Foster Corporation

Foster FDA Color Pigments

Custom Colored Polymers

- Colored polymers play a vital role in the identification, differentiation and aesthetic of medical devices

- Polymers are commonly colored using two techniques including:
  - Melt blending/compounding
  - Color concentrates / masterbatch

Foster Coloring Capabilities:

- Pre-colored Compounds
- MediBatch™ Color Concentrates

Pigment Selection

- Pre-color compounds and color concentrates for medical applications can be manufactured using two categories of color additives:
  - ***FDA Food Contact Pigments***
  - ***FDA Medical Device Pigments***
- The selection of one pigment classification over the other may affect the FDA approval process for medical devices

What is FDA 21 CFR?

- The Code of Federal Regulations (CFR) is a codification of the general and permanent rules published in the Federal Register by the Federal Government
- Title 21 of the CFR is reserved for rules of the Food and Drug Administration
- Each title is revised every calendar year; revisions to Title 21 are issued in April and is usually available several months later

Food, Drug & Cosmetic Act

- Color additives in medical devices are subject to the same provisions that apply to Food, Drugs & Cosmetics (FD&C)
- The FD&C Act states that devices containing a color additive are considered unsafe, unless a regulation is in effect listing the color additive for such use
- This provision limits applicability of color additives that directly contact the body for a “significant period of time”

What is a “Color Additive”?

The term "color additive“ is defined as:

“… a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source [and] when added or applied to a food, drug, or cosmetic, or to the human body…is capable (alone or through reaction with other substance) of imparting color thereto…”

**Please note that black, white, and intermediate grays are considered “color additives”*

Pigments for Food Contact

- Code of Federal Regulations, Title 21 (FDA) sections 173-178 contain pigments listed for use as food-contact substances (FCS).
  - An FCS is any substance that is intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food
- Medical device manufacturers often utilize pigments listed in these sections when a specific color is desired that is not obtainable using pigments listed in FDA 21 CFR 73 and 74.
  - When using pigments listed for food contact, additional documentation and testing is often required with submittals to the FDA when seeking device approval.

Pigments for Medical Devices

- The FDA has published a list of pigments that are classified as safe for use in medical devices
  - The pigments are listed under the CFR, Title 21, Parts 73 and 74 and are the only colors listed for medical manufacturing
  - Use of these additives over food grade pigments, may expedite the FDA approval process

- This particular presentation will address FDA Medical Device pigments, listed under Title 21, Parts 73

- A link to FDA's website with a list of "Color Additives Approved for Use in Medical Devices is below:

https://www.fda.gov/industry/color-additive-inventories/summary-color-additives-use-united-states-foods-drugs-cosmetics-and-medical-devices

What Sections Apply to Pigments?

- Part 73 of Title 21 applies to “color additives” or pigments that are exempt from batch certification
  - Subpart A is for colors for Foods
  - Subpart B is for colors for Drugs
  - Subpart C is for colors for Cosmetics
  - **Subpart D is for colors for Medical Devices**

Applications
For FDA 21 CFR 73, Subpart Pigments

- Under the FD&C Act, color additives must conform to a listing regulation under Title 21 of the CFR Parts 73, Subpart D

- The regulation permits use of color additives in a generic types of medical devices, such as contact lenses and non-absorbable sutures

- Although pigments approved under 21 CFR 73, Subpart D were initially intended for contact lenses and sutures, the FDA has recognized and approved these additives in other medical device applications (including catheters)

Why Are Some Pigments Exempt From Certification?

- Colors listed under 21 CFR 73, Subpart D do not need to be batch certified (lot to lot), as they have already been tested by the additive manufacturer to ensure that they meet FDA specifications
- The medical manufacturer that intends to use the additive should obtain documentation from the pigment manufacturer to ensure compliance, prior to use

**Please note that medical device manufacturers are still responsible for FDA submission and final product testing. This exemption to batch certification only applies to the testing of the color additive ingredient*

How do Pigments Become FDA Listed?

- Color manufacturers may submit for approval by providing chemistry and toxicology information to federal parties including:
  - Food & Drug Administration
  - Center for Food Safety and Applied Nutrition
  - Office of Cosmetics and Colors
  - Color Certification Branch
- Testing requirements are dependent on the level of exposure and perceived risk of toxicity
- Failure to meet specifications will result in a statement of refusal; petitions may be issued by the color additive manufacturer or by the end user

Pre-Color Compounds vs. Masterbatch
for Medical Applications

	Pre-Color Compounds	Concentrates / Masterbatch
Convenience and handling	✓	
Cost advantage		✓
Flexibility		✓
Prototyping and design		✓
Color consistency Small, low shear equipment	✓	
Inventory		✓

Color Options: Pre-Color Compounds

- 9 pigments listed under FDA 21CFR 73, Subpart D are available in Foster compounds
- The colors shown are a representation of available base colors, matched to the nearest Pantone
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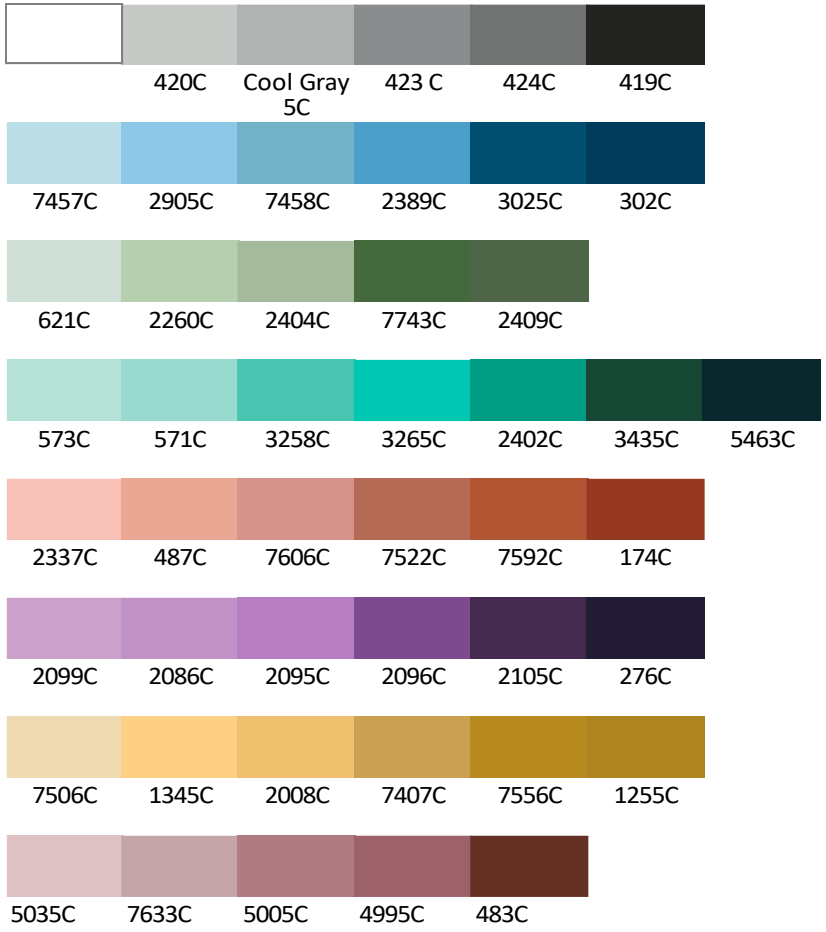
- Custom blends of these pigments can also be requested



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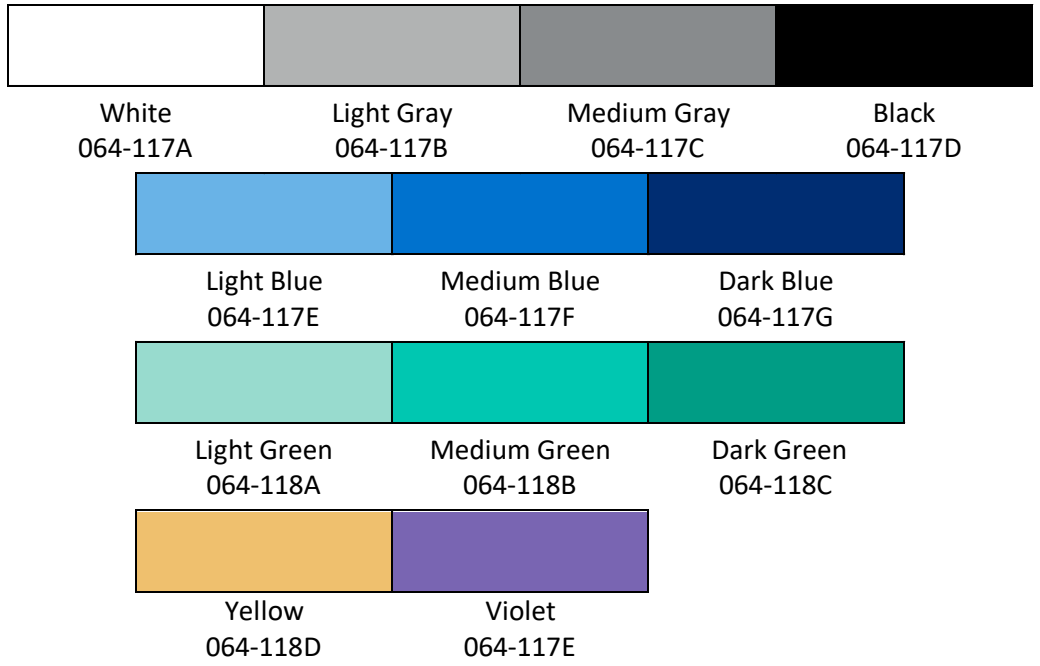
FDA Listed Colors
Color Concentrates

- Color concentrates that are manufactured using FDA 21 CFR 73, Subpart D pigments are available in 14 stock colors (25:1)
- These concentrates are manufactured using a universal USP Class VI compliant carrier that is compatible with resins, including PEBA, TPU, PA 11/12, EVA, PE & PP
- Stock colors are available in 1 lb., 5 lb., and 10 lb. lots with a 24 hour turnaround



Summary: 21 CFR 73, Subpart D

- 21 CFR 73, Subpart D pigments are the only color additives listed by the FDA for use in medical devices (food grade pigments may still be used; additional documentation may be required)
- The color palette available for these additives is limited; not all custom Pantones can be achieved
- Manufacturing using FDA listed additives may expedite regulatory approval process for medical device applications
- Standard testing requirements must still be met as part of FDA approvals for new medical devices, use of 21CFR 73, Subpart D pigments does not remove these requirements

Thank You!