FDA Law and the Body Art Industry

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Outline

- What is a Cosmetic?
- What is Body Art?
- How does the Federal Food, Drug and Cosmetic Act (FFDCA) and regulations apply?
- Parting Considerations
- Questions

What is a Cosmetic?

- FDCA 201(i) - The term "cosmetic" means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.

What is Body Art?

- **Body art** is defined as body piercing, tattooing, branding, scarification, subdermal implants, tongue splitting, transdermal implants or the application of permanent cosmetics.[1]
- It is form of personal expression

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[1] https://www.neha.org/eh-topics/body-art

Federal Food, Drug and Cosmetic Act (FFDCA) and Regulations

- FDA considers the inks used in intradermal tattoos, including permanent makeup, to be cosmetics.
- The pigments used in the inks are color additives, which are subject to premarket approval under the FFDCA.
- The actual practice of tattooing is regulated by local jurisdictions.

FFDCA and Regulations

- FDA traditionally has not exercised regulatory authority for color additives on the pigments used in tattoo inks. Why?

FFDCA and Regulations

- What changed?
  - 2003-2004 more than 150 reports of adverse reactions to certain permanent makeup ink shades
  - 2012 reports of infections from contaminated inks
  - 2017 two recalls of several colors and sizes of tattoo inks due to microbial contamination
  - Wide-spread concerns raised regarding pigments used in tattoo inks

FFDCA and Regulations

- Areas of Concern
  - Infections resulting from tattooing
  - Increasing variety of pigments and diluents being used in tattooing
  - No color additives approved for use in tattooing
  - Tattoo removal

FFDCA and Regulations

- Color Additives
  - Requires pre-approval for intended use
  - Use of an unapproved color additive in a product, makes the ink adulterated
  - Many pigments used in tattoo inks are not approved for skin contact (i.e. industrial grade colors suitable for printers' ink or auto paint)

FDA FY18 Inspection and Sampling Assignment of Tattoo Ink Distributors/Manufacturers

- FDA inspected **12** tattoo ink distributors and manufacturers.

Sampling and Analysis:

- FDA Collected and analyzed **60 tattoo ink samples**
- Analysis: **microbial analysis following BAM Chapter 23**

Summary of Findings

- **7 out of 60 (12%)** inks sampled were identified as being of "regulatory concern":
  - Microbial species of concern (*Pseudomonas aeruginosa*, *Escherichia coli*, *Staphylococcus aureus*, *Candida albicans*, but also *Bacillus cereus* [1-2] and anaerobes from genus *Clostridium*[3], and possibly others)
    - 2 samples had high counts (>1,000 CFU/ml) of bacteria
    - 3 samples had bacterial species of concern – 2 *Bacillus cereus*, 1 *Clostridium spp.* at "low count" (<1,000 CFU/ml)
    - 2 samples had both high counts and species of concern

https://www.fda.gov/cosmetics/cosmetics-recalls-alerts/fda-advises-consumers-tattoo-artists-and-retailers-avoid-using-or-selling-certain-tattoo-inks

[1] Dolan SA, Littlehorn C, Glodé MP, Dowell E, Xavier K, Nyquist AC, Todd JK. Association of Bacillus cereus infection with contaminated alcohol prep pads. Infect Control Hosp Epidemiol. 2012 Jul;33(7):666-71. doi: 10.1086/666334. Epub 2012 May 7.

[2] MMWR Morb Mortal Wkly Rep. 2005 Dec 9;54(48):1233-5. Outbreak of cutaneous Bacillus cereus infections among cadets in a university military program--Georgia, August 2004.

[3] Forrester JD & Spain DA. 2014. Clostridium Ramosum Bacteriemia: Case Report and Literature Review. Surg.Infect. 15:343-346.

Summary of Findings (Continued)

- 25 out of 60 (42%) samples show bacterial growth with
  - <1,000 CFU/ml or "low level" growth (with 7/25 with bacterial growth estimated to ~5-100 CFU/ml and 18/25 with bacterial growth only following 7-day enrichment

  AND

  - "non-pathogenic" microorganisms (species of microorganisms that were either not considered of a regulatory concern at this time or because they could not be identified (5 samples)
- 28/60 (47%) samples did not show bacterial growth using BAM Chapter 23 method
- **33/60 tattoo ink samples 33** were labelled as "sterile" or "sterilized"
  - 15/33 "sterile" or "sterilized" samples were found to contain microorganisms

Tattoo Ink Recalls

- Three firms voluntarily recalled their tattoo inks: https://www.fda.gov/cosmetics/cosmetics-recalls-alerts/fda-advises-consumers-tattoo-artists-and-retailers-avoid-using-or-selling-certain-tattoo-inks
  - Scalp Aesthetics
    - Recall 2/22/2019
    - Scalpaink SC, Scalpaink PA, and Scalpaink AL basic black tattoo inks (no lot #s)
  - Color Art Inc. dba Solid Ink
    - Recall 3/29/2019
    - Solid Ink - Diablo (red) tattoo ink (lot 10.19.18)
  - Dynamic Color
    - Recall 3/12/2019
    - Dynamic Color Black tattoo ink (lots 12024090 and 12026090)

FDA Warning Letters to Tattoo Manufacturers

- Three firms received Warning Letters (September 18, 2019):
  - Color Art Inc. (dba Solid Ink)
    - adulterated 601(a) - microbial contamination (<1,000 CFU/ml; *Clostridium spp.*)
    - adulterated 601(c) –insanitary conditions
    - misbranded 602(a) – misleading labeling claim of sterility on non-sterile products
  - Dynamic Color
    - adulterated 601(a) - microbial contamination (<1,000 CFU/ml; *Bacillus cereus*)
  - Intenze Products Inc.
    - adulterated 601(a) - microbial contamination (>1,000 CFU/ml; *Bacillus cereus*)
    - misbranded 602(a) – misleading labeling claim of sterility on non-sterile products

https://www.fda.gov/cosmetics/warning-letters-related-cosmetics/warning-letters-cite-cosmetics-adulterated-due-microbial-contamination

FDA Warning Letters to Tattoo Manufacturers

- After WLs were issued, AFDO BAC held a Conference Call to discuss. Some questions were:
  - Why were the WLs issued now? Even when a firm issues a recall for affected product on the market, a Warning Letter can be issued because the adulterated and/or misbranded product was on the market. Manufacturers are responsible for their products.

FDA Warning Letters to Tattoo Manufacturers

- What directions do you (FDA) give facilities?
- FDA doesn't give specific directions to a facility on how to bring a product into compliance. It is the facility's responsibility to make sure that the product is safe for it's intended use.

- Have these problems [identified in the WLs] been addressed?
- FDA works with firms in response to regulator actions; however, specifics regarding a firm's response and its adequacy cannot be openly discussed.

FDA Warning Letters to Tattoo Manufacturers

- Does FDA come back and retest inks?
- Yes, FDA can retest inks to check if microbial contamination issue has been addressed. This may be accomplished by collecting samples during the follow up inspection, after the recall, or as a part of a survey of cosmetic products that may include tattoo inks.

- Why didn't Intenze issue a recall?
- FDA work with firms in response to regulator actions; however, specifics regarding a firm's response and its adequacy cannot be openly discussed.

FDA Warning Letters to Tattoo Manufacturers

- Who is responsible for disseminating information to the industry from the WLs? What are the next steps?
- FDA posts WLs on its website at fda.gov. Next steps include the firm's response to the WL; FDA's determination of the adequacy of the response; a subsequent inspection to verify compliance.

- Microbiological testing is a moment in time because it continues to grow. Could the levels of tested inks now be elevated? Is this a concern?
- For the firms whose product demonstrated levels of microbes below the BAM 23 standards, a regulatory meeting was held to discuss the implications and next steps; however FDA cannot elaborate on those discussions.

Additional FDA Follow Up to the FY 2018 Tattoo Inspection Assignment

- FDA met with the tattoo industry to discuss the following points:
  - Some inks tested by FDA contained microorganisms below the current level of regulatory concern (<1,000 CFU/ml and not-objectionable microbes)
  - To find out if the firms conducted sterility testing of finished tattoo inks
  - To ask about methods used by the tattoo industry to conduct sterility testing of finished tattoo inks
  - To discuss misbranding issues identified in the FDA sampling assignment:
    - Misleading claims of sterility on products that are not sterile
    - Use of unrecognized ingredient names
- FDA will continue to monitor for contamination

Parting Considerations

- The application of tattoos are under state/local jurisdictions
- FDA regulates the inks/pigments used in tattooing
- Color additives require FDA pre-approval
- To date, no petition has been submitted for pre-approval of any color additive used in tattoo inks
- FDA continues to be concerned about microbial contamination of tattoo inks and labeling of tattoo inks as ‘sterile’ when they are not
- Safety substantiation remains the responsibility of the manufacturer but the onus of proving harm is FDA’s

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