

## Board AF-04

### Development of Methods for Safety Testing of Pigments Used for Tattooing, Including Permanent Make-Up

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It has been estimated 3% of the population in the US has tattoos. Although a large number of both inorganic and organic pigments are currently used for dermal implantation in tattoos, there are currently no pigments approved by the FDA for this use. A collaborative project between CFSAN and NCTR has recently been established to develop methods for testing the safety of tattoo pigments. Studies being conducted at CFSAN and NCTR focus on *in vitro* and *in vivo* methods to assess tattoo pigment safety. Investigators in CFSAN are applying *in vitro* screening methods for identifying cytotoxic and photocytotoxic tattoo pigments. Preliminary results from *in vitro* screening tests suggest that a small number of pigments currently marketed for tattooing are phototoxic. Studies being conducted at NCTR focus on the chemical composition and metabolism of tattoo pigments, as well as development of animal models for assessing the acute and long-term safety of pigments used in tattooing. Additionally, studies at NCTR will examine the effects of UV light on biological responses to tattoo pigments. The methods being developed at CFSAN and NCTR should provide a foundation for establishing tests for the safety of tattoo pigments.

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