



July 27, 2018

Mitzi Ng Clark
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Re: Prenotification Consultation PNC 2183

Dear Ms. Clark:

This letter is in response to your submission (PNC 2183), received on April 3, 2018, amended June 21, 2018, requesting on behalf of Nuvida Plastic Technology Inc. (Nuvida) a letter of no objection (LNO), confirming the capability of Nuvida's secondary recycling process in cleaning and producing post-consumer recycled polypropylene (PCR-PP) and post-consumer recycled high-density polyethylene (PCR-HDPE) blend that is suitable for food contact. The PCR-PP/PCR-HDPE blend is intended for use at levels of up to 60% recycled content in manufacturing articles that may contact all food types under Conditions of Use B through H, as described in Table 2, which can be accessed from the Internet in the Ingredients, Packaging & Labeling section under the Food topic at www.fda.gov.

We have reviewed the proposed recycling process as well as surrogate testing and migration testing, which were submitted to demonstrate the capability of the proposed recycling process in removing potential contaminants from PCR-PP/PCR-HDPE blend. Based on our review of these data, we have determined that the proposed recycling process, as described in the subject submission, is effective in reducing potential contaminants from PCR-PP/PCR-HDPE material to levels that do not migrate to food at a dietary concentration exceeding 0.5 ppb, FDA's threshold of regulatory concern. Therefore, we concluded that the PCR-PP/PCR-HDPE blend produced from the proposed recycling process may be used under the intended use conditions as described above. This determination covers the use of PCR-PP/PCR-HDPE derived from the feedstock that consists of PCR-PP/PCR-HDPE material, complying with 21 CFR 177.1520 (a)(1) and (a)(2) and other applicable authorizations. The feedstock excludes industrial or chemical containers. If the proposed recycling process is modified, new data may need to be re-evaluated.

The PCR-PP/PCR-HDPE blended material must comply with all applicable authorizations, including 21 CFR § 174.5 - General provisions applicable to indirect food additives. For example, in accordance with section 402(a)(3) of the Federal Food, Drug and Cosmetic Act, use

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of the recycled material should not impart odor or taste to food rendering it unfit for human consumption.

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

Sincerely,

Vanee Komolprasert, Ph.D., P.E.
Consumer Safety Officer
Division of Food Contact Notifications HFS-275
Office of Food Additive Safety
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