## O7. UPDATE ON REGULATORY ACTIVITIES RELATED TO TATTOO INKS IN THE UNITED STATES (U.S.)

**Katherine Hollinger[1], Linda Katz[1], Nakissa Sadrieh[1]**

*[1]Food and Drug Administration, Cfsan Office of Cosmetics and Colors, College Park, Maryland, United States*

In the U.S. there is no pre-market approval of cosmetics or their ingredients, other than color additives. While state and local authorities oversee the practice of tattooing, inks and pigments used in tattoos are subject to U.S. Food and Drug Administration (FDA) oversight. Manufacturers must adequately demonstrate the safety of cosmetic products; however, safety data is not submitted to FDA prior to marketing. Adverse event reports (AERs) are reviewed and investigated, however, they often lack sufficient information including; the brand, name and lot of ink to track trends. As a result of five recalls since 2011, FDA has tested 75 inks from Internet sources, for microbiological contamination. Our work has focused on the evaluation of inks for aerobic microorganisms, non-tuberculous mycobacteria and endotoxin. However, we are also working toward the development of methods to characterize pigments, as well as the detection and quantification of potential contaminants, in tattoo pigments and inks. To increase awareness of the risks of infection associated with contaminated inks, we have developed outreach for consumers, tattooists and the industry. Outreach is intended to educate consumers to ask the tattooist for the names of the specific inks used in their body art, in the event they need to report an adverse event to improve the quality of reports. We continue to work with state and local governments and industry to share information.