



In September 2019, the FDA sent warning letters to three tattoo ink manufacturers about microbial contamination in the products.

The agency conducted microbial analysis of tattoo ink samples collected from customers around the country. The warning letters noted that the tattoo inks contained pathogens and microorganisms that rendered them adulterated under the Federal Food Drug & Cosmetic Act (*FFDCA*). The agency regulates tattoo inks as "cosmetics" under the *FFDCA* because the inks are introduced into the body to "promot[e] attractiveness" or "alter[] the appearance." *See* 21 U.S.C. § 321(i). The FDA's letters expressed particular concern that the contaminated inks were to be injected under the epidermis and would bypass the "skin's ability to protect the body from microbiological infection and [therefore] increase[e] health risk to the recipient." Among other things, the warning letters noted that the pathogens and microorganisms found could cause serious skin infections and

endocarditis, an infection related to the heart's chambers. Similarly, at least one of the adulterated inks was also misbranded under the FFDCA because it was labeled "sterile." As the agency noted, "[p]roducts labeled as 'sterile' are expected to be free of viable microorganisms," so the presence of microorganisms in the products made the labeling false and misleading. The FDA's September 18, 2019 warning letters are available [here](#).

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