



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740-3835

December 21, 2015

Naeem Mady
Intertek Health, Environmental & Regulatory Services
1060 Holland Drive, suite G
Boca Raton, FL 33487
Email: Naeem.Mady@intertk.com

Re: Prenotification Consultation (PNC) 1702

Dear Mr. Mady:

This letter is in response to your submission (PNC 1702) on July 28, 2015, requesting on behalf of Aaron Industries (AI) an opinion letter from FDA confirming the capability of AI's secondary recycling process to produce recycled polystyrene (R-PS) material that is suitable for use at levels of up to 100% recycled content in the manufacture of disposable, single use food-contact articles.

The proposed AI's recycling process is a typical physical recycling process. The incoming source material is strictly controlled of a blended post-consumer and post-industrial PS initially obtained from known fixed sources. The post-industrial polystyrene scraps are sourced from the product production of PS compliant with 21 CFR 177.1640 (polystyrene and rubber-modified polystyrene). The post-consumer recycled polystyrene (PCR-PS) is derived from single-use vegetable trays sourced from a local farming facility. You also submitted analytical data to demonstrate that the recycled PS meets the specifications and limitations as described in 21 CFR 177.1640.

We have reviewed the information you submitted, above, and found that because of strict source control, there is little likelihood of unacceptable contaminant levels in your recycled PS. Therefore, we have determined that the proposed recycling process, as described in the subject submissions, may produce recycled PS material that may be suitable for use at levels of up to 100% recycled content in the manufacture of disposable, single use food-contact articles, provided that the finished R-PS complies with 21 CFR 177.1640 and additives added to the reaction step or present in the finished R-PS, must be already authorized, and used within the limitations as described in all applicable authorizations.

While the agency encourages the use of tight source control in the collection of products for recycling into food-contact articles, it remains the responsibility of the manufacturer to ensure that the final plastic article is free of possible chemical and microbiological contaminants. Furthermore, if any adjuvants are used in the blending of virgin and recycled resin to form the food-contact articles, those adjuvants and their levels must be appropriately regulated for the proposed use. The use of unregulated adjuvants or the use of regulated adjuvants at levels higher than are currently authorized would require further review by FDA.

Please note that the resultant recycled 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 of the recycled PS 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
Center for Food Safety
and Applied Nutrition