COLOR ADDITIVES: THE OTHER 'C' IN THE FD&C ACT

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GOALS OF THIS PRESENTATION

- Color Additives:
  - Statutory Perspectives
  - Regulation: Certification and Certification-Exempt Categories
  - Color additives: Labeling Names
  - Import Considerations

LAW AND REGULATION

LAWS AFFECTING THE SAFETY AND LABELING OF COSMETIC PRODUCTS

- 1938 Federal Food, Drug, and Cosmetic Act (FD&C Act)
- ***1960 Color Additive Amendments to the FD&C Act***
- 1966 Fair Packaging and Labeling Act (FPLA)

COLOR ADDITIVE

- FD&C Act, §201 (t); § 721; 21 CFR 70.3
- 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 to a food, drug, or cosmetic or to the human body or any part thereof is capable of imparting color thereto
- Includes black, white, and intermediate grays.

COLOR ADDITIVE

- 21 CFR 70.3 (g)

"…. For a material otherwise meeting the definition of 'color additive' to be exempt from § 721 of the Act, on the basis that it is used (or intended to be used) solely for a purpose or purposes other than 'coloring', the material must be used in a way that any color imparted is clearly unimportant insofar as the appearance, value, or marketability, or consumer acceptance is concerned…" (*i.e., Not enough to claim that the 'primary' purpose is other than to impart color*)

COLOR ADDITIVES – FDA'S AUTHORITY (COSMETICS)

- Color Additives are the only category of ingredients formulated in cosmetics that are subject to pre-market approval.

- Premarket Approval and listing by regulation is required for color additives in foods, drugs, cosmetics, medical devices

GENERAL COLOR ADDITIVE SPECIAL PERMITS AND RESTRICTIONS

- Eye Area Use (21 CFR 70.5 (a); 21 CFR 70.3 (s))
- Surgical Sutures (21 CFR 70.5 (c)
- Injections (21 CFR 70.5 (b))
- External Use (21 CFR 70.3 (v))
  - General Body Surface Integument; no “lips” or “mucuous membrane” structures.

COLOR ADDITIVES: BATCH CERTIFICATION AND CERTIFICATION-EXEMPT COLORS

COLOR ADDITIVES (21 CFR 73, 74, 82) "POSITIVE LIST"

- Uses - Color Additives in all ranges of FDA-regulated products… certifiable and certification-exempt… must be listed by regulation to be used legally in U.S. marketed products. "Listing" a Color Additive:
- Color Additive Petition (CAP) Process (21 CFR 71.1)
  - Safety/Toxicity (including Carcinogenicity) (21 CFR 70.40, 70.50)
  - Chemistry/Specifications/Uses-Restrictions
- Colorant (21 CFR 178.3297) (Food Contact Substance) vs. Color Additive
- Color Additive Certification Program (21 CFR 80)
- Some color additives subject to "batch certification " requirements
  - 1960 Color Additive Amendments to the FD&C Act
  - User Fee Program (21 CFR 80.10) Payment per pound certified (4.oz.samples); FDA certified 24.2M lbs. within 5 day turnaround time in 2018.

CERTIFICATION – EXEMPT COLORS (21 CFR 73)

- Natural Sources (Animal, Botanical, Mineral)
- Pearlescent Pigments (Mica-based) – Approved in 2005, 2006
  - Food and Ingested Drug use only
  - Not approved for Cosmetic use

COLOR ADDITIVE CERTIFICATION

- **Certifiable Colors (21 CFR 74)**
  - Synthetic Organic ('coal-tar') colors
  - Every batch of a certifiable color must be certified by FDA-CFSAN-OCAC labs for use in foods, drugs, cosmetics, medical devices
  - **D&C Black No. 3** (Bone Black) – eye area cosmetics, face powder - must comply with BSE recordkeeping rule (21 CFR 700.27 (e))
  - **D&C Black No. 2** (Carbon Black) – eye area & facial decorative (color) cosmetics – must comply with PAH trace specification

CERTIFICATION

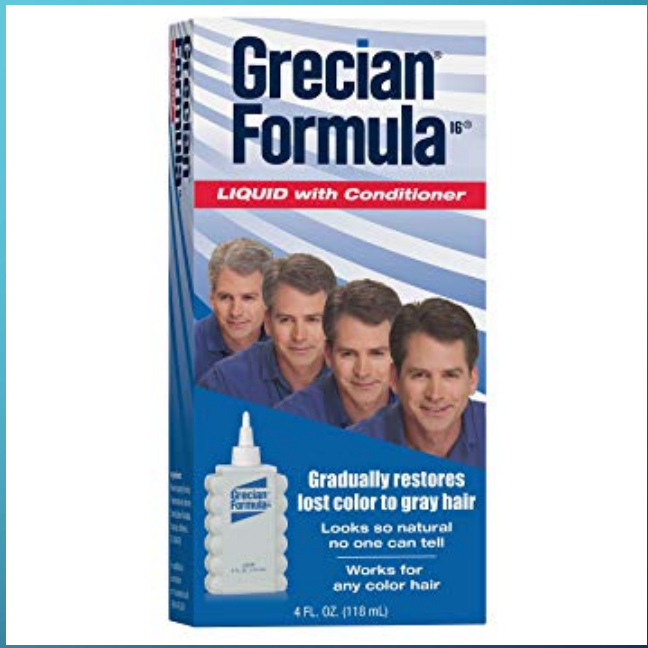
- Manufacturers must submit samples to OCAC Labs for every batch of certifiable color additive marketed in the US to screen for:
  - Heavy metals
  - Potential carcinogens
  - Product purity (quality assurance)
- Certifiable color additive batches are generally NOT tested by FDA for microbial contaminants

COLOR ADDITIVES – LABELING NAMES

- FD&C, D&C, Ext. D&C Color Names (or Simplified Names authorized by regulation (1996, 1999); "Ext." must continue to be used.
  - FD&C Yellow No. *5* vs. Yellow *5*
- Color Index Numbers (CI) or E104 (EU) as standalones not permitted in U.S.
  - PCPC Link: compares FD&C colors to CI Colors: http://www.personalcarecouncil.org/colors-cosmetics-regulation-and-nomenclature-united-states
  - "C.I." declaration NOT synonymous with certified color additive; detain DWPE
- "Dual": FD&C Green No. 3 (CI 42053) permitted for cosmetics marketed both in the U.S. And EU (or other foreign countries)
- Labels with "ingredient stickers" added – possible color additive problems

DELISTING OF LEAD ACETATE IN "PROGRESSIVE HAIR DYES" (21 CFR 73.2396)

- FDA recently concluded in response to CAP 7C0309 that data currently available no longer support a "reasonable certainty of no harm" from the use of lead acetate as a color additive in "progressive hair dyes" authorized since 1980 under listing regulation 21 CFR 73.2396. FDA has issued a Final Rule delisting this color additive. (*83 FR 54665, October 31, 2018*). See, https://www.federalregister.gov/documents/2018/10/31/2018-23725/termination-of-listing-of-color-additive-exempt-from-certification-lead-acetate
- FDA will exercise 12 mo. "enforcement discretion" from effective date of the final rule (12-3-18)
- During this period of time, "progressive hair dyes" formulated with lead acetate must continue to comply with color additive specifications at 21 CFR 73.2396, uses and restrictions, and cosmetic labeling requirements.
- An alternative color additive, "bismuth citrate" (21 CFR 73.2110) is currently available for use in "progressive hair dyes" and is being used in the U.S. and many other countries at levels up to 2.0% (w/v)



COSMETICS COMPLIANCE PROGRAM

- Cosmetics Program: CP 7329.001
  - Revised in 2010
  - Combines Import & Domestic Programs
  - Risk-based enforcement priorities
- Color Additives Programs
  - CP7329.001 Cosmetics
  - CP7309.006 Foods

COMPLIANCE PROGRAMS: ENFORCEMENT AND IMPACT ON IMPORTS

FDA ENFORCEMENT ACTIONS

Include (but not limited to) :

- Warning Letters
- Targeted Establishment Inspections (domestic and foreign) and Sampling Programs
- Seizure
- Detention/Refusal (Imports)
- Injunction
- Criminal Prosecution
- Recalls (21 CFR 7.45-7.59)

WARNING LETTERS

- Drug Claims
- Medical Device Issues
- Unapproved Color Additives
- Microbiological
- http://www.fda.gov/Cosmetics/ComplianceEnforcement/WarningLetters/default.htm

IMPORTED COSMETICS (FD&C ACT, § 801 (A))

May be refused admission if :

- FDA shows that a product appears to be adulterated or misbranded
- Such article is forbidden or restricted for sale in the country in which it was produced or from which it was exported (*product dumping*)

FY 2014 Import Refusals

1955 Product Violations

COSMETIC IMPORTS AND COLOR ADDITIVE VIOLATIONS

- IA # 53-06
- Published: March 6, 2019 (Update)
- Type: DWPE
- Description: "Detention Without Physical Examination Of Cosmetics *** That are Adulterated and/ or Misbranded Due to Color Additive Violations
- Charges:
  - -Non-permitted color additives
    -Uncertified color additives
    -Undeclared color additives

HENNA
21 CFR 73.2190

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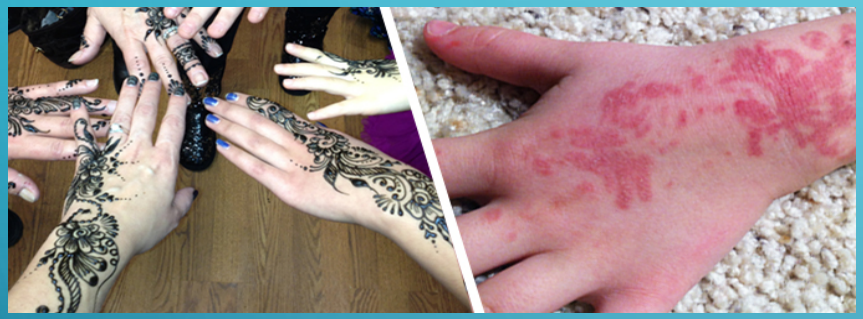
21 CFR 73.2190

- Dried leaf and petiole of plant, *Lawsonia alba* Lam. (*Lawsonia inermis* L)
- Approved only for use as a hair dye (21 CFR 73.2190)
- Henna hair dye typically produce brown, orange-brown, or reddish-brown tint

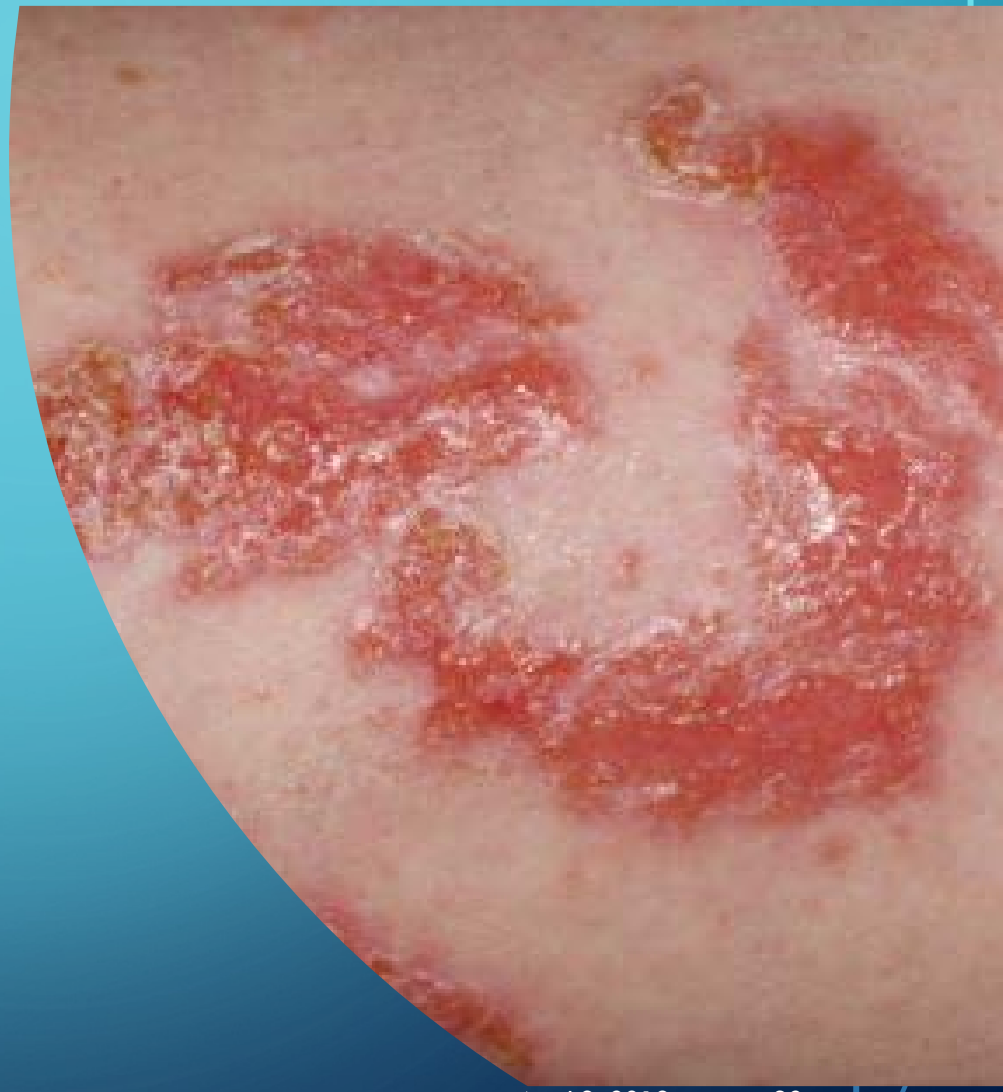
HENNA MEHNDI



- Unapproved for direct application to the skin, as in the body-decorating process known as Mehndi.
  - Unapproved use of a “Henna” as a skin tattoo makes these products adulterated. illegal to introduce an adulterated cosmetic into interstate commerce. (see. FD&C Act, § 301)

HENNA, MEHNDI, AND "BLACK HENNA" (21 CFR 73.2190)

- Other ingredients, such as p-Phenylenediamine (PPD), may be added to produce colors, such as those marketed as "black henna" and "blue henna."
- PPD – A potent “skin sensitizer” that can cause dangerous skin allergic reactions. .
- FDA has received reports of injuries to the skin from products marketed as henna and products marketed as "black henna." For more information on Henna, see the consumer update: Temporary Tattoos May Put You at Risk.
- Warning Letterr: Black Henna, Inc. August 14, 2006



WARNING LETTER: "*BLACK HENNA, INC.* AUGUST 14, 2006; FLA-06-32.

- Violation, Product is sold for intended use (function) as a temporary "decorative" skin tattoo. See, www.blackhennausa
- This product is "adulterated" under section 601(e) of the Act [21 U.S.C. 361(e)], in that it is a cosmetic and it bears or contains a color additive that is unsafe within the meaning of section 721(a) of the Act [21 U.S.C. 379e].
- FDA analysis found the product contains approximately 28% of the color additive p-phenylenediamine (PPD). A color additive is deemed to be unsafe within the meaning of section 721(a) There is no regulation listing the color additive p-phenyenediamine as safe for use in coloring the skin.

HENNA
IMPORTS AND ENFORCEMENT

- Import Alert: Henna-Based Skin Color
- IA # 53-19
- Published Date: 2-28-19
- Type: DWPE
- Charge: The article is subject to refusal of admission pursuant to Section 801(a)(3) in that the article appears not to be a hair dye and it appears to bear or contain, for the purpose of decorating the skin, a color additive which is unsafe within the meaning of Section 721(a) [Adulteration, Section 601(e)]."

COSMETICS AND COLOR ADDITIVES: HOMEPAGES

Cosmetics Division (internet):

http://www.fda.gov/Cosmetics/default.htm

Division of Color Certification and Technology (internet):

http://www.fda.gov/ForIndustry/ColorAdditives/default.htm

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THANK YOU FOR YOUR INTEREST! QUESTIONS?