Keith W Warner PhD

From: Anna Benevente <abenevente@registrarcorp.com>
Sent: Tuesday, October 31, 2017 6:29 AM
To: Keith W Warner PhD
Cc: Brenda Romero Escobar; Lara Luzak
Subject: Food Contact Substances Review: Bullseye Products, LLC, Food Contact Review Analysis
Attachments: Bullsey QuickPatch 1st Review Final Report.pdf

Good day,

We present our report and recommendations for your Quick Patch product, which you submitted for our review. Attached to this email, please find the food contact review analysis for your product. Based upon our research, it appears that your product will not require a premarket submission to FDA, and may be marketed with its current formulation.
Please do not hesitate to contact us if you have any questions or concerns regarding the attached information. If I am temporarily unavailable, please feel free to contact Lara Luzak (lluzak@registrarcorp.com), who assisted me in completing your FCS review. We look forward to assisting in any way possible.

Best regards,
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Food Contact Review

October 31, 2017

Bullseye Products, LLC
3595 Polaris Ave
Las Vegas, NV 89103
United States

RE: Your Food Contact Substances – Quick Patch

Dear Sir or Madam,

We present our report and recommendations regarding the food contact material ("FCM") you have submitted for our review. Based on the information provided to Registrar Corp, it appears that your product may be identified as a cross-linked glass-reinforced polyester resin with styrene as an additional component. The information provided states that the product is intended to repair grain silos and bins. Accordingly, this review describes the regulations promulgated for these substances by the United States ("U.S.") Food and Drug Administration ("FDA") for incorporation into your food contact articles. Please confirm that this is accurate for your product.

After review of your food contact substances, it does not appear that your product requires premarket notification to FDA so long as your food contact substances comply with FDA regulations indicated in the following review. Please see Section 2.2 and Appendix II of this report for the extractive limitations that must be met. Please ensure that your FCM complies with these limitations.

On November 27, 2015, FDA published a final rule establishing the Foreign Supplier Verification Program ("FSVP"), codified in Title 21, Part 1 of the Code of Federal Regulations (80 FR 74226). The FSVP regulations make importers responsible for verifying that the food they import into the U.S. has been produced in a manner that meets US safety standards. Importantly, the "food" that is covered by this final rule includes not only food for consumption and food additives, but also FCSs and substances that have both food and non-food uses, if the substance is reasonably likely to be directed to a food use. The rule became effective January 26, 2016, with the compliance date being set for most importers for May 28, 2019. Accordingly, any U. S. importers of your product will be required to monitor your firm for compliance with FDA regulations by the dates set in the rule.

Our recommendations for this particular FCM are detailed. Please feel free to contact us after you have reviewed this material to discuss our findings in detail.

Very truly yours,

Registrar Corp

Food Contact Review

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Section 1: Overview of Definitions and Requirements for a Food Contact Substance

The following definitions may be of use to you in interpreting this report:

1.1 Definition of Food Contact Surfaces – Food contact surfaces are any surfaces of equipment, utensils, containers, or wrappings that come in direct contact with food. Food contact surfaces shall be corrosion-resistant when in contact with food (21 CFR 110.40(a)). They shall be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds and sanitizing agents. Food contact surfaces shall be maintained to protect food from being contaminated by any source including unlawful indirect food additives (*Id.*). Seams on food contact surfaces shall be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms (21 CFR 110.40(b)).

1.2 Definition of Food Contact Article ("FCA") – The FCA is the finished film, bottle, dough hook, tray, or other item that is formed out of the food contact materials ("Food Ingredients and Packaging Terms," *FDA*, available at https://www.fda.gov/food/ingredientspackaginglabeling/definitions/default.htm).

1.3 Definition of Food Contact Materials ("FCM") – FCMs are made with FCSs and usually other substances. It is often, but not necessarily, a mixture such as an antioxidant in a polymer (*Id.*). The composition may be variable (*Id.*). An example of an FCM may be plastic, glass, rubber, and other such materials that are used to make a final product that comes in contact with food.

1.4 Definition of Food Contact Substances – Once known as indirect food additives, FDA now refers to these materials as FCSs (21 USC 348(h)(6)). The United States Food and Drug Administration ("FDA") defines FCSs as any substance that is intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food (*Id.*). The regulatory status of a FCM is dictated by the regulatory status of each individual FCS that comprises the article ("Determining the Regulatory Status of Components of a Food Contact Material," *FDA*, available at https://www.fda.gov/food/ingredientspackaginglabeling/packagingfcs/regulatorystatusfoodcontactmaterial/default.htm). It is the responsibility of the manufacturer of an FCS to ensure that FCMs comply with the specifications and limitations in all applicable authorizations (*Id.*). When reviewing your composite formulations to determine compliance, consider each authorization to be composed of three parts: the *identity* of the substance, *specifications* including purity or physical properties, and *limitations* on the conditions of use (*Id.*). The individual substance that is reasonably expected to migrate to food because of its intended use in the FCM shall be covered by one of the following (*Id.*):