



Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

October 29, 2007

Frank Welle, Ph.D.
Fraunhofer Institut
Verfahrenstechnik und Verpackung
Giggenhauser Str. 35
D-85354 Freising
GERMANY

Re: Prenotification Consultation (PNC) 608

Dear Dr. Welle:

This is in response to your electronic submission, received on May 8, 2007 and amended on September 10, and 11, 2007, requesting on behalf of Starlinger & Co. Gesellschaft m.b.H. (Starlinger) an opinion letter from the FDA confirming the capability of Starlinger's secondary recycling process (referred to as "Starlinger iV+") (called "Super Clean") to produce post-consumer recycled polyethylene terephthalate (PCR PET) of suitable purity for use in the manufacture of articles in contact with all food types under Conditions of Use C through G, as described in [Table 2](#) on our website: <http://www.cfsan.fda.gov/~rdb/opa-fcn3.html>.

We have reviewed Starlinger's recycling process as well as the information obtained from surrogate testing and migration modeling, which were submitted to demonstrate the capability of the Starlinger's secondary recycling process to remove potential contaminants from PCR PET. Based on our review of these data, we have determined that Starlinger's secondary recycling process, as described in the May 8, 2007 submission, would be effective in reducing potential contaminants from the feedstock, consisting of food and non-food PET containers, to levels that result in dietary concentrations below 0.5 ppb, FDA's threshold of regulatory concern. Therefore, we have concluded that Starlinger's secondary recycling process, as described in the May 8, 2007 submission, can produce PCR PET that is of a purity suitable for use in the manufacture of articles in contact with all food types under Conditions of Use C through G, as described in [Table 2](#) on our website: <http://www.cfsan.fda.gov/~rdb/opa-fcn3.html>, provided that the PCR PET complies with 21 CFR 177.1630, and the feedstock consists of food and non-food PET containers, excluding industrial PET containers. If Starlinger's recycling process is modified, new data may be needed to be evaluated.

If you have any further questions concerning this matter, please do not hesitate to contact us.

Sincerely,

A handwritten signature in black ink that reads "Vanee Komolprasert".

Vanee Komolprasert, Ph.D., P.E.
Consumer Safety Officer
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