

Insanitary Conditions and the Risk of Microbial Contamination in Tattoo Inks

October 31, 2024 Suzie Trigg, Kayla Cristales, Kristi Weisner

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Nearly one-third of Americans have at least one tattoo, but tattoos remain subject to a patchwork of local, state, and federal regulation that has historically failed to prevent consumer injuries from contaminated tattoo ink. After years of warning letters, safety alerts, and recalls citing microbial contamination in tattoo inks, in October 2024, FDA finalized its prior draft guidance titled [Insanitary Conditions in the Preparation, Packing, and Holding of Tattoo Inks and the Risk of Microbial Contamination](#) (the “**Guidance**”), to help tattoo ink manufacturers and distributors recognize and prevent insanitary conditions that may potentially render tattoo inks injurious to health.

How does the FDA regulate tattoo inks?

FDA regulates tattoo inks, as cosmetics under the Food, Drug & Cosmetic Act (FDCA) because they are “intended to be applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance.” However, FDA does not have the authority to regulate the practices of tattoo parlors or individual tattoo artists.

Why is the contamination of tattoo inks a concern for FDA?

After receiving multiple reports of adverse events caused by tattoo inks, FDA tested sealed tattoo inks in the United States and found many to be contaminated with microbes. As a result, in 2019, FDA alerted consumers, tattoo artists, and retailers to the potential for serious injury from contaminated tattoo ink and issued several related warning letters. There have also been 18 recalls of contaminated tattoo ink between 2003-2024.

Since tattoo inks are inserted below the epidermis, they bypass the body’s primary physical barrier against pathogens, which makes their potential for harm higher than that of topical cosmetics. As a result, contamination introduced into tattoo inks from insanitary conditions can cause serious infections and potentially life-threatening complications, especially in individuals who are immunocompromised or have other underlying medical conditions. For this reason, FDA’s aim in issuing the Guidance is to assist tattoo ink manufacturers and distributors in recognizing situations that may put their products at risk of adulteration that may be injurious to consumer health.

[Read the full article here.](#)