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Tattoo Ink and Permanent Makeup Safety

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July 13, 2020

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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.

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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.

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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

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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!

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Color Additive Amendments of 1960

- 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.

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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.

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Tanning Chemicals

- 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.

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TiO2 Color Additive Petition

- 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.

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FDA Response to Pre-CAP Correspondance

- 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!

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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.

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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.

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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

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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.

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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).

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Sterile water – single use

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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
- MedWatch: https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda

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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.

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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!**

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AFDO Resources for the Body Art Industry

- http://www.afdo.org/body-art-committee
- Body Art Committee chairs
  - Ken Stevenson (kcstevenson@ceuticallabs.com)
  - Sarah Robbin (sarahrobbin1@gmail.com)
  - Laurel Arrigona (larrigona@ceuticallabs.com)
- Join AFDOS and AFDO!
  - http://www.afdo.org/membership