2014 FDA/JIFSAN
Food and Nutrition Webinar –
Color Additives in Foods

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Outline

• Definition of color additive
• Color additives permitted in foods
• Declaration of color additives on food labels
• FDA’s enforcement of the requirements for color additives
• Resources for color additives
Definition of color additive

• A color additive is a substance that imparts color to a food, drug, cosmetic, or medical device.

• FDA has regulatory responsibilities for all of these products when they are marketed in the U.S.

• FDA must pre-approve the color additives used in FDA-regulated products.
Types of color additives

- Water-soluble dyes
- Extracts, spices, and mineral compounds
- Lakes – insoluble pigments formed by chemically reacting water-soluble dyes with precipitants and substrata
- Mixtures – color additives combined with other components by simple mixing
Why do we use food coloring?
Purposes of food coloring

• To provide identity to foods
  – Red coloring of maraschino cherries (naturally beige)
  – Candy flavors
• For effect
  – Children's cereals
  – Green ketchup
  – Cake decorations
• To mask natural variations in color
  – Citrus Red No. 2 in orange skins
• To enhance naturally occurring colors
  – Astaxanthin in salmon feed
• To protect products from damage or color loss
  – Light, air, moisture
  – Temperature extremes, other storage conditions
Color additives in foods

• FDA does not consider any color additives to be “natural”
  – All color additives are artificially added to foods

• Food ingredients that contribute their own natural colors are not color additives
  – Examples: strawberries, green or red peppers, chocolate
Color additive approval

• Color additives must be petitioned for FDA approval
• FDA lists approved color additives in the Code of Federal Regulations
• Color additives are listed for specific uses
  – Foods generally or specific foods
• Four requirements for listing color additives
  – Probable exposure from use
  – Cumulative effect in the diet
  – Evaluation of safety by qualified experts
  – Analytical methods to assure purity
Color additives permitted in foods

• “FD&C” color additives
  – Synthetic organic dyes and pigments
    • “Synthetic” means man-made
    • “Organic” means made of carbon, hydrogen, nitrogen, oxygen, and sulfur
  – Required to be batch certified by FDA
    • Assures conformity to purity requirements
    • Strict limitations for lead, arsenic, and mercury
  – Not much dye needed to achieve desired coloring
Common names for FD&C color additives

Common name:
• Allura Red AC ...........
• Brilliant Blue FCF ......
• Erythrosine .............
• Fast Green FCF ........
• Indigotine ..............
• Sunset Yellow FCF ....
• Tartrazine ..............

Certified as:
• FD&C Red No. 40
• FD&C Blue No. 1
• FD&C Red No. 3
• FD&C Green No. 3
• FD&C Blue No. 2
• FD&C Yellow No. 6
• FD&C Yellow No. 5
Other color additives permitted in foods

• Non-“FD&C” color additives
  – Generally derived from plant or mineral sources
    • One insect source
  – May be synthesized or chemically processed
  – Not required to be batch certified
  – Must conform to purity requirements
    • Strict limitations for lead, arsenic, and mercury
  – Relatively large amounts may be needed to achieve desired coloring
Non-“FD&C” color additives permitted in foods

• Extracts
  – Annatto extract
  – Carrot oil
  – Cochineal extract
  – Grape color extract
  – Tomato lycopene extract

• Insoluble pigments
  – Carmine
  – Mica-based pearlescent pigments

• Spices
  – Paprika
  – Saffron
  – Turmeric

• Others
  – Caramel
  – Dehydrated beets
  – Fruit juice
  – Vegetable juice
How many color additives are permitted in food products marketed in the U.S.?

Multiple Choice:
A. 20
B. 50
C. 200
New listings for food color additives

- Mica-based pearlescent pigments
  - Titanium dioxide chemically bonded to mica
    - Sparkle effect with various shades
    - May be used in cereals, frostings, candies, chewing gum
    - New use in distilled spirits containing 18-23% alcohol
- Spirulina extract
  - New blue color additive
  - Aqueous extract of cyanobacterium
  - May be used in candy, chewing gum, yogurt, desserts
Color additive regulations

• Listed color additives
  – 21 CFR Part 73
    • Non-“FD&C” color additives
  – 21 CFR Part 74
    • “FD&C” color additives
  – 21 CFR Part 82
    • Most “FD&C” color additive lakes

• Other color additive regulations
  – 21 CFR Parts 70, 71, 80, and 81
Declaration of color additives on food labels

- Artificial coloring must be declared on food labels
  - 21 CFR 101.22(k)
- “FD&C” color additives must be declared by their listed names or appropriate abbreviations
  - FD&C Red No. 40
  - Yellow 5 Lake
- Alternative names may be declared in parentheses
  - European E numbers, Colour Index (C.I.) numbers
- Most non-“FD&C” color additives may be declared as “Artificial color” or “Color added” or by their listed names
Some specific requirements for declaring color additives on food labels

- Color additives do not have to be declared on the labels of butter, cheese, and ice cream
  - Unless specifically required in 21 CFR parts 73 or 74
- Cochineal extract and carmine
  - Required to be declared by their listed names on all food labels
- FD&C Yellow No. 5
  - Required to be declared on all food labels
- These three are possible allergens or sensitizers
FDA’s enforcement of color additive requirements

- Authorized by Federal Food, Drug, and Cosmetic Act and other applicable laws
- Adulteration provisions
- Misbranding provisions
- Apply to domestic and imported products
  - Imported products only need to have the “appearance” of a violation
Common color additive violations

• **Adulteration**
  – Uncertified material used in a product
  – Certified color additives declared as “permitted color,” “artificial color,” or “color added”
  – Non-permitted color additives

• **Misbranding**
  – Added color on ingredient label but not on finished product label
  – *Except:* Not declaring cochineal extract, carmine, or FD&C Yellow No. 5 always makes a product adulterated
Some non-permitted color additives permitted in food in other countries

- Amaranth (E123, C.I. 16185)
- Anthocyanins
  - In the U.S., fruit juice and grape extracts are permitted in food
- Azorubine/Carmoisine (E122, C.I. 14720)
- Curcumin (E100, C.I. 75300)
  - In the U.S., turmeric and turmeric oleoresin are permitted in food
- Green S (E142, C.I. 44090)
- Patent Blue V (E131, C.I. 42051)
- Ponceau 4R/Cochineal Red A (E124, C.I. 16255)
- Vegetable carbon (E153, C.I. 77266)
  - In the U.S., D&C Black No. 2 is permitted in cosmetics
FDA’s enforcement tools

- **Domestic products**
  - Recalls
  - Warning letters
  - Untitled letters
  - Detentions
  - Seizures
  - Injunctions
  - Prosecutions
  - Civil money penalties

- **Imported products**
  - Detentions
  - Import alerts
  - Detention without physical examination (DWPE)
Summary:
Important color additive requirements

• Only approved and listed color additives may be used in foods, drugs, cosmetics, and medical devices marketed in the U.S.

• All color additives must comply with the requirements in their listing regulations
  – Including purity requirements

• Color additives must be used appropriately
  – Manufacturers must consult the listing regulations

• Certified material must be used in products when required
Resources for color additives

• FDA’s web site
  – http://www.fda.gov

• Summary of Color Additives for Use in United States in Foods, Drugs, Cosmetics, and Medical Devices
  – http://www.fda.gov/ForIndustry/ColorAdditives/ColorAdditiveInventories/ucm115641.htm
Thank you for your attention!

I am happy to answer questions.

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