Tattoo Ink and Permanent Makeup Safety

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Overview

- TI and PMU are cosmetics...with a twist.
- TI and PMU safety concerns.
- Microbiological Contaminants in TI and PMU.
- Color additives...what are the issues?
- Body Art Committee Charge 2: Color Additive Petition for Titanium Dioxide for Intradermal Tattooing
- Body Art Committee Charge 4: Tattoo Ink and PMU Sterilization Standard of Best Practices
- What can artists do to protect themselves.
FDA Regulation of Tattoo Ink and Permanent Makeup

- Regulated as cosmetics
  - Never specifically mentioned in FD&C Act.
  - As popularity grew and problems arose FDA declared that products used to alter the appearance that are placed into the dermis are Cosmetics.
  - Carbon black regulated as a medical device for use in tattooing during medical procedures.
  - In Europe, tattoo ink pigments are regulated as chemicals under Reach, not as cosmetics.
  - Are tanning chemicals any different? More on this later.
TI and PMU Safety Concerns

- **Microbiological**
  - Contain water thus capable of sustaining growth
  - When placed into the dermis should be sterile
  - Presence of some microorganisms can cause disease

- **Chemical**
  - Color additives not approved for use in TI and PMU
  - Presence of contaminants
Color additives...what are the issues?

- FDA has not exercised authority to regulate color additives in TI and PMU.
- Color additives in TI and PMU have not been approved by FDA.
- The law is clear that color additives require pre-market approval.
- No regulations specific to TI and PMU have been promulgated.
- In comes the Body Art Committee to the rescue!
In the fall of 1950, many children became ill from eating an orange Halloween candy containing 1-2% FD&C Orange No. 1. Subsequently several other issues with color were discovered. U.S. House Representative James Delaney began holding hearings on the possible carcinogenicity of pesticide residues and food additives. Industry was developing new colors synthesized from petroleum. FDA provisionally listed 200 colors. New colors require scientific data to establish safety.
Regulation of Pigments used in TI and PMU

- No color additives are listed for use in TI or PMU.
- 21 CFR 70.5(b) *Color additives for use in injections.*
- Are tattoos injections? According to FDA, yes.
- FDA considers “intradermal” to mean the same thing as “injection”.
- AFDO’s goal is to clarify regulatory requirements for improved safety of TI and PMU.
• Canthaxanthin, ingested to turn the skin a range of colors from orange to brown.
  - Can also cause serious health problems including liver damage; hives; and an eye disorder called canthaxanthin retinopathy, in which yellow deposits form in the retinas.

• Dihydroxyacetone (DHA), a color additive that darkens the skin by reacting with amino acids in the skin's surface.
  - DHA is a color additive that is approved for external application, but not for use in the eye area or on the lips.
  - Regulation in salons and tanning booths is regulated by state and local laws.
• BAC Charge #2 Color Additive Petition for Titanium Dioxide for Intradermal Tattooing.
• First color additive petition for TI or PMU.
• Goal is to get listed regulation of TiO2 used in TI and PMU.
• Title 21 of the Code of Federal Regulations part 70.5(b), color additives for use in injections for cosmetic purposes (tattoos) must be specifically listed for that use.
• FDA has responded to AFDO pre-petition correspondence.
• There is an opportunity to define what tattooing and permanent makeup are in the regulations.
• FDA has provided a preliminary list of what research needs to be performed prior to listing TiO2.
• There are no color additives approved by FDA for use in injectable cosmetics.
• FDA has traditionally exercised enforcement discretion in this area, leaving the regulation of the tattoo industry up to state and local authorities.
• FDA does not have formal guidance for the type of toxicology data needed for color additives in injectable cosmetics.
• This is a new frontier!
Research to be performed prior to listing TiO2 (At a minimum)

- The results from a literature search for all relevant published toxicology data on the proposed color additive and its impurities.
- Acute sensitization bioassays in tattooed animals addressing the sensitization, phototoxicity, and allergenicity through intradermal exposure.
- Genotoxicity testing from a battery of bacterial and mammalian testing to assist in evaluating the carcinogenicity potential of the color additive.
- Long term (life-time) bioassay in tattooed animals with UV light to evaluate chronic sensitization, photosensitization, and dermal carcinogenic potential.
Color Additive Research
Issues

- Use of animals to conduct research.
  - Is very specialized and costly
  - Using animals is ethical problem in US and illegal in EU
- Can non-animal models be substituted?
- Request FDA to perform or fund research.
- AFDO does not have the resources to accomplish research as expected by FDA.
- Keeping current regulatory position of “enforcement discretion” is a possibility.
Microbiological Contaminants in TI and PMU

- Should meet standards for cosmetics and be sterile.
- If labelled “Sterile” is it sterilized?
- Recent statements on fda.gov (https://www.fda.gov/media/130664/download) suggest sterility is expected.
- In order to be free of pathogens a method to control microbiological contaminants is needed. (HACCP)
  - USP 71 – FDA suggested test method
  - Control bioload of pigments, water and other ingredients
  - Manufacture in a sanitary environment
  - Test packaged product prior to terminal sterilization or sale
Sterilization Standard of Best Practices

- BAC Charge #4 Tattoo Ink and PMU Sterilization Standard of Best Practices.
- Creating guideline for industry to follow.
- Specific to gamma irradiation.
- Gamma is useful for controlling bio load in pharmaceuticals.
- Other methods may be applicable to TI and PMU. (heat, pressure, filtration)
- Downside to any sterilization process is the affect on pigments and packaging.
What Should An Artist Do?

- Know and trust your suppliers. Ask questions. What are the ingredients?
- Only use properly labelled ink following AFDO Tattoo Ink Labeling Guide.
- Ask for proof of sterilization or finished product test results specific to the lot supplied.
- If you accept untested lots there may be problems.
- Do not dilute inks. If you must, only use sterile water (distilled water is not sterile and may be a source of pathogenic microorganisms).
Sterile water – single use
What to do? (Continued)

- Keep track of all pigments used on a specific customer.
  - Record lot #, location, volume (approximate)
- In case of a serious adverse event, report to local health department, FDA (if it involves ink) and MedWatch.
- Serious adverse event: the event has or may jeopardize the customer requiring medical intervention.
- FDA Offices: https://www.fda.gov/about-fda/contact-fda
Recap

- TI and PMU are much safer than they were 20 years ago.
- Best practices will help improve the safety record for the entire industry.
- Color Additive Petition for Titanium Dioxide for Intradermal Tattooing going forward.
- Tattoo Ink and PMU Sterilization Standard of Best Practices will be completed.
- AFDO Tattoo Ink Labeling Guide should be followed.
- Protect yourself, document everything.
- Report serious problems.
AFDO Partners

• National Environmental Health Association (NEHA) Body Art Model Code Committee
  – Contact:
  – Kaylen Celestin (KCelestin@neha.org)

• Body Art Education Alliance (BAEA)
  – Contact:
  – Laurel Arrigona: larrigona@ceuticallabs.com
  – KC Stevenson: kcstevenson@ceuticallabs.com
  – Matt Bavougian: m.bavougian@gmail.com

• Join in – be a part of the solution!
AFDO Resources for the Body Art Industry

- [http://www.afdo.org/body-art-committee](http://www.afdo.org/body-art-committee)

- Body Art Committee chairs
  - Ken Stevenson ([kcstevenson@ceuticallabs.com](mailto:kcstevenson@ceuticallabs.com))
  - Sarah Robbin ([sarahrobbin1@gmail.com](mailto:sarahrobbin1@gmail.com))
  - Laurel Arrigona ([larrigona@ceuticallabs.com](mailto:larrigona@ceuticallabs.com))

- Join AFDOS and AFDO!
  - [http://www.afdo.org/membership](http://www.afdo.org/membership)