



**Ceuti
Reg**

CGMP COMPLIANCE SPECIALISTS

**Color Additives Used In Foods
Current Standards and Requirements**

Overview

- **1960 Color Additive Amendments to the FD&C Act.**
- **Color Additive Safety.**
- **Exempt vs. non-exempt colors.**
- **GRAS color additives and their requirements.**
- **Color Additive Certification.**
- **Followed the Delany clause of 1958**

The safety of all colors is substantiated by the petitioner. FDA OFAS reviews the petition and grants or denies it. The US is the only country that does this.

The Color Additive Amendments of 1960

- The Color Additive Amendments of 1960 were significant regulatory changes in the United States concerning the use of color additives in food, drugs, cosmetics, and medical devices. Here's a synopsis of these amendments:
- The amendments aimed to ensure the safety of color additives used in various products consumed or applied by the public.
- Established stricter regulatory oversight over the approval and use of color additives.
- Requires manufacturers to submit safety data and conduct studies to assess the safety of color additives before approval for use.
- Sets labeling requirements for products containing color additives.

What are color additives?

- Any substance that imparts color to a food, drug, cosmetic, or medical device.
- Includes substances that are used alone or in combination with other substances to produce a color effect.
- The key aspect is that the substance is not a food or drug itself but is added to these products to provide color.
- Pigments, diluents, preservatives
- Ingredients that are allowed are outlined under the color listing.
- Part 70 – General provisions
- 71 – Color Additive Petitions
- **73 - Exempt**
- **74 – Non-exempt**
- 80 – Certification fees
- 81 – General Specifications
- 82 – Lakes
- 84 – Food Contact

Lakes – are not for fishing!

- A lake of a color additive refers to a type of colorant that is formed by combining a water-soluble dye with a water-insoluble substrate, typically aluminum hydroxide.
- This process creates a colored pigment that is insoluble in water but soluble in certain other solvents, such as oils or fats.
- Lakes are commonly used in food and cosmetic products where water solubility is not desired but color dispersion in fats or oils is needed.
- Substances are additives and require pre-approval.
- Some wild colors (Pearlescent) that are actually cosmetics have gone over the line in foods.

Colors Approved For Food Use

- **Synthetic Color Additives:**

- **FD&C Red No. 3 (Erythrosine)**
- **FD&C Red No. 40 (Allura Red AC)**
- **FD&C Yellow No. 5 (Tartrazine)**
- **FD&C Yellow No. 6 (Sunset Yellow)**
- **FD&C Blue No. 1 (Brilliant Blue)**
- **FD&C Blue No. 2 (Indigo Carmine)**

- **Natural Color Additives:**

- **Annatto Extract**
- **Caramel Color**
- **Beta-Carotene**
- **Paprika Oleoresin**

Types of Colors

- **Synthetic Colors** are chemically derived.
- **Natural Colors** are derived from natural sources.
- **Beet juice extract, turmeric, and caramel color.**
- **Mineral Pigments:** titanium dioxide and iron oxides
- **Exempt Colors:** annatto extract (from the seeds of the achiote tree, used for yellow to orange colors) and beta-carotene (a natural pigment found in carrots, used for orange color).
- **Pearlescent Pigments:** These are additives that create a pearlescent or iridescent effect. They are used in cosmetics, not food.

Banned or Restricted Colors

- **FD&C Red No. 2 (Amaranth)**
- **FD&C Red No. 4 (Scarlet GN)**
- **FD&C Yellow No. 1 (Orthonitrophenol)**
- **FD&C Green No. 1 (Brilliant Green BS)**
- **FD&C Green No. 2 (Aminodiphenyl)**
- **FD&C Orange No. 1 (Chrysoine Resorcinol)**
- **FD&C Violet No. 1 (Rhodamine B)**
- **Most banned in 60s and 70s due to safety concerns.**
- **FD&C Red No. 32 (Cochineal Extract, Carmine): While not banned, the use of cochineal extract (derived from insects) and carmine (derived from cochineal extract) is restricted in some products due to concerns about allergenicity and potential adverse reactions.**

Exempt vs. Non-exempt Color Additives

- Exempt color additives are considered safe based on established safety data or historical use and do not require individual batch certification.
- Typically extracted from natural materials like Annatto.
- Mineral based colors such as iron oxides have their own set of requirements.
- CFR Title 21, Part 73.
- Non-exempt color additives must undergo rigorous testing and certification processes before they can be used in food products
- They are made from synthetic compounds.
- Batch certification required.
- Labelled as “FD&C “ colors.
- CFR Title 21, Part 74



Food-Contact Colors

- Part 84 pertains to substances used in food-contact articles.
- Limits colors that can be used in packaging, utensils, etc.
- Specific to types of applications
- Outlines safety data required for new chemicals and uses.
- Colors used for food contact are typically also approved for direct food use under parts 73 and 74.
- Must meet requirements of Part 82 for manufacturing.



Color Additive Petitions

- All colors, exempt and non exempt, all color additives, including diluents and preservatives, must be approved.
- The petitioner must supply toxicology and other data to support the safe use of the color.
- When FDA completes the approval process the color additive will be listed in the appropriate section of the rules.
- Synthetic colors will be given an FD&C# indicating it may be used in food, drugs and cosmetics.
- D&C# given if the color is limited to drugs and cosmetics.
- The CFR citation gives all approved uses, any limitations and testing requirements.



Post Marketing Surveillance

- FDA is required to monitor the safety of color additives and remove colors or change requirements based on new information.
- Color additive violations are the most common reason for import refusals.
- Bakeries are a common recipient of inspection violations.
- The IOM specifically outlines color additive violations.
- FD&C Yellow No. 5 is specifically required to be declared on food product labels (see 21 CFR 74.705(d)(2)).
- Use of uncertified colors.
- Unapproved colors (colors approved in other country's, but not in the US).
- Color violations are “adulteration” under the Act.
- Must meet all aspects of the color listing.

Batch Certification

- Manufacturers pay FDA for certification testing.
- Use of uncertified FD&C colors is a violation of The Act.
- A certified color additive must be labeled with the name of the color additive as it appears in the CFR, general limitations for use, any other limitations or tolerances, and the FDA certification lot number.
- FDA lists companies that have requested certification in the past 2 years
- If not on the list a color label may be fraudulent.
- Questions about color certification can be directed to: color.cert@fda.hhs.gov

California Bans Red Dye #3

- California becomes the first state to ban 4 food additives linked to disease.
<https://www.npr.org/2023/10/10/1204839281/california-ban-food-additives-red-dye-3-propylparaben-candy>
- Red dye 3 — used in candy, fruit juices, cookies and more.
- Banned by FDA for use in Cosmetics in 1990.
- California ban will be implemented in 2027.
- Previously banned in Europe, along with other colors.
- New bill would ban Red Dye No. 40, Yellow Dye No. 5, Yellow Dye No. 6, Blue Dye No. 1, Blue Dye No. 2 and Green Dye No. 3 and the food additive titanium dioxide.

Tattoo and Permanent Makeup Ink

- Are regulated as cosmetics
- The practice of tattooing or any means of forcing pigment into the skin (microblading) is referred to as “injection” under the regulations.
- Industry prefers “placement” or “insertion” as opposed to injection.
- Tattooing does not use hollow needles to pump ink into the dermis.
- Elephant in the room – no color additives have been approved for “injection”, so why are they available everywhere?
- Answer: “enforcement discretion”
- FDA has determined it has competing priorities as a justification for not enforcing.
- The industry is lucky because FDA definitely has the authority.

Recap

- All colors must be listed.
- Non-exempt (synthetics) colors **Part 74** require certification.
- Exempt (natural) colors **Part 73** do not require certification, but they must be listed.
- New colors and new uses of colors must have an approved petition **part 71**
- Tattoo and PMU pigments are currently under “enforcement discretion”
- California is taking the lead in US.

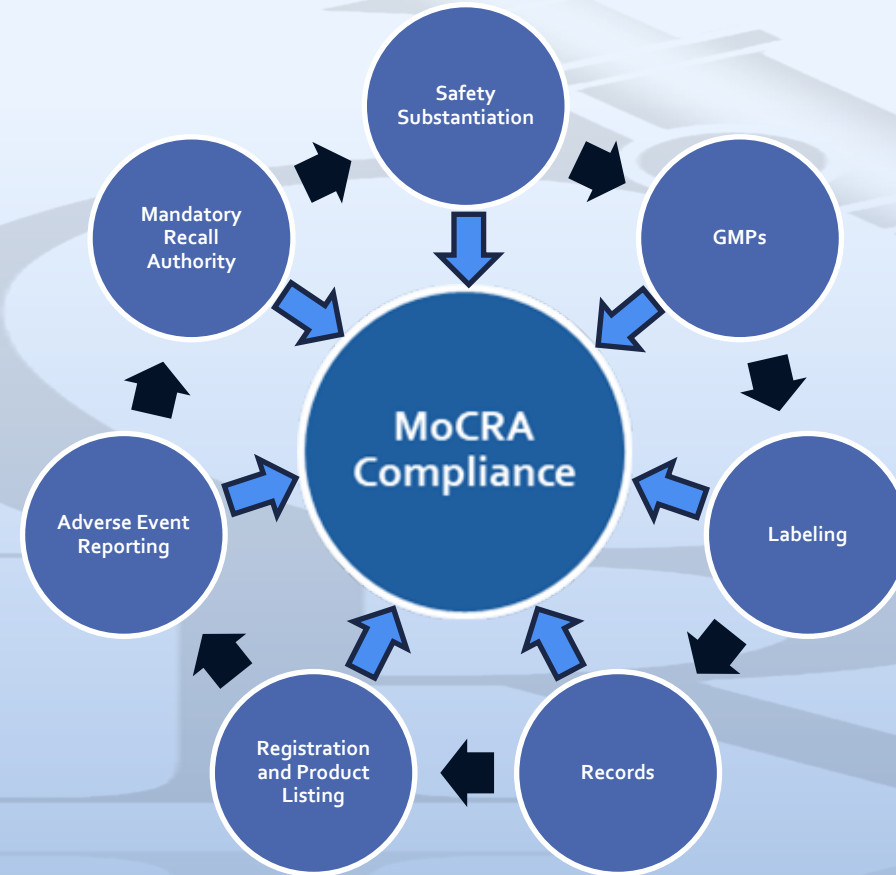
FDA Color Certification Branch (CCB) Office of Cosmetics and Colors

- Summary of color additives:
- <https://www.fda.gov/industry/color-additive-inventories/summary-color-additives-use-united-states-foods-drugs-cosmetics-and-medical-devices>
- Contact:
- **Bhakti Petigara**
Bhakti.Petigara@fda.hhs.gov
- If you need an answer – Bhakti is the best there is.
- Lead author on many color testing methods.

We Can Help You with MoCRA Compliance

The Elements of MoCRA Include:

- Safety Substantiation
- GMPs
- Labeling
- Records
- Registration and Product Listing
- Adverse Event Reporting
- Mandatory Recall Authority



Any of these elements, if not adequately addressed can be an issue for your cosmetic business. Let us help you **TODAY!**

