerely yours,

/s/

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