TiO2 and Synthetic Color Status - Potential Impact on Pharmaceuticals

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October 28, 2025

Multiple stakeholders; **one objective.**

Disclaimer

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Update on the use of Titanium Dioxide in pharmaceuticals in the EU

Regulators around the world (including FDA) disagreed with the EU ban on TiO2 use in food and found no safety concerns with the use of TiO2 in food applications!

Health Canada

Food Standards Agency

FOOD STANDARDS Australia New Zealand

FDA U.S. FOOD & DRUG ADMINISTRATION

EU Position on Pharma Uses – E171

Pharmaceuticals

NEWS ANNOUNCEMENT | 6 August 2025 | Directorate-General for Health and Food Safety | 1 min read

Commission staff working document on the use of titanium dioxide in medicinal products

The Commission Staff Working Document confirms that titanium dioxide should continue to be allowed in medicines, following the updated analysis of the European Medicines Agency of April 2024.

5 AUGUST 2025

Commission Staff working document on titanium dioxide

EU Commission confirms that titanium dioxide should continue to be allowed in medicines!

Developing Situation with FD&C (Synthetic) Colors in the United States

FD&C Red #3 Ban

There were no effects at any of the dose levels except at the highest dose level, where 4% of the food was pure dye — an amount that no human would ever get exposed to in food

The skin of the Rats in the study had turned bright red because they'd been fed so much dye!

The FDA concluded that the rats' thyroid tumors which were found were caused by a hormonal mechanism that is rat-specific and there is no direct human health risk of Red No. 3 at current exposure levels.

The FDA stated that "claims that the use of FD&C Red No. 3 in food and in ingested drugs puts people at risk **are not supported by the available scientific information**"

However, the Delaney Clause requires this dye to be banned due to this animal study that is not relative to human safety

Recent FDA Request for Voluntary Removal of FD&C (Synthetic) Colors from Foods – Based Justification on a Lancet Study from 2008: Southampton Six

Dr. Marty Makary, speaking at RFK Press Conference
Courtesy: Fox 5 DC, 22 Apr 2025

"Natural Colors can be a replacement for "Petroleum-based dyes":

"Try Watermelon Juice … or Beet Juice"

Stated that these synthetic colors are banned in Europe and many other countries

NOT TRUE!

Southampton Study 2008:

The "Southampton Six" Color Additives (with FD&C Names where applicable)

EU (E Numbers):	US FDA Status
✅ Tartrazine (E102)	✅ *FD&C Yellow No. 5*
✅ Carmoisine (E122)	❌ *Not permitted in U.S.*
✅ Ponceau 4R (E124)	❌ *Not permitted in U.S.*
✅ Allura Red AC (E129)	✅ *FD&C Red No. 40*

There are no scientifically credible studies showing that there are any significant safety concerns with the FD&C Colors at the existing exposure levels.

- US FDA only permits <u>three</u> of these substances.
- Note that FD&C Blue #1 & #2 and FD&C Red #3 are not even included in this study
- UK and EU continue to permit use of ALL six substances (with special labels required by politicians)

Both EFSA and FDA determined that the Southampton Study was a flawed study and that no regulatory actions or warning labels were warranted – no causal connection to hyperactivity (FDA Advisory Committee Mtg. (2011)

State Actions to Ban or Require Warning Labels

- **March 2025** - West Virginia bans 7 synthetic food dyes and 2 preservatives (butylated hydroxyanisole and propylparaben)
  - First actual ban of these colors - Only applies to Foods, not Drugs
- **June 2025** - Texas and Louisiana pass 44-Substance labelling bills which include the Synthetic Colors AND TiO2 as well as many other important excipients
  - "WARNING: This product contains an ingredient that is not recommended for human consumption by the appropriate authority in Australia, Canada, the European Union, or the United Kingdom."
  - Last minute amendment - Does NOT apply to Dietary Supplements and Drugs
- Several other States have either implemented or are planning to implement various type of bans or warning labels involving the synthetic colors and other important excipients

State Actions to Ban or Require Warning Labels

- **October 6, 2025 - International Association of Color Manufacturers (IACM) Filed Lawsuit Challenging West Virginia Ban on FD&C Colors**
  - **Claim** "Covered ingredients are universally recognized as safe; the ban is unconstitutional, has no rational basis, and should be voided"
  - Asks the court to strike down recently enacted legislation banning certain food colors and ingredients, because it violates the West Virginia and U.S. Constitutions.
  - IACM contends the West Virginia law usurps the power of the U.S. Food and Drug Administration (FDA) to make food safety decisions, interferes with interstate commerce, and causes economic harm to IACM member companies and their customers, without providing any substantiated or rational basis for classifying covered products as unsafe.

It will be very important to follow the outcome of this test case

Reformulation Challenges

What will happen if the synthetic colors were banned?

Limited Natural (Exempt) Colors available for Drug Use – Difficult to Match Colors

Exempt Colors Approved for Drugs	
Alumina	Ferric ammonium citrate
Aluminum powder	Ferric ammonium ferrocyanide
Annatto extract	Ferric ferrocyanide
Bismuth oxychloride	Guanine
Bronze powder	**Logwood extract**
Calcium carbonate	Mica
Canthaxanthin	Mica-based pearlescent pigments
Caramel	**Potassium sodium copper chlorophyllin**
Beta-Carotene	Pyrogallol
Carmine	Pyrophyllite
Cochineal extract	**Spirulina extract**
Chromium-cobalt-aluminum oxide	Synthetic iron oxide
Chromium hydroxide green	Talc
Chromium oxide greens	Titanium dioxide
Copper powder	Zinc oxide
Dihydroxyacetone (external drugs only)	

- The shades of the approved exempt drug colors are very limited compared to those approved for foods
- Not many plant (red) or animal (purple) derived exempt drug colors
- Most are mineral derived colors (black)

Supply Chain Limitations

The current global supply of natural food colorings is entirely inadequate to meet US demand if all products need to be reformulated and this will significantly increase costs

Technical Manufacturing Hurdles

Natural colorants differ drastically from synthetic dyes in how they're processed and used – usually higher levels needed

Product Stability Challenges

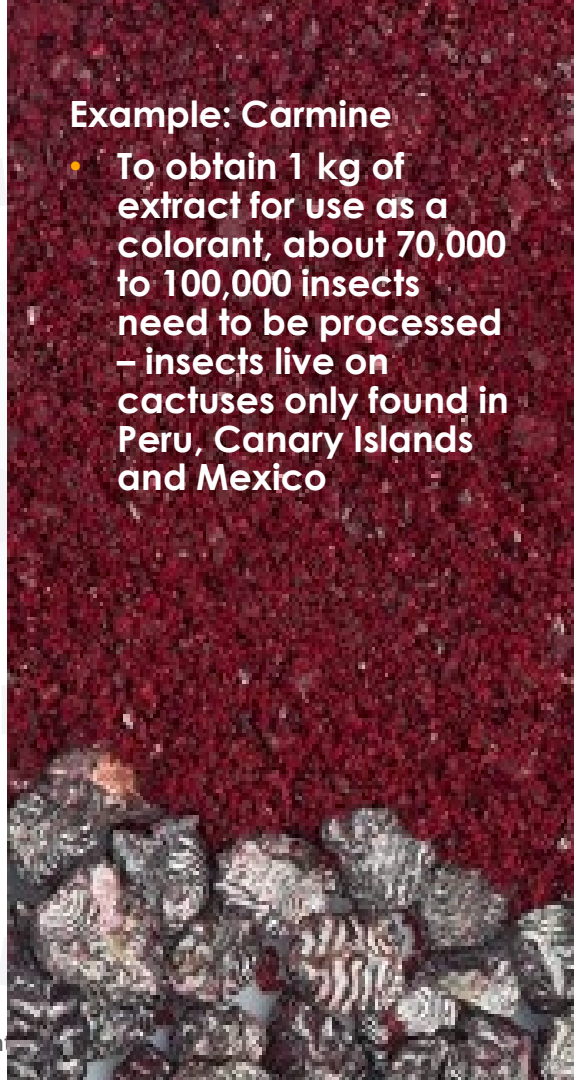
Beyond the manufacturing process itself, the finished products face significant stability issues and short shelf lives

Equipment and Facility Modifications

Manufacturers can't simply "swap ingredients" - they may need facility modifications too

Unexpected Environmental Impacts

The "natural = better" assumption overlooks significant environmental and sustainability considerations



Key Points

- There is no scientific justification for banning or removing the FD&C Colors
- If a ban occurs, it will take significant time (many years) before FD&C colors can actually be replaced by “Natural” colors
- Food and Drug Companies will need significant dedicated resources and tools to help them determine reformulation strategies and do all the associated technical work
- Persistence and a focus on science (as seen in the TiO2 case in the EU) pays off and can sometimes defeat misinformation

Acknowledgements

- Kevin Kenney – Invenimus/Food Chain ID
- FoodChain ID

Questions