



August 13, 2013

Kelly Chen
Fullyarn Packaging (USA) Inc.
13181 Crossroads Parkway North, #222
City of Industry, CA 91746
Email: kelly@fullyarn.com

Re: Prenotification Consultation (PNC) 1321

Dear Ms. Chen:

This letter is in response to your electronic submission, received on July 30, 2013 (PNC 1321), requesting on behalf of Fullyarn Packaging (USA) Inc. an agency's opinion on the regulatory status of polyethylene terephthalate (PET) clamshell containers, made of 80% recycled PET (RPET) and 20% virgin PET for use to hold fresh produce (i.e., blueberries, strawberries, grapes and tomatoes), which are likely stored at refrigeration temperatures and below for a short period of time. You submitted for our review two test reports from Intertek Testing Services (Shenzhen, China), and an opinion letter from Registrar Corp (Hampton, VA). We also received on August 12, 2013 in the mail your FDA Form 3479 requesting the regulatory status of the same PET clamshell containers, and this is unnecessary since there is no new information provided for our review.

Based on the test reports indicating that your PET clamshell containers meet the specifications as described in 21 CFR 177.1630 (f)-(g), we determined that your PET clamshell containers are FDA-compliant and may be used for food contact. Keep in mind that the test reports do not address the potential chemical contaminants that may be present in your RPET and if these contaminants migrate to food, Fullyarn Packaging will be responsible for the safety of these PET clamshell containers. The PET clamshell containers are intended for holding fresh produce, which is likely to be rinsed or washed prior to consumption, therefore, it is less likely that the contaminant would migrate to food to a level that will pose a safety concern. Thus, your PET clamshells made of 50% RPET and 20% virgin PET may be used for holding fresh produce and stored at refrigeration temperatures and below.

If you have any 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

Division of Food Contact Notifications, HFS-275

Office of Food Additive Safety

Center for Food Safety

and Applied Nutrition