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TECHNICAL BULLETIN

DATE: February 2, 2024

TOPIC: Invasive Body Decoration, Serums for Healing

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TO: All Invasive Body Decoration Firms, Local Health Authorities

The U.S. Food and Drug Administration considers the inks used in intradermal tattoos, including permanent makeup, to be cosmetics. Under the federal Fair Labeling Act, as defined by section 201(i), and the Food, Drug and Cosmetic Act (the FD&C Act) 21 U.S.C. 321(i), the pigments used in the inks are considered color additives that are subject to premarket approval because they are articles intended to be introduced into or otherwise applied to the human body for beautifying, promoting attractiveness or altering the appearance.¹

Camouflage tattoo is also known as paramedical tattooing, which may include micropigmentation, MCA (multitrepennic collagen actuation), medical needling or inkless needling. In some instances, the process of camouflage tattoo uses a serum that reduce the appearance of stretch marks and increase collagen production which leads to improved skin color, texture and elasticity.

The application of serum products may involve procedures like microneedling. The attrition of the needle on the skin causes minor, controlled traumas in scars, which can stimulate the production of elastin, collagen, and cellular renewal in those areas. The inkless needling technique is similar to permanent makeup camouflage tattoos. However, instead of skin tone pigments on the skin, a mixture of serums, oils and vitamins is deposited in each stretch mark to help reduce their appearance.

The U.S. Food and Drug Administration Office of Cosmetics and Colors (OCAC), which regulates tattoo inks, indicates that serum products with claims on the label such as "skin healing, promotion of collagen production, maintaining elasticity of skin, and/or protecting treated areas" are not cosmetics. Because the intended purpose of these products is "use in the diagnosis, cure, mitigation, treatment or prevention of disease" and/or "intended to affect the structure of any function of the body of man," OCAC does not find such serum products to be cosmetic for the use of "cleansing, beautifying, promoting attractiveness, or altering the appearance" as defined under section 201(i) of the FDA & C Act.

Serum products like this one are generally used in microneedling treatments. "Microneedling" means the use of multiple small needles which are solid and designed to pierce the skin for the purpose of stimulating collagen production or cellular renewal ([Nevada Revised Statutes 644A.113](#)). Advanced Estheticians are licensed for this practice under the [Nevada State Board of Cosmetology \(NRS 664A.012\)](#).

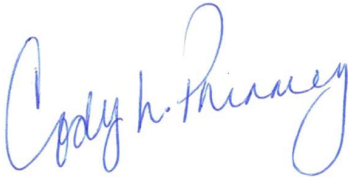
¹ [Draft Guidance for Industry](#)

The Division of Public and Behavioral Health, Environmental Health Section regulates “permanent makeup” and “tattoos,” as defined by [Nevada Administrative Code Chapter 444](#), which does not include the use of inkless serums.

Care should be taken to thoroughly review all ink and “inkless” products to ensure that the product is being used as it is intended and in compliance with state and federal law.

Questions

For updated guidance, review [the Division of Public and Behavioral Health Technical Bulletin web page regularly](#). Email ehscustomerservice@health.nv.gov for other questions regarding this topic.



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