



**January 1, 2020**

## **Regarding: FDA Compliance and Screen-Printing Inks**

Many questions arise regarding the Food and Drug Administration's (FDA) policy and the compliance of screen-printing inks used to decorate packaging that could contain foods. The use of screen-printing inks (solvent-based, water-based and Ultraviolet) for this application is allowed by the FDA. The essence of the allowance resides in two basic criteria:

Is this a "Direct Food Additive?" Are the components in question intentionally added to foods? Are they an ingredient, preservative, color, or a stabilizer? If the answer is yes, then these components should be considered direct food additives.

Are the components in question considered an "Indirect Food Additive?" In general, this refers to components that are NOT intentionally intended to be added to foods but that CAN become a component resulting from application to an article that contacts food (e.g. inks used for food packaging).

Once these two criteria have been considered and the questions answered, then it should be understood, that both require significant and complicated petitions and filings with the FDA. This is likely to be costly, time consuming and could burden the organization with unwanted regulatory activity.

**Inks designed and manufactured by Polymeric US are not designed as nor approved for use as Direct or Indirect Food Additives.** If the end-user (printer) can assure that the ink in question is not expected to become a component of the food, then it is not a food additive, and then by definition, it could then be used without obtaining permission from the FDA.

Before considering decorating a food-related package with screen-printing inks, Polymeric US strongly suggests implementing a third-party migration study which could then provide a reasonable determination that the component in question would not become a food additive due to a "functional barrier" existing from the construction of the finished/printed package. The third-party provider should follow the appropriate FDA guidance document found at <https://www.fda.gov/food/food-ingredients-packaging/food-additives-petitions>. Secondly to the migration study, an end-user (printer) could consider the package itself to be an appropriate "functional barrier", preventing the ink from becoming a food additive. However, it is up to the end-user to determine, by appropriate testing, whether an actual, true functional barrier exists. For additional information regarding food packaging please go to the following resource; <https://www.packaginglaw.com/special-focus/regulation-food-packaging>.

For additional questions or concerns regarding this topic please contact Polymeric US's Regulatory Compliance Department at 816-221-5567 or via email at [regulatory@polymericgroup.com](mailto:regulatory@polymericgroup.com)