AUG 28 1997

Mr. Ryan Deakin
Purchasing Manager
Health Products International
P.O. Box 4000
Springville, Utah 84663

Dear Mr. Deakin:

This is in response to your letter dated July 17, 1995, requesting a "No Objection Letter" for the use of post-consumer recycled high density polyethylene (PCR-HDPE) to manufacture bottles for packaging dietary supplements and over-the-counter drugs that are in hard gelatin capsules, soft-gel capsules, and tablet form. You state that the bottles would be made from PCR-HDPE obtained from discarded HDPE milk containers.

We have forwarded your request for a "No Objection Letter" to the Center for Drug Evaluation and Research for use of your PCR-HDPE bottles to package over-the-counter drugs.

Based upon our review of the information you have provided and other data, we find that PCR-HDPE produced by grinding and washing the resin with appropriate production aids can reduce potential contaminants to a level that would be unlikely to result in their migration to dry dietary supplements in other than insignificant amounts. We therefore conclude that the use of 100 percent PCR-HDPE to package dry, dietary food supplements only will not require an amendment to the food additive regulations. Also, the use of any production aids and adjuvants in the processing of PCR-HDPE must be appropriately regulated.

Although we have concluded that your intended use of PCR-HDPE does not require an amendment to the food additive regulations, 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.

If we can be of any further help, please do not hesitate to contact us.

Sincerely yours,

/S/

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