



Kustom Group's FDA Position

Revised June, 2011

Interpreting FDA regulations for using inks, coatings and overprints in food applications tends to cause much confusion and concern for those involved. Over the years we have also wrestled with the whole FDA issue. Following is our policy as a company.

WHAT WE DON'T HAVE:

Kustom Group does not manufacture or sell products that are FDA-Compliant for direct food contact. This is because direct food contact materials are governed by the Food Additive regulations which ultimately require the dried film components to be ingestible, which our products are not. These regulations also require a manufacturing environment capable of food preparation.

WHAT WE DO HAVE:

Kustom Group offers a wide array of overprints and coatings that are formulated with non-volatile components that are in compliance with FDA indirect rules set out in 21 CFR 175.300. In our interpretation of these rules, these special products are needed if the printed side comes in contact with the food contact side of a printed piece and a chance for migration can occur. The printed surface must also be separated from food stuffs by a functional barrier that prevents migration through the substrate to the food contact surface. Some examples of circumstances that require these indirect food compliant products are; sheetfed printed sheets where the printed side comes in contact with the food contact side in the stack, nested cups or tubs that are stacked after printing and being formed and re-rolled printing from a web are just a few.

Examples of suitable functional barriers, mentioned in the paragraph above, are aluminum foil, impermeable plastic films, grease resistant paper, etc. Paper and paperboard may not provide the most effective barrier. The printer or end-user is best equipped to provide specifics for each job that is being considered for each type of FDA application. The suitable barrier position is supported in the June 23, 1980 letter from FDA to NAPIM. Additionally, you can reference NAPIM's "Printing Inks for Food Packaging – FAQ" under this Resource Tab for additional information.

Kustom Group, 3 Carbon Way, Richwood, KY 41094

TEL 859-485-8600 <http://www.kustomgroup.com>