DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington DC 20204

MAR 10 1992

Mr. Alex Malaspina
Senior Vice President
The Coca-Cola Company
P.O. Drawer 1734
Atlanta, Georgia 30301

Dear Mr. Malaspina:

This responds to our meeting with Dr. Bayer and Ms. Martin on February 4, and your submission of February 7, 1992, concerning the use of by-product ethylene glycol in the manufacture of polyethylene terephthalate (PET) resin intended for food-contact use. You stated that the ethylene glycol is reclaimed by the as a by-product from their manufacturing process for virgin PET, and that the virgin PET, catalysts, and adjuvants are currently regulated by FDA for food-contact use. You further stated that by-product ethylene glycol is purified by the using a procedure.

We have reviewed the data that you have provided demonstrating the purity of ethylene glycol for use in the manufacturing of PET bottle resin. Specifically, you have provided analytical data, including gas chromatographic data, demonstrating that ethylene glycol is of a suitable purity for use in the manufacture of PET resins intended to contact food. Your data indicate that there is virtually no difference between PET resins manufactured with a mixture of percent virgin ethylene glycol and percent by-product ethylene glycol, as compared with PET resins manufactured with 100 percent virgin ethylene glycol. Furthermore, you have noted that PET manufactured with a mixture of percent virgin ethylene glycol and percent by-product ethylene glycol meets the specifications in § 177.1630(f) of Title 21 Code of Federal Regulations (21 CFR 177.1630(f)).

Based on our review of these data, we believe that ethylene glycol, reclaimed as a by-product from manufacturing process for PET and re-purified by the process, is of a suitable purity for reuse in the production of PET resin intended for food-contact use, in accordance with 21 CFR 174.5. In addition, because ethylene glycol reclaimed by is a by-product from the manufacture of PET resin regulated for food-contact use and the resin is in fact a pre-consumer

material, post-consumer contamination and abuse are not issues. Further, the purity data supplied in your submission indicate that the very low levels of contamination detected result from materials currently regulated in § 177.1630. Therefore, we do not object to the use of by-product ethylene glycol that has been purified by the process as a component in the manufacturing of PET packaging for food contact, provided that its use in making such articles is in compliance with 21 CFR 177.1630.

We emphasize that the data you submitted, and the opinion set forth in this letter, address only the use of ethylene glycol obtained as a by-product from the manufacturing process for PET intended for food-contact use which has been purified by procedure. Thus, this opinion does not authorize or approve the reuse of ethylene glycol obtained as a by-product from and purified by other processes.

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 202-254-9541.

Sincerely yours,

/S/

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