



FEB 22 1995

Food and Drug Administration
Washington DC 20204

COPY

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

Dear Mr. Deakin:

This is regarding your letter of February 15, 1994, requesting our review of your proposed use of a three layer, co-extruded bottle for packaging dietary supplements and over-the-counter drugs that are in capsule and tablet form. In our letter of March 18, 1994, we referred you to the Center for Drug Evaluation and Research for review of your proposed use for packaging over-the-counter drugs.

You state that the middle layer of the co-extruded laminate bottle would be made from recycled high density polyethylene (HDPE) obtained from _____ while the inner and outer layers would be made from virgin HDPE. You further state that the dietary food supplements will be separated from the recycled HDPE by a mil-thick layer of virgin HDPE.

Based upon our review of the information you have provided and other data, we find that there will be little likelihood that substances from the recycled HDPE layer will migrate at significant levels from the packaging into dry dietary supplements. Therefore, your intended use of post-consumer recycled HDPE, as the non food-contact layer in laminated bottles where the post-consumer recycled HDPE will be separated from dry dietary food supplements by a layer of virgin HDPE at least mils thick, will not require an amendment to the food additive regulations. The virgin HDPE must comply with all applicable regulations. Also, any sanitizers, processing aids and adjuvants used in the manufacture of the post-consumer recycled HDPE must meet the appropriate regulations for virgin HDPE.

Although we have concluded that your intended use of recycled 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.

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

Sincerely yours.



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