

June 1, 2023

Food and Drug Administration (FDA) Public Meeting on Good Manufacturing Practices for
Cosmetic Products
Washington, DC

RE: NEHA response to request from FDA for Good Manufacturing Practices on tattooing inks and pigments

The National Environmental Health Association (NEHA) represents more than 7,000 governmental, private, academic, and uniformed services sector environmental health professionals in the U.S., its territories, and internationally. This workforce represents the second largest constituent of the existing public health workforce, second only to nursing. We are the profession's strongest advocate for excellence in the practice of environmental health as we deliver on our mission to build, sustain, and empower an effective environmental health workforce.

We first released the NEHA Body Art Model Code (BAMC) in 1998 to assist in the development of standardized regulations and inspection practices for body art facilities. An updated version of the BAMC was published in 2019 and another update is anticipated this year. The NEHA Body Art Committee oversees updates to the BAMC and is made up of both industry and regulatory professionals. The committee works to ensure that the BAMC reflects the current science and protects the health and safety of consumers and practitioners.

These comments reflect the thoughts of the NEHA Body Art Committee.

Body art is regulated by state, local, tribal, and territorial (SLTT) public health agencies, with regulation done primarily by local public health agencies. Approximately 20% to 30% of U.S. adults have at least one tattoo, necessitating a public health oversight by these local agencies over the body art profession.

The body art standards and regulations advanced by these agencies struggle to keep up with the growing popularity and evolving trends of the art of tattooing. The requirements to ensure safe tattooing vary greatly by each local agency, as does training and guidance. The lack of national public health guidance to promote safe tattooing, including safe inks, places the burden of safe tattooing on SLTT agencies.

FDA considers the inks used in tattoos as cosmetics and will respond to health and safety concerns; however, FDA commonly does not regulate the pigments in tattoo inks. FDA leaves the oversight of tattooing, as well as body art, to local public health agencies.

We surveyed SLTT agencies that regulate body art and the respondents noted that most tattooing regulations are outdated and more current standards and guidelines are needed. The

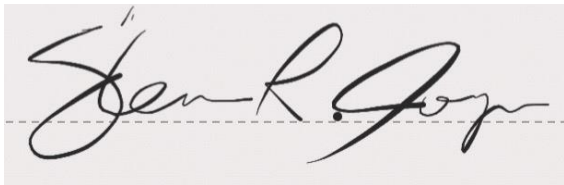
data show that updated and uniform guidelines—particularly related to inks and pigments—are essential to equip public health professionals with the tools and knowledge necessary to ensure tattooing operations remain safe.

Tattoo inks and pigments have been shown to include contaminants, heavy metals, degradants, potentially toxic chemicals (including pH stabilizers, microbicides, and coating agents), and other materials that are not intended to be placed into the body. Tattoo inks contain everything from pigments used in printer toner to pigments used in car paint.

FDA research on safe inks is needed to ensure that body art practitioners are using the safest, most effective practices involved in the art of tattooing. Both body art regulators and the profession operating body art facilities must be aware of and knowledgeable about changes to the industry, and regulations must reflect those changes. Body art is a rapidly growing industry. Research and guidance on inks and pigments, as well as on various tattooing procedures, enables body art practitioners to perform these activities safely and empowers environmental health professionals to regulate them effectively.

We support the development of cosmetic Good Manufacturing Practices guidance and regulations. We support FDA in this initiative and encourage FDA to work with the industry and associations such as NEHA to develop regulations that focus on protecting public health. Furthermore, we support additional research into the effects of tattoo inks and pigments on human health, as well as the practice of tattooing on public health.

In health,



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A handwritten signature in black ink, appearing to read "D. Dyjack". The signature is fluid and cursive, with a large initial "D" and a stylized "Dyjack" following.

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