Direct Food Contact Printing Inks & Coatings

Understanding FDA regulations is vital for printers of direct food contact packaging.

by Michael F. Gettis

Printers interested in producing food and pharmaceutical packaging materials are faced with the responsibility of providing the food or drug company/packager with written guarantees of Food & Drug Administration (FDA) regulatory compliance. The food or drug company has the responsibility to comply with various regulations established by the FDA in Title 21 of the Code of Federal Regulations (21CFR). Typically, a list of regulations is provided by the food company. Printers rely on the information provided by their ink, coating, and substrate vendors. Since printers guarantee the finished product, an understanding of the regulations is prudent, especially for direct food contact.

History Of The CFR

Man has had food and drug laws since ancient times. Early Egyptian and Hebrew laws regulated meat purity. During the Middle Ages, from the 400s to the 1500s, European merchants set up trade organizations to inspect food and drugs. The Industrial Revolution, which occurred during the 1700s and early 1800s, brought many changes in food production methods. For example, producers began to use chemicals to preserve and color food. Food laws in the American Colonies provided for the inspection of meat, fish, and flour. In 1784, Massachusetts passed the first state food law in the United States. Other states also passed food laws, but these regulations differed. As a result, products that were legal in one state violated the laws of other states. In 1883, Harvey W. Wiley, Chief of the Bureau of Chemistry in the US Department of Agriculture, ordered an increase in scientific studies of food purity. For more than 20 years, Wiley gathered enough information to prove the need for a federal food and drug law. In 1906, Congress passed two food and drug acts — the Meat Inspection Act and the Food and Drugs Act. Stronger legislation — the Federal Food, Drug and Cosmetic Act — (the Act) was passed in 1938. In 1950, J.J. Delaney chaired the Select Committee to Investigate the Safety of Chemicals in Foods, resulting in legislation known as the Delaney Clause. This prohibits known carcinogens and substances, whose chemical structures provide reason to suspect that they may be carcinogens, to be used as food additives. Other amendments have been added since 1950 covering such topics as pesticides, color additives, and medical devices. In 1958, Congress amended the Act to require premarket approval of food additives, and for more than three decades the FDA has been diligently reviewing submissions by industry. However, in October of 1993 a proposed rule was published in the Federal Register — Food Additives; Threshold of Regulation for Substances Used in Food-Contact Articles.

Food Additives & Packaging

Most food companies today supply packaging specifications to their printing vendors so that they are ensured of regulatory compliance. Many people involved in the process are concerned and confused about the terminology, let alone the specifications themselves. Direct additives, indirect additives, direct contact, indirect contact, minimal contact, incidental contact...what does it all mean?

A "food additive," as defined in the Act, is "*...any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food;...), if such substance is not generally recognized, among experts qualified by scientific training or experience to evaluate its safety, as having been adequately shown through scientific procedures...to be safe under the conditions of its intended use....*"

A strict interpretation of the food additive definition would make all substances that migrate, or may be expected to migrate, from food-contact materials into food, subject to premarket approval as food additives. FDA Agency personnel, in response to inquiries from manufacturers of food-contact articles, have stated that certain specific uses of substances in food-contact materials do not require regulation under the food additive provisions. The Agency felt it necessary to formalize the system of premarket approval since historically, a number of companies have made their own determination that a particular substance effectively does not migrate to food and thus is not a food additive under its conditions of use. They have marketed the products without recourse to the regulatory process. Nothing in the regulatory scheme of the 1993 proposed rule would prevent a company from making its own determination that a particular substance does not meet the definition of a food additive. However, as always,

A Glossary of Terms Related to Food Package Printing

FDA TERM	*DEFINITION OF FOOD ADDITIVES*
Direct Additives	Edible materials intended to become part of a food product including items such as preservatives, flavors, gums, and colorants.
Indirect Additives	Materials in the packaging, processing, holding or transporting of food that have no functional effect in the food but that may reasonably be expected to become components of food or to affect its characteristics. Items in which food may be packaged or wrapped and come into contact with the food, may become part of the food, and be subject to regulation.
Food Additive Note:	These do not include materials that do not migrate to food. If there is no migration of a packaging component from the package to the food, it does not become a component of the food and is not a food additive.

TERM	*DEFINITION OF FOOD CONTACT*
Direct Contact	Materials in intimate contact or touching the food.
Indirect Contact	Materials that might come in contact with food, such as the outside of bags, boxes or cartons.
Incidental Contact	Contact not on purpose or not intended, such as on a part of a food-processing machine.

the company makes such a determination at its own risk. If the Agency learns of a substance use from, for example, a competitor and reaches a different conclusion than the company, the Agency may take regulatory action against the substance as an unsafe food additive or against the company that makes the substance for introducing an adulterated food into interstate commerce.

Ink Color Additives

The only formal regulations that the FDA has regarding printing inks are those regulations for color additive diluents contained in 21CFR Part 73. In general, substances listed in Section 73.1 for a specific use in inks are color additives listed for direct use in food; and substances that are generally recognized as safe (GRAS) for use in food are acceptable in ink formulations used on food or food packaging. In addition, substances regulated for use in food-contact material may also be acceptable if the use in inks is encompassed by the permitted use in food-contact materials. In cases where food packaging is a functional barrier to migration, the inks on the packaging exterior are not food additives and do not need to be regulated by the FDA. The category into which food packaging inks and coatings typically fit is Indirect Food Additives. Inks and coatings may have direct, indirect (commonly referred to as minimal), or incidental contact with the food. This means that they are not intended to become a part of food, but they may through some type of food contact.

Definition Of A Functional Barrier

The FDA states that if there is a food-contact-approved functional barrier (e.g., resinous coating, protective film, transparent cover, etc.) separating printed material from the food, then such use of printing ink is not a food-additive situation, and the ingredients would not need to be approved for that use. However, even though a resinous coating is acceptable on the basis of its containing components approved under the food-additive regulations for their use, it must be applied to form an effective functional barrier; that is, it must be of sufficient thickness and continuity that it prevents the ink from passing through the coating and migrating to food. The manufacturer must employ good manufacturing practices to ensure that the coating has formed a continuous coating over the ink and substrate so that no pinholing is present and/or the coating is of sufficient thickness to prevent ink migration. When these conditions are met, a functional barrier is formed. Most printers and converters will agree that a continuous coating, free of voids and pinholes, would be a difficult task to monitor and ultimately guarantee to an end-user company.

The FDA regulations require Good Manufacturing Practices (GMPs). There are three GMP general concepts that apply to inks and coatings:

(1) The quantity that is used is not more than is reasonably required to accomplish the intended physical or technical effect and does not exceed any limitations.
(2) The material must be of a purity suitable for the intended use.
(3) The methodology for production and use should ensure compliance with the regulations.

Several 21CFR Sections reference quality assurance tests, which are described in sections of Parts 175 and 176. They are often confused with testing done to either get listed in the CFR or be accepted as GRAS for their intended use. Such tests are more rigorous than the quality assurance tests mentioned.

Colorants For Polymers

The 21CFR regulations covering most ingredients used in direct-food-contact inks and coatings are found in Parts 170 through 189. Often overlooked, however, are the colorants used in ink formulations. The FDA published a final rule on colorants for polymers in August 1991. This final rule, which was amended in December 1993, transferred various scattered listings for colorants in polymeric food-contact material to a single regulation. Therefore, ink suppliers, in their written printer guarantees, should reference Part 178, Subpart D, Section 178.3297 for direct food contact.

Enforcement

The FDA publishes regulations that explain the Act. However, manufacturers sometimes violate the Act, accidentally or intentionally. In most cases, the FDA does not prosecute the producers if they voluntarily stop

shipping an illegal product. If they have sold an illegal product, the manufacturer may be required to notify the people who bought it and arrange to take unsold stocks of the product off the market. Evidence of Act violations is gathered by FDA scientists and inspectors. The FDA employs scientists, including bacteriologists, chemists, and veterinarians who use hundreds of different laboratory tests to check the purity, safety, and usefulness of foods, drugs, and cosmetics. They also investigate complaints of illness or injury caused by impure or faulty foods, drugs, and cosmetics. In addition, FDA inspectors supervise the enforcement of court rulings on violations. Three kinds of legal action can be taken if the FDA finds that producers have violated the federal food and drug laws: (1) A federal court may issue an injunction (court order) directing them to stop. (2) The court, acting on evidence from the FDA, may seize a product that is in violation. (3) A lawsuit of such violations can result in a fine or imprisonment, or both.

What is meant by the term *FDA-approved* product, especially as it applies to packaging materials for food and drug products? The concern and confusion in this industry are furthered by this term for both suppliers of packaging materials and their customers. It is also an area about which the FDA has been historically sensitive. If the term is used improperly, the FDA will issue a warning letter. In general, unless referring to a new drug or specific types of medical devices that require premarket FDA approval, people using this phraseology are either speaking loosely or simply know nothing about the FDA's regulatory powers and scope of authority.

Other than the products mentioned above, there is no such thing as an FDA product approval. Just about every other product under the FDA's jurisdiction is regulated, if at all, on a generic basis, not on a product-specific basis. When the FDA has promulgated a regulation on a component of food packaging material, the proper way to let someone know that the product is satisfactory from a regulatory point of view is to state that it conforms with, or is in compliance with, the applicable food-additive regulations. One could even say that the FDA has approved the safe use of a listed chemical substance for a specified use or that it is FDA acceptable. You risk incurring the Agency's wrath if you use the phrase *Approved by the FDA* in connection with the marketing or labeling of a product that has been processed through the Food Additive Regulations, or otherwise imply that the FDA endorses or has approved a specific product when it has not done so.

Ultraviolet Printing Ink & Coatings

UV products were introduced more than 25 years ago. During those years, the technology has gone through a metamorphosis resulting in significant improvements. UV technology offers an alternate compliance strategy to the problem of volatile organic compounds (VOC). Superior chemical and product resistance, print quality with no dot-gain, high gloss, and color stability can be achieved. UV inks are being used more frequently in the conventional printing area, and they will continue to grow in popularity over the years. However, there are still safety concerns.

Although raw material and safety improvements, with regard to skin sensitivity, toxicity, and eye protection, are evident in UV technology, most pigments and UV-curable ink ingredients are still not approved by the FDA as either direct or indirect additives. Therefore, they cannot be used in direct contact with foods and pharmaceuticals.

Where the UV inks may only be in indirect contact, there are still concerns about the safety of many raw materials used, should they migrate to edible products. Most experts agree that 100 percent polymerization or cure cannot be achieved or guaranteed in the UV process. Some untreated residual monomers, oligomers, and photoinitiators remain in and on the surface of the printed ink film, where they can migrate to food, pharmaceutical, and even medical products. Many companies feel that these chemicals do not belong on packaging where even incidental contact with edible products is a possibility. The technology has its place in the ink, coating, and paint markets. Until new generations of safer raw materials present themselves, or until 100 percent polymerization is achieved, UV inks for any regulated packaging application are not recommended.

Understanding the FDA regulations is critical to the success of an ink supplier, printer or end-user. When the reputation of your company rests on the wording of a document used to guarantee your product, prudence is highly recommended.

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Food & Drug Administration – Regulations Applicable to Food Contact Printing Ink
Title 21 of the Code of Federal Regulations, Chapter I

COLOR COMPONENTS	*ALL OTHER INGREDIENTS – SUBCHAPTER B*
Subchapter A, Part 73; Part 74, Subpart A; Part 81; Part 82, Subparts A and B	Components of resinous and polymeric coatings under Part 175, Subpart C, Section 175.300; Components of paper and paperboard in contact with aqueous and fatty foods under Part 176, Section 176.170;
Subchapter B, Part 178, Subpart D, Section 178.3297 and all applicable cross-references	Components of paper and paperboard in contact with dry foods under Part 176, Section 176.180; Prior sanctioned food ingredients Part 181; Generally Recognized As Safe, Parts 182 and 184; Other applicable Sections in Parts 170 through 189.

Direct Food Contact Printing Inks & Coatings

A DIVISION OF BERWIND PHARMACEUTICAL SERVICES, INC.

Specialty Markets, No-Tox Products

As a certified color manufacturer, Colorcon complies with all FDA/USDA regulatory issues. Our products are manufactured from FDA approved components in a dedicated facility, and we offer specific references and listings from the Code of Federal Regulations (CFR), Title 21. In addition, our inks and coatings meet all current CONEG requirements for heavy metal content.

Colorcon offers the food and confectionery industries a wide range of high quality, FDA acceptable products that will meet all your regulatory requirements. Utilizing the services of the GMP Institute, Inc. we are moving toward CGMP and ISO 9000 certification. We also feature the most experienced technical assistance where personnel provide you with regulatory updates and, if necessary, on-site support.

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