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Via Facsimile and Mail

Evergreen Plastics Ltd.
202 Water Tower Drive
Clyde, Ohio 43410

Re: Reliance on EREMA Letters of No Objection from FDA

The purpose of this letter is to respond to your request for our advice as to whether Evergreen Plastics Ltd. (Evergreen) is entitled to rely on the letters of no objection (now called opinion letters) issued by the Food and Drug Administration (FDA) with respect to the EREMA process for recycling post-consumer polyethylene terephthalate (PET), which Evergreen has purchased. The short answer is that Evergreen may properly rely on these FDA opinion letters as long as you operate the process in accordance with the parameters presented to FDA by EREMA that were the basis for FDA's favorable conclusion as to the safety of the recycled PET for contact with food under the conditions specified in the letters. This letter provides further explanation for our opinion below.

First, it is important to recognize that FDA's "no objection letter," now "opinion letter," process for plastic recycling processes is entirely voluntary. There is no law or regulation that requires companies to obtain FDA review of the recycling process and issuance of a favorable opinion letter. Obtaining such letters is driven only by the demands of customers who will use the recycled PET in food-contact applications and who want the additional assurance of an FDA "blessing." In your case, customers should be willing to accept the EREMA letters as covering your recycled PET because you will be operating the EREMA process.

The legal and regulatory requirements applicable to recycled PET are no different from the requirements for virgin PET with respect to qualifying for use in contact with food. The PET must have a composition that meets FDA's generic regulations or other clearances for PET (including, but not necessarily limited to, Title 21 of the Code of Federal Regulations (C.F.R.), Section 177.1630). FDA does not consider this to be a significant issue for PET because the Agency has been convinced that the PET used in both food and non-food containers is almost always food-grade because the food market is so large for PET compared to other markets.

The only issue for PET recycling is establishing that the recycled polymer is suitably pure for contact with food, as required by 21 C.F.R. Section 174.5, FDA's good manufacturing practice regulation for all food-contact materials. In the case of the EREMA process, data was submitted to FDA by the prestigious Fraunhofer Institut in Germany, which demonstrated to FDA's satisfaction that the process achieves suitable purity in the recycled PET. This finding of suitable purity is equally applicable to the same EREMA process purchased and operated by Evergreen as long as you operate the process according to the critical parameters described to FDA by Fraunhofer in the requests for the opinion letters. These parameters are not described in the letters issued by FDA (because they are confidential to EREMA), but EREMA certainly can advise you of the parameters that assure suitable purity under their process.

In providing our advice on this subject, we also note that the FDA opinion letters, taken together, confirm the acceptability of the PET for use in contact with all types of food at temperatures represented by FDA's Condition of Use C (Hot filled above 150 degrees F (not C as indicated in FDA's February 10, 2003 letter)) through G (Frozen storage (no thermal treatment in the container)). The FDA letters will cover PET produced by Evergreen with the EREMA process for the same conditions of use.

I hope that this letter provides a satisfactory explanation as to why Evergreen and your customers should feel comfortable in relying on the opinion letters provided by FDA for the EREMA process. If you have any questions or if we can be of any further assistance in any way, please do not hesitate to contact me. Best regards.

Cordially yours,

Ralph A. Simmons