# Regulation of Tattoo Inks in the US

Linda M. Katz, M.D., M.P.H.
Director, Office of Cosmetics and Colors
U.S. Food and Drug Administration

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# Tattoo Ink: FDA's Evolving Regulatory Policy and Overview of Color Additive Regulation

# Tattoo Ink Overview

- Role of tattoo ink in recent outbreaks
- Factors contributing to contamination
- What can industry do?
- FDA's current actions and  future goals

# Tattoo Ink Current Regulatory Authority

- Tattoo inks are cosmetics regulated under:
  - Section 601 – Adulteration
  - Section 602 – Misbranding
  - Section 801 – Imports

# Tattoo Inks and Tattoo Pigments

- **Tattoo inks** are a mixture of pigments and diluents intended for introduction into the skin
- FDA traditionally has not exercised its color additive regulatory authority over tattoo inks or tattoo pigments
- The **practice** of tattooing is regulated by state and local jurisdictions

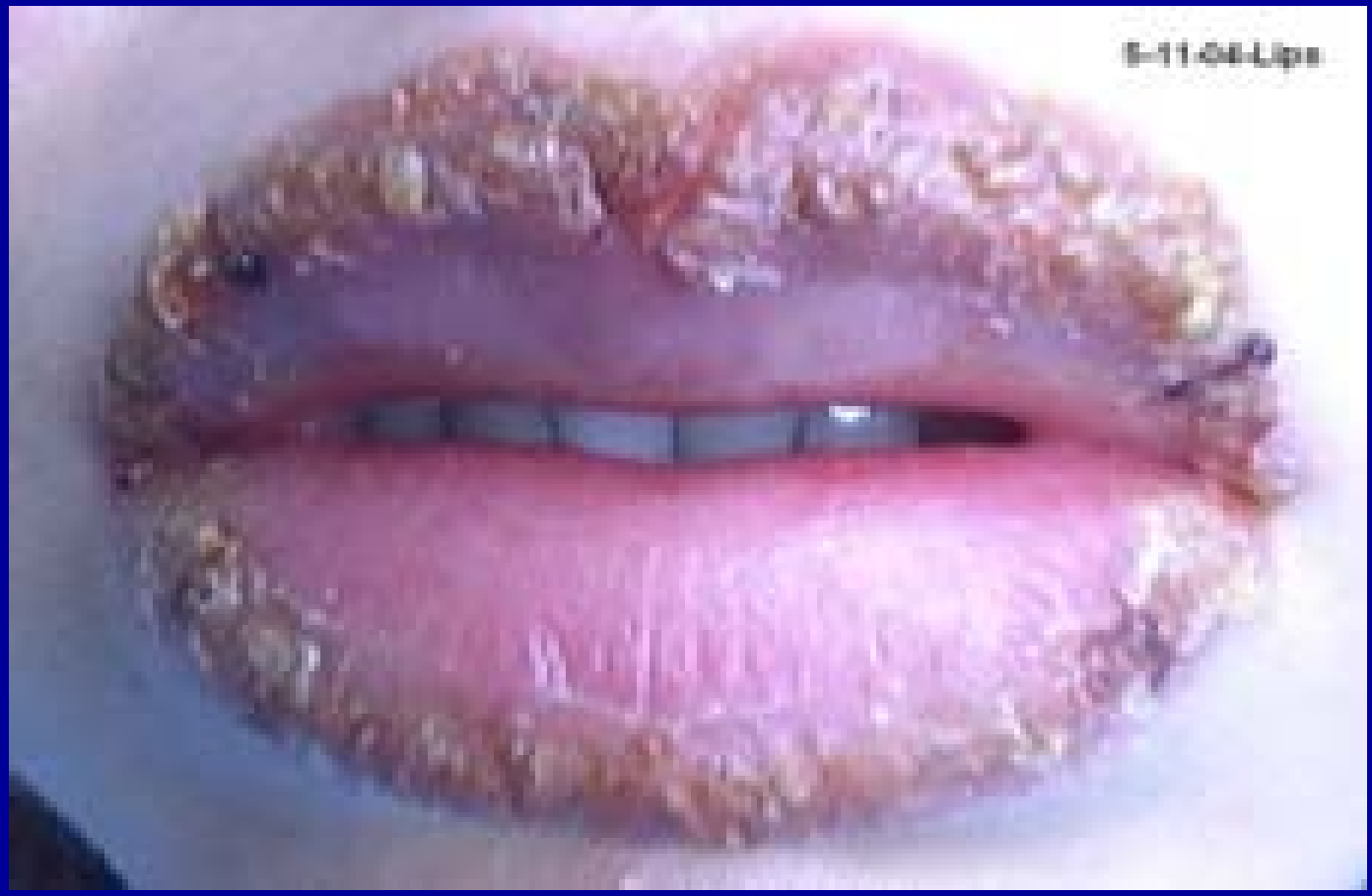
# How Safe Are Tattoos?

- Tattoos growing in popularity – 25% of population sports a tattoo!
- Reports of adverse reactions linked to tattoos and permanent makeup reported in Medwatch have steadily increased over past decade
- Reactions sometimes hard to control
- Recovery can be painful, effects long-lasting

# Complications From Tattoos and Permanent Makeup

- Swelling, cracking, peeling, blistering, scarring
- Granulomas (small nodules of inflamed skin)
- Keloids (scars that grow beyond normal boundaries)
- Allergic reactions
- Photosensitivity
- Serious disfigurement

# Adverse Reaction to Permanent Makeup



# Allergic Reaction

# Non-tubercular Mycobacterium (NTM) in Tattoo Ink

- In 2011 there were several outbreaks in US possibly linked to bottled tattoo ink
- Non-tubercular mycobacterium (NTM) isolated from bottled ink
- Other pathogens have been isolated
- New England Journal of Medicine Article
  - Kennedy, BS, Bedard B, Younge M, et al. Outbreak of Mycobacterium chelonae Infection Associated with Tattoo Ink. N ENGL J MED 2012; 367:1020-1024 September 13, 2012

# NTM Infection

# Contamination Sources

- NTM commonly found in public water supplies
- Cannot be removed by filtration
- Spores can only be destroyed by sterilization
  - Problem: sterilization may affect pigments
- NTM and other pathogens may be introduced by the user
  - Diluting with water, pouring back unused ink, storing open containers

# Current Issues

- NTM contamination in sealed bottles of tattoo ink
- Alcohol preservation may not be bactericidal
- Sterilization methods are untested
- Industry has not demonstrated microbiological expertise
- FDA’s rapport with industry is limited

# FDA is Reconsidering Its Regulatory Position on Tattoo Ink

- Single vs. multiple use?
- Preservation requirements?
- Sterilization treatment options?
- Required labeling statements?

# More Information Is Needed

- Tattoo ink ingredients
  - FDA is in the process of sampling and testing tattoo inks to learn more about ingredients and contaminants
- Processing methods
  - FDA planning to inspect more manufacturers to learn more about prevailing practices

# FDA's Future Goals

- Better understanding of composition, methods of preservation and safe use
- Development of better tools to assess human health risks from tattoo inks and pigments
- Better understanding of the tattoo industry
- Continued outreach with all stakeholders
- Consideration of changing color additive enforcement policy

# Current Regulatory Status of Tattoo Pigments

- **Tattoo pigments** are unapproved color additives
- **No** color additives have been listed for injected use
  - *See* **21 CFR 70.5(b)**

# Color Additive Overview

- Definition of color additive
- Petition process for listing color additives
- Certified color additives
- Color additives exempt from certification
- FDA’s color certification process
- Common color additive violations

# Definition of Color Additive

- A substance that imparts color to a food, drug, cosmetic, medical device, or human body
- Color additives used in FDA-regulated products must be pre-approved (listed)
- Individual color additives may only be used as allowed by regulation
- Does not include colorants used in packaging

# Color Additive Petition Process

- FDA receives about 3 petitions per year for review
- If approved, color additives are listed in the CFR specifically for use in
  - Food, drugs, devices and/or cosmetics

# Requirements for Listing Color Additives

- Probable exposure from use
- Cumulative effect in the diet (applies to color additives in food and drugs)
- Evaluation of safety by qualified experts
- Analytical methods to assure purity
- Particle size (for eye area use only)

# Listed Color Additives

- Exempt from certification - 21 CFR Part 73
- Subject to certification - 21 CFR Part 74
- “Lakes” subject to certification  21 CFR Part 82
- Most other color additive requirements
  - 21 CFR Parts 70, 71, 80, and 81

# Certified Color Additives

- Synthetic organic dyes and pigments
  - "Synthetic" means man-made
  - "Organic" means made of carbon, hydrogen, nitrogen, oxygen, and sulfur
- "FD&C," "D&C," and "Ext. D&C" color additives
- Not much dye needed to achieve desired coloring
  - Dyes have high absorptive values

# Common Names for FD&C and D&C Color Additives

| *Common name:* | *Certifiable as:* |
|---|---|
| • Allura Red AC ……. | FD&C Red No. 40 |
| • Erythrosine …….. | FD&C Red No. 3 |
| • Fast Green FCF …….. | FD&C Green No. 3 |
| • Alizarine Cyanine Green. | D&C Green No. 5 |
| • Carbon Black ..... | D&C Black No. 2 |
| • Tetrabromofluorescein.. | D&C Red No. 21 |

# FDA's Color Certification Program

- FDA's oldest user fee program – color additive amendments of 1960
- Manufacturers submit samples from each new batch
  - OCAC's Color Certification Branch conducts analyses
  - Certificate and lot number issued if all specifications are met
  - Average 5-day turnaround
- New web-based certification system
  - Online certification requests and results

# Certification Analyses

- Total color
  - Spectrophotometry
  - $TiCl_3$ titration
  - Gravimetric analysis
- Volatile matter
- Insoluble matter
- Soluble matter
- Extractable matter
- Salts
- Soluble barium
- Leuco base
- Intermediates
- Subsidiary colors
- Component colors
- Reaction by-products
- Aromatic amines
- Heavy metals
  - Lead, arsenic, mercury
  - Manganese, chromium
- Surface area
- Polynuclear aromatic hydrocarbons
- Sulfur and carbon

# Certification-exempt Color Additives

- Manufacturers are responsible for compliance with CFR specifications
- Must conform to purity requirements
- Mostly metal oxides or mineral origin
- Some are derived from animal or plant sources
- Less coloring power than synthetic

# Common Color Additive Violations

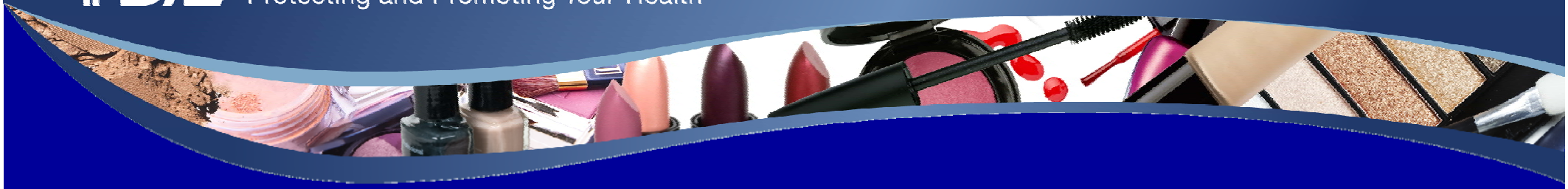
- Adulteration
  - Color additive use violations
  - Uncertified color additive used in a product
  - Non-permitted color additives used in a product
- Misbranding
  - Color additives not declared by their listed names
  - Food labeling requirements not followed

# Summary: Important Color Additive Requirements

- Only approved and listed color additives may be used in food, 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 regulation
- Batch-certified material must be used in products when required

# Summary/Challenges

- Regulatory oversight
- Development of better tools to assess human health risks from tattoo inks and pigments risk
- Improvement in recognition of problems (both clinically and scientifically)
- Communication and outreach with stakeholders and constituents



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# Resources for Color Additives

- FDA's web site
  - **http://www.fda.gov**
  - **http://Industry@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**
- Companies That Have Requested Color Certification Within the Last Two Years,"
  - **http://www.fda.gov/ForIndustry/ColorAdditives/ColorCertification**