

Issues with Tattoo and PMU Ink -

*The AFDO Tattoo Ink and
Permanent Makeup
Labeling Guidelines*

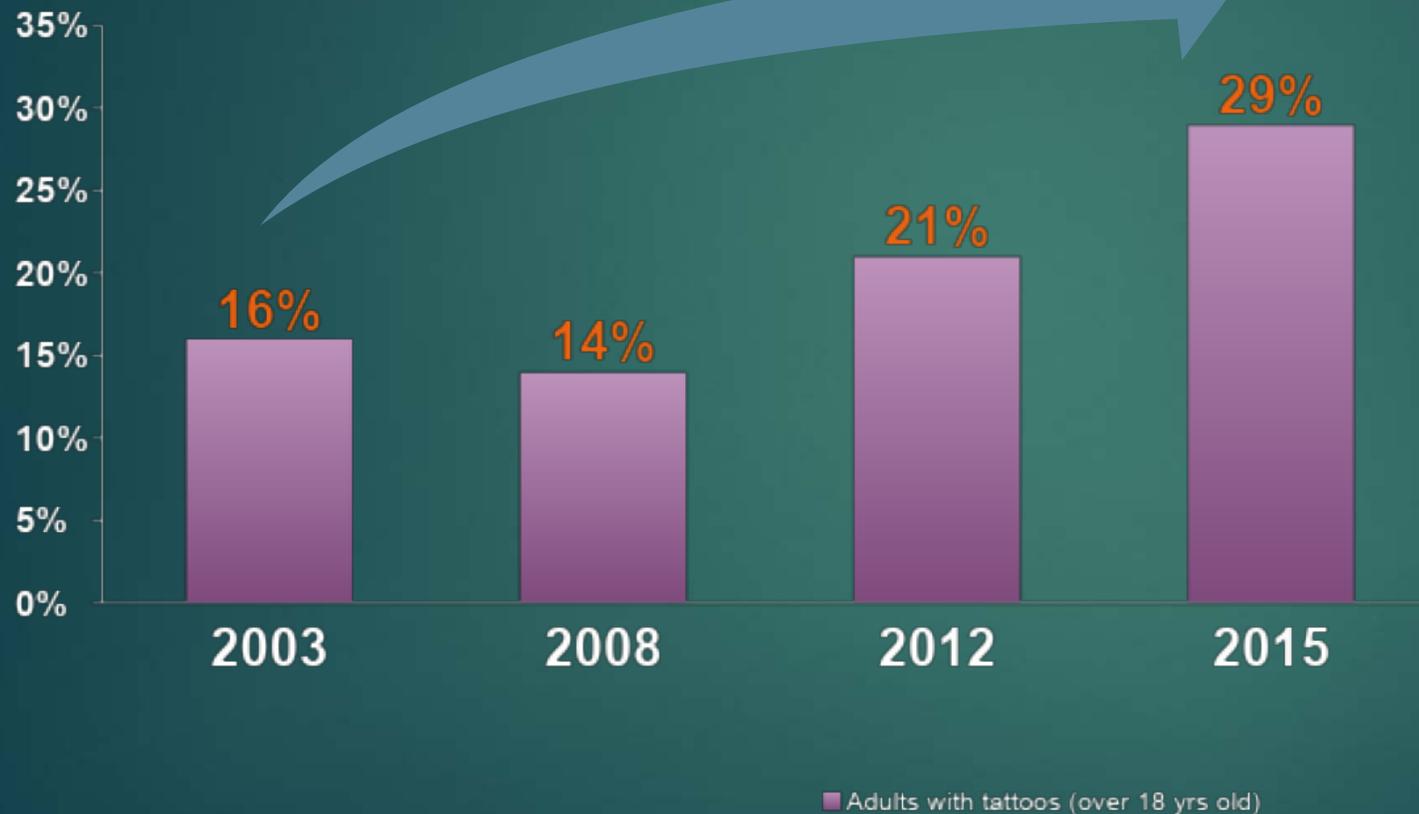
2019 CEHA Annual Education Conference
Keystone, Colorado

Laurel Arrigona
Regulatory, Ceutical Labs
AFDO BAC, Chair
BAEA, Chair
NEHA BAMC, Committee Member

Jodi Zimmerman
Environmental Health Specialist II, El Paso County
Public Health
BAEA, Committee Member
AFDO BAC, Committee Member



As You Know - Tattooing is on the Rise



- 2015 Harris Poll showed that about 29% of Americans have at least one tattoo.
- Tattoos are more prevalent among younger Americans, with nearly 50% of millennials.



Tattooing and PMU Procedures

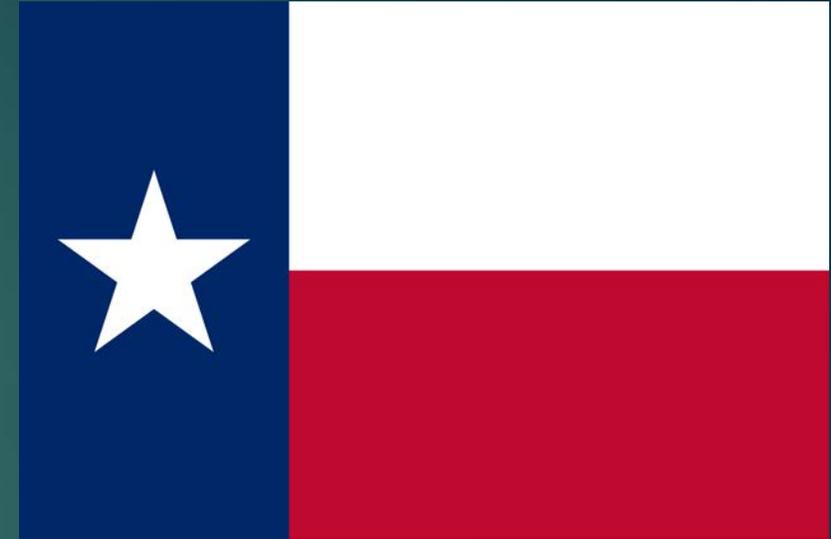
Practice of Tattooing and PMU Procedures

- The practice of tattooing and PMU procedures are regulated by **State and Local jurisdictions**, focusing on safe practices at the tattoo parlors and salons.



In the Shop - Tattooing Regulations Across the Country

- ▶ Some states have regulations for entire state
- ▶ Some states have regulations per county or city
- ▶ Some states have voluntary programs



Problems with the Current Shop Regulations

- ▶ Consistency
 - ▶ Inspections and practices within one jurisdiction
 - ▶ Inspections and practices within one state
 - ▶ Inspections and practices across the country
- ▶ Education requirements
- ▶ Licensing Requirements

Causes

- ▶ Confusion
- ▶ Adversarial relations between industry and regulators
- ▶ Inconsistent shop inspections
- ▶ Risk to artist and the public



FDA Regulates Tattoo Ink and PMU

Cosmetics

- Any product intended to be applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance. (FD&C Act, sec. 201(i))

Color Additive

- "a material which ... is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source, and ... [that] when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with [an]other substance) of imparting color thereto ... The term 'color' includes black, white, and intermediate grays..." (FD&C Act, sec. 201(t))

Tattoo Inks

- "Tattoo inks" sold and used in the US are considered as "Cosmetics" containing "Color Additives". As such they fall under FDA jurisdiction.



Problems with the Product Regulations

- ▶ Many in industry argue against the cosmetic regs being applied to tattoo ink and PMU.
- ▶ None of the color additives are approved for the use.
- ▶ Historically there has been little regulatory action.
- ▶ Confusion in industry and the public
- ▶ If not as a cosmetic, how should tattoo ink and PMU be classified?
- ▶ BAM 23 specs



Acknowledgement

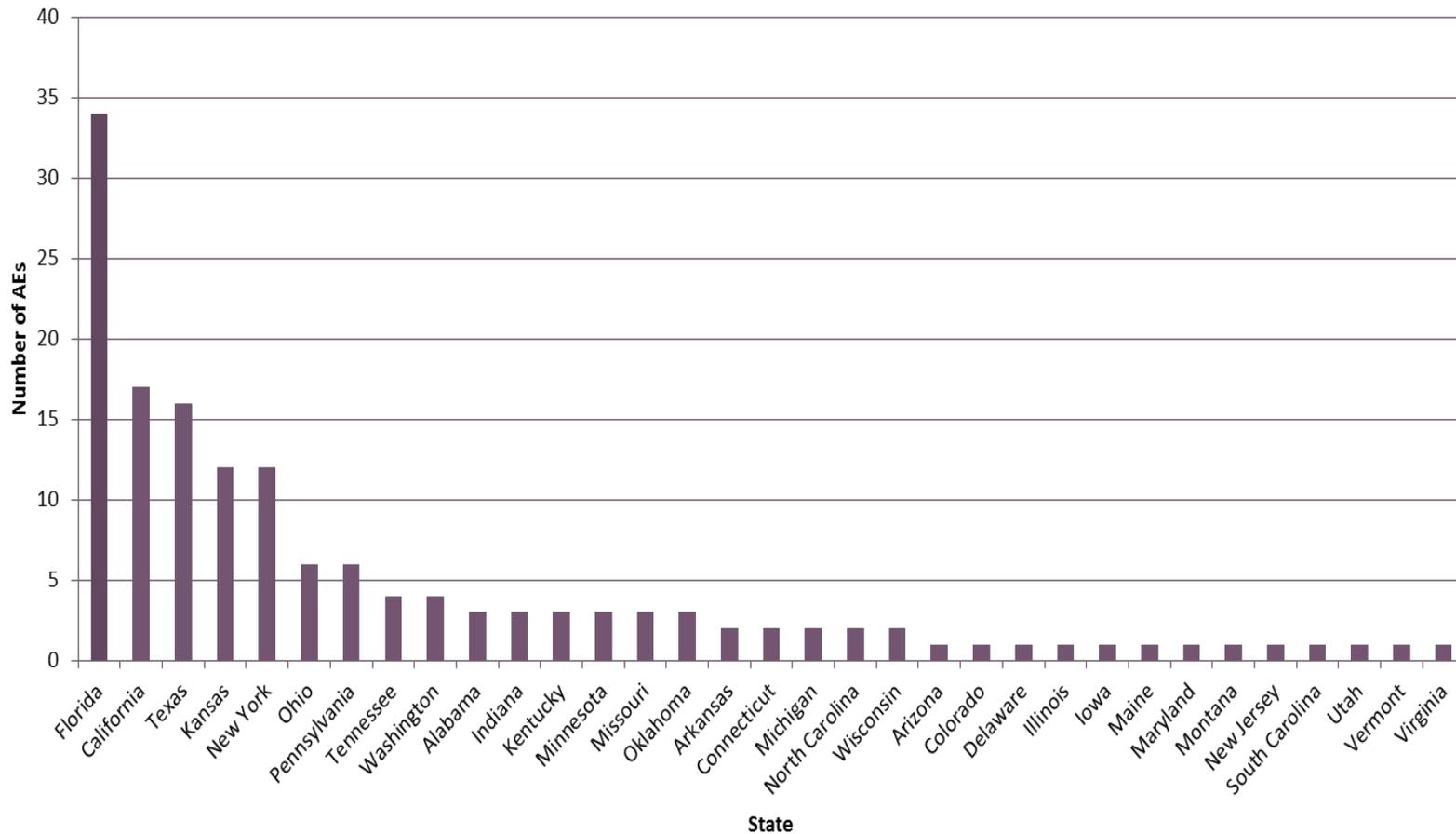


- The FDA Office of Cosmetics and Colors have given the AFDO Body Art Committee permission to communicate the information they presented at the AFDO Annual Education Conference of 2019.
- The findings presented by FDA were the result of inspections of distributors and manufacturers, routine surveys of tattoo inks, and the subsequent microbiological analysis of tattoo ink available on the United States market.



Adverse Events Reported to FDA from 2004-2016

Reported Tattoo AEs by State, 2004-2016



- ▶ 363 from 2004-2016
- ▶ Some reports resulted in voluntary recall of inks



Tattoo Ink and Permanent Makeup Recalls, 2003-2015

Brand	Color	Ink Type	Year of Recall	Issues	Source of Issues
1	All Colors	PMU	2003, 2004	Allergic	Benzimidazolone was suspected as a cause of allergic reaction but not confirmed
2	Black	Tattoo	2004	Micro	Pseudomonas aeruginosa Mold: Acremonium spp.
3	Black	Tattoo	2011	Micro	NTM: Mycobacterium abscessus, M. chelonae
4	Grey washes	Tattoo	2012	Micro	NTM: Mycobacterium chelonae
5	Black	Tattoo	2014	Micro	Nocardia. farcinica and Nocardia spp.
6	All colors	Tattoo	2014	Micro	Multiple Microbes: Sphingomonas paucimobilis, Bacillus spp.
7	Grey washes	Tattoo	2015	Micro	NTM: M. chelonae, Mold: Penicillium spp., and Cryptococcus albidus



Case Report: Tattoo-Associated Nontuberculosis Mycobacterial Skin Infections – 2011-2012

- ▶ Oct 2011 – A person (Rochester, New York), presented with a persistent papular rash beginning 1 week after being tattooed
- ▶ Jan 2012 – The Monroe County Dept. of Public Health (NY) investigated an outbreak:
 - ▶ *M. chelonae* was isolated from a skin biopsy
 - ▶ 14 confirmed with *M. chelonae* out of a total of 19 infections
 - ▶ Company A prediluted gray ink was used
 - ▶ *M. chelonae* was isolated from tissue specimen, one opened and one unopened bottle of company A prediluted gray ink (indistinguishable)
 - ▶ Water and environmental samples: negative for *M. chelonae*
- ▶ Feb 2012 – CDC disseminated an Epi-X public health alert:
 - ▶ Identified additional tattoo-associated NTM skin infections from three states (Washington, Iowa, and Colorado)



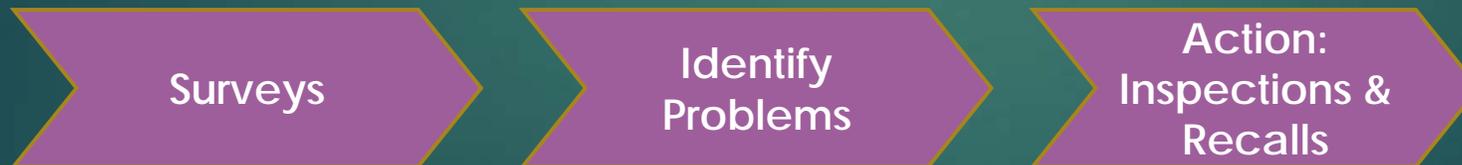
Nontuberculous Mycobacterium (NTM)

- ▶ NTM species (e.g. *M. abscessus* and *M. chelonae*)
 - ▶ Environmental mycobacterium (found in water)
 - ▶ NTM contamination can occur:
 - ▶ During the ink manufacturing process as a result of using contaminated raw materials
 - ▶ As a result of dilution of inks with non-sterile water by the tattoo artist before use
- ▶ Tattoo-associated NTM infections
 - ▶ Range from mild inflammation to severe abscesses requiring extensive and multiple surgical debridement
 - ▶ Difficult to treat and can require a minimum of 4 months of treatment with a combination of two or more antibiotics

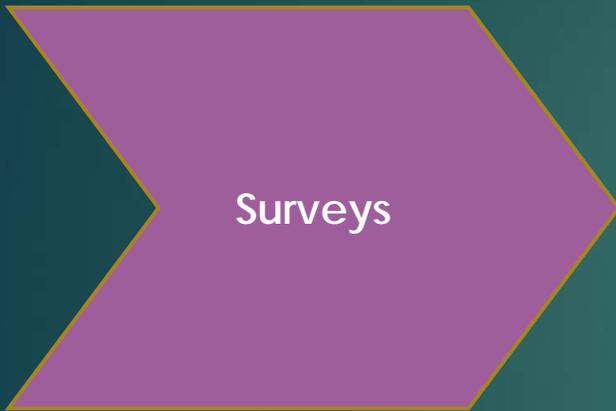


FDA's Tattoo Ink & Permanent Makeup Research

- ▶ Conducted multiple surveys of tattoo and permanent makeup inks on the US market.
- ▶ NCTR developed effective detection methodologies for microbial contamination of tattoo and permanent makeup inks.
- ▶ This research is publicly available.
- ▶ Published in the Journal of Applied Microbiology January 2018.
- ▶ “Microbiological survey of commercial tattoo and permanent makeup inks available in the United States”



FDA's Tattoo Ink Survey Results



Years / Lab	Number of Samples	Number Positive	BAM 23* Non-Compliant
2013-2015, private	75	32 (43%)	12 (16%)
2015-2017, FDA	85	42 (49%)	16 (18%)
2017-2018, FDA	41	18 (44%)	10 (24%)
Total	201	92 (46%)	38 (19%)

*Samples were evaluated following Bacteriological Analytical Manual, Chapter 23

- BAM 23 Microbiological Methods for Cosmetics
 - Eye-area products, no greater than 500 CFU/g
 - Non-eye-area products, no greater than 1000 CFU/g



What Was Learned From the Surveys



Identify
Problems

- ▶ Much of the tattoo and PMU inks available in the US that were assessed were contaminated with Micro.
- ▶ Some had high levels of microorganisms, more than 1000 CFU/mL (CFU/g) (e.g., 16 out of 42 contaminated tattoo inks).
- ▶ Some were opportunistic human pathogens.
- ▶ Higher risk for people with weakened immune systems



FDA Action: Tattoo Inspection and Sampling



Action:
Inspections &
Recalls

- ▶ Focused on firms identified during recall investigations
- ▶ 12 firms inspected
- ▶ 61 samples tested
- ▶ 31 samples positive (51%)
- ▶ 7 of 31 samples resulted in the need for a voluntary recall (23%)



Tattoo Ink Recalls 2017-2019

Brand	Location	Recall Initiation Date	Colors	Issues	Source of Issues
1	TX	11/14/2017	Blue, Green, Orange, Purple	Micro	Multiple Microorganisms
2	CA	12/12/2017	Lining Black	Micro	Bacillus altitudinis, Paenibacillus spp.
3	FL	5/15/2018	Orange	Micro	Bacillus pumilus and Bacillus licheniformis
4	NJ	6/26/2018	Red, Blue	Micro	Bacillus halosaccharovorans, Brachybacterium conglomeratum, Pseudomonas andersonii, P. balearica
5	MI	9/25/2018	Red, Blue	Micro	Bacillus cohnii, Pseudomonas andersonii, Lysinibacillus fusiformis
6	NY	2/22/2019	Black	Micro	Pseudomonas aeruginosa, Brevibacillus chashinensis, Clostridium butyricum/clostridioforme, others
7	FL	3/12/2019	Black	Micro	Bacillus cereus
8	FL	3/20/2019	Red	Micro	<i>Clostridium clostridioforme</i> , <i>C. ramosum</i> & <i>Clostridium spp.</i> , others



FDA Inspection Conclusions

- ▶ Industry is not addressing contamination issues
- ▶ "Sterilization" not validated or controlled
- ▶ Gamma levels used only lethal to vegetative bacteria, not spores
- ▶ A standard for tattoo ink sterilization is needed



“Sterile” Tattoo Ink

- ▶ 31 samples were labeled “sterile”
- ▶ 15 tattoo inks labeled as “sterile” were found to contain microorganisms (48%)
- ▶ Manufacturers not following a validated procedure
- ▶ Validated procedure is not currently required.
- ▶ Sterility of inks is not currently required.
- ▶ If the product is labeled as “sterile,” it needs to be sterile.



Current Situation

- ▶ Contamination is found in all colors, not just black and greywash
- ▶ High plate counts or presence of known pathogens is “adulteration”
- ▶ Sterility labeling and sterilization methods are a concern
- ▶ Inks labeled “sterile” but contain microorganisms below BAM 23 limits are misbranded.
- ▶ If a product is labeled “sterile” it must be free of microorganisms



Public Health Impacts of Surveys

- ▶ Surveys are used to help assess prevalence of the contaminated inks on the US market.
- ▶ The survey results provide scientific evidence to develop policies.
- ▶ Helps FDA undertake appropriate enforcement activities in order to remove unsafe products from the market.
- ▶ Recent tattoo ink recalls protect consumers from potentially serious adverse events caused by contaminated inks.
- ▶ FDA's tattoo ink surveys and regulatory actions increase awareness in the tattoo and PMU industries and with the consumers about the risk.



FDA's Future Direction

Safety	<ul style="list-style-type: none">• Additional , focused assignments• Monitoring Adverse Events• Determine health effects of endotoxin
Methods	<ul style="list-style-type: none">• NTM method (Multi-lab validation)• Endotoxin Assay• Sterility testing
Guidelines/Policies	<ul style="list-style-type: none">• Guidance for Industry• Policy Development
Collaboration	<ul style="list-style-type: none">• Working with Local/State Jurisdiction• Develop sterilization protocol for tattoo ink with industry/AFDO
Education	<ul style="list-style-type: none">• Education for tattoo artists, public, and health professionals



How Can the AFDO Body Art Committee Help?

Safety	<ul style="list-style-type: none">• Monitoring and communicating adverse events, recalls, product specific warnings, health risks• Determine health effects of pigments
Methods	<ul style="list-style-type: none">• Standard Analytical and Micro Methodology for products• Color Additive Petitions for Approval of Colors for use
Guidelines/Policies	<ul style="list-style-type: none">• Labeling guidelines• Sterilization standard• Policy Development• Establishment inspection standards
Collaboration	<ul style="list-style-type: none">• Working with Local/State Jurisdictions• Working with FDA• Working with NEHA• Working with Industry
Education	<ul style="list-style-type: none">• Education for tattoo artists, public, and health professionals



Tattoo Ink and Permanent Make-Up Labeling Guide

Tattoo Ink and Permanent Makeup Labeling Guide



Association of Food and Drug Officials
Body Art Committee



- ▶ Provides guidance for industry, professionals, and regulators with compliance to U.S. laws and related regulations.
- ▶ Consistent labeling
- ▶ Where possible used established industry nomenclature
- ▶ Consistent with other current established regs - BAMC
- ▶ Presents
 - ▶ Information required on labels per regulations
 - ▶ Suggested best practices
- ▶ Includes a checklist
- ▶ Available for free www.afdo.org/publications
- ▶ AFDO Podcast



Tattoo Ink and Permanent Make-Up Labeling Guide

Tattoo Ink and Permanent Makeup Labeling Guide



Association of Food and Drug Officials
Body Art Committee



- ▶ Label info required for safe use, recalls, and investigations.
 - ▶ General
 - ▶ PDP Specs
 - ▶ Product Identity
 - ▶ Conspicuous warning statement about unsubstantiated safety
 - ▶ Net quantity
 - ▶ Material facts
 - ▶ Warnings
 - ▶ Manufacturer/distributor info
 - ▶ Ingredients/professional use
 - ▶ Directions for safe use



Tattoo Ink and Permanent Make-Up Labeling Guide

Tattoo Ink and Permanent Makeup Labeling Guide



Association of Food and Drug Officials
Body Art Committee

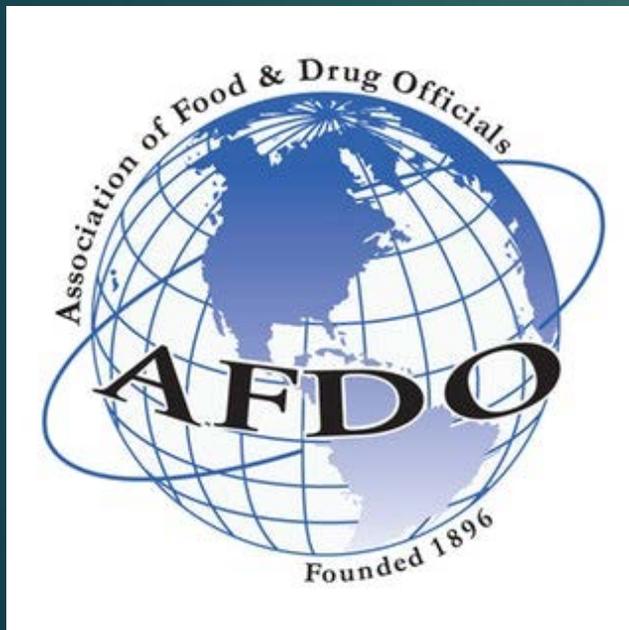


- ▶ Label info suggested for safe use, recalls, and investigations.
 - ▶ Lot/batch numbers
 - ▶ Use by date
 - ▶ Do not dilute
 - ▶ Storage and handling info
 - ▶ Allergy statements
 - ▶ Pregnancy warning
 - ▶ Keep out of reach of children
 - ▶ Do not reuse
 - ▶ Broken seal warning



How can you get involved?

- ▶ Association of Food and Drug Officials (AFDO)
- ▶ Body Art Education Alliance (BAEA)
- ▶ National Environmental Health Association (NEHA)



AFDO Body Art Committee

- ▶ Charges for the year:
 - ▶ Color Additive Petition for Titanium Dioxide for Intradermal Tattooing
 - ▶ Body Art Establishment Inspection Guide and Checklist
 - ▶ Tattoo Ink and PMU Sterilization Best Practices
 - ▶ System to assist in expeditious response to body art related public health risks
 - ▶ Guidance for Consumers
 - ▶ Agenda for 2020 AFDO AEC
- ▶ Phone call 2nd Thursday of the month
- ▶ Chairs:
 - ▶ KC Stevenson – kcstevenson@ceuticalabs.com
 - ▶ Laurel Arrigona – larrigona@ceuticalabs.com
 - ▶ Sarah Robbin – sarahrobbn1@gmail.com



Body Art Education Alliance

- ▶ Collaboration between AFDO, NEHA, APP, APT, SPCP, CTS, FDA, and other industry and regulatory groups
- ▶ Training modules for body art establishments and regulators
- ▶ Inspection Basics of Body Art Establishments
- ▶ Phone call 3rd Friday of every month
- ▶ Chairs:
 - ▶ KC Stevenson – kcstevenson@ceuticalabs.com
 - ▶ Laurel Arrigona – larrigona@ceuticalabs.com
 - ▶ Matt Bavougian – m.bavougian@gmail.com



Body Art Education Alliance

Established in 2018 by members of AFDO, NEHA, APP, APT, SPCP, CTS, FDA

Organizations Represented

AFDO	AFDOSS
NEHA	MCAFD0
APP	GEHA
APT	NEHA (Nebraska)
SPCP	CEHA (Colorado)
CTS	CEHA (California)
FDA	FEHA
WAFDO	MEHA (Montana)
MEHA (Missouri)	CCDEH BA TAC

States and Countries Represented

Alaska	Louisiana	Oregon
California	Michigan	Pennsylvania
Colorado	Minnesota	Texas
Connecticut	Missouri	Washington
Florida	Montana	West Virginia
Georgia	Nebraska	Wisconsin
Illinois	New Jersey	Canada
Iowa	New York	
Kansas	Ohio	



Questions and Concerns?

- ▶ Laurel Arrigona
- ▶ larrigona@ceuticallabs.com
- ▶ 972-241-8374
- ▶ Jodi Zimmerman
- ▶ jodzimmerman@elpasoco.com
- ▶ 719-433-3685

