December 23, 2022

Martha E. Marrapese
Wiley Rein LLP
2050 M Street, NW
Washington, DC 20036
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Re: Prenotification Consultation (PNC) 2869

Dear Ms. Marrapese:

This opinion letter is in response to your electronic submission (PNC 2869), received on November 29, 2022, submitted on behalf of Material Difference Technologies, LLC (MDT), requesting the Agency to confirm the MDT's recycling process to produce post-industrial recycled polypropylene (PIR-PP) for food contact applications. The PIR-PP is intended for use at levels up to 100% recycled content in the production of articles in contact with food under Conditions of Use (COU) complying with all applicable authorizations. PNC 2689 is a follow-up to PNC 2816 to address use of additives in the production of finished PIR-PP material.

We reviewed the information provided in PNC 2816 for MDT's recycling process, and determined that the feedstock is PIR-PP, complying with FDA requirements for food contact. According to FDA's Recycling Guidance[1], MDTs primary recycling process of PIR-PP scrap produced during the manufacture of food contact articles is acceptable, and is not expected to pose a hazard to the consumer, provided the current good manufacturing practice (cGMP) is followed. Therefore, we concluded that the PIR-PP material produced from the MDT process described in PNC 2816 is expected to be suitable for use in contact with food under COU complying with all applicable authorizations. Please note that use of the additives as described in PNC 2869 is not part of the recycling process. Approved additives may be used in post-processing of PIR-PP material.

The finished PIR-PP material should 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 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,

[1] Guidance for Industry: Use of Recycled Plastics in Food Packaging (Chemistry Considerations) | FDA

U.S. Food and Drug Administration
Center for Food Safety & Applied Nutrition
5001 Campus Drive
College Park, MD 20740
www.fda.gov

Material Difference Technologies

Committed to Sustainability and Quality

Phoenix Pro Certified PCR-PP

- Post-Consumer recycled plastic material
  - Natural, Black & White Repro Grades
- Certified by AM Testing & Services, an ISO/IEC 17025:2017 laboratory
- PhoenixPro PCR-PP meets requirements of ISO°14021:2016
- Association of Plastic Recyclers (APR) PCR Certification Program
- Continuing certification based upon quarterly data submissions to AM Testing laboratory

PureOlene FDA Grade Certified PIR-PP

- Verified FDA PNC Letter
- Food contact articles approved
- Approved up to 100% recycled content
- Approved additives allowed
- Conditions of Use A – J approved

Available Grades Include:

- PureOlene 2020 PIR, Natural
- PureOlene 4010 PIR, Natural
- PureOlene 4020 PIR, Natural
- PureOlene 6020 PIR, Natural
- Your Spec too!

Material Difference Technologies

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Replas ReNew PIR-PP

A wide range of Extruded grades
- Available with Certified recycled content.
- Custom compounding
- Natural & Black colors

Multiple logistics options
- Bulk Truck
- Super Sacks
- Gaylord Box delivery

Bromley ReNew PIR-PP

A wide range of Extruded grades
- Multiple material conversion options
- Custom compounding
- Black, White & Mixed color options

Multiple logistics options
- Bulk Truck
- Super Sacks
- Gaylord Box delivery