



Ceutical Labs

cGMP COMPLIANCE SPECIALISTS

Regulation of Tattoo Ink, Permanent Makeup and Color Additives in the US

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August 25, 2021

Tattoo Ink and Permanent Makeup Ink

- Regulated as cosmetics by FDA.
- Pigments and dyes are color additives.
- All color additives are regulated under The Color Additive Amendment of 1960.
- These amendments to the FD&C Act came about as a result of horrific adverse events caused by color additives.
- Did the US Congress ever intend tattoo and PMU ink to be covered?...It's doubtful, but FDA has determined they are.
- Tattoo and permanent makeup artistry is regulated by the states.

Color Additive Amendments of 1960

- Requires pre-approval of all color additives in FDA regulated products.
- Tattoo and Permanent makeup ink are cosmetics regulated under the FD&C Act.
- Places the responsibility for proving the safety of color additives on the user.
- 21 CFR 70.5(b) requires color additives that are “injected” to obtain a separate approval specifically for that use.

Ink and Injection

- In 1960 there was no concern about tattoo ink safety.
- Since the growth in popularity of tattoos and reports of health-related adverse events linked to tattooing and permanent makeup, FDA has taken the position that pigments used in tattoo ink and permanent makeup must be approved for injection.
- No ink has been approved for injection therefore FDA has taken an “enforcement discretion”.
- Will this position change?

AFDO Body Art Committee

- The Body Art Committee (BAC) of the Association of Food and Drug Officials (<http://www.afdo.org/about>) has taken on the task of proposing a pathway for approval of pigments used in tattoo ink and permanent makeup.
- AFDO is open to regulatory and industry membership.
- The BAC has submitted a Color Additive Petition (CAP) aimed at getting approval for TiO₂ under 21 CFR 70.5(b). The goal is to develop a model for how a CAP should be submitted for any color additive.
- Problem, FDA has no guidance on submitting a CAP for injection.

TiO₂ Color Additive Petition

- TiO₂ allowed for use in all FDA products (Food, Drugs, Medical Devices and Cosmetics) with only minor restrictions.
- Considered “safe” by many standards
- TiO₂ is also one of the most common pigments used in inks.
- Once we have succeeded with TiO₂ the next pigment to tackle is carbon black which adds additional dimensions to the equation.

FDA's Requested data for TiO₂ CAP

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

We Have Work To Do!

- A literature search (Number 1.) has been completed and submitted to the CAP.
- Addressing the other three points on FDA's list are more troublesome. In a subsequent meeting with FDA the necessity of filling in data gaps became apparent.
- There is an opportunity to make a scientific case for what data is possible to obtain from the studies FDA is requesting and how they should be applied to an approval process.
- There is an opportunity to write the next chapter in tattoo ink and permanent makeup regulation in the USA.

What Next?

- Fill the research gap.
- Unlike color additive approvals for food, drugs, etc. there is no organization with a sizable economic interest to fund research.
- It is going to take a team effort.
- Everything is on the table.
- AFDO BAC is coordinating.
- Can you help? Researchers needed...
- Thanks to Jorgen Syrup and Wolfgang Baumler!

Going Forward...

- Will FDA continue “enforcement discretion”
- Will US Congress step in?
- Get involved!
- Contact:

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Questions...Discussion?