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**U. S. Food and Drug Administration  
Center for Food Safety and Applied Nutrition  
Office of Cosmetics and Colors Fact Sheet  
November 29, 2000**

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## TATTOOS and PERMANENT MAKEUP

The inks used in tattoos and permanent makeup (also known as micropigmentation) and the pigments in these inks are subject to FDA regulation as cosmetics and color additives. However, FDA has not attempted to regulate the use of tattoo inks and the pigments used in them and does not control the actual practice of tattooing. Rather, such matters have been handled through local laws and by local jurisdictions.

But with the growth in popularity of tattooing and permanent makeup, FDA has begun taking a closer look at related safety questions. Among the issues under consideration are tattoo removal, adverse reactions to tattoo colors, and infections that result from tattooing.

Another concern is the increasing variety of pigments and diluents being used in tattooing -- more than fifty different pigments and shades, and the list continues to grow. Although a number of [color additives](#) are approved for use in cosmetics, none is approved for injection into the skin. Using an unapproved color additive in a tattoo ink makes the ink adulterated. Many pigments used in tattoo inks are not approved for skin contact at all. Some are industrial grade colors that are suitable for printers' ink or automobile paint.

Nevertheless, many individuals choose to undergo tattooing in its various forms. For some, it is an aesthetic choice or an initiation rite. Some choose permanent makeup as a time saver or because they have physical difficulty applying regular, temporary makeup. For others, tattooing is an adjunct to reconstructive surgery, particularly of the face or breast, to simulate natural pigmentation. People who have lost their eyebrows due to alopecia (a form of hair loss) may choose to have "eyebrows" tattooed on, while people with vitiligo (a lack of pigmentation in areas of the skin) may try tattooing to help camouflage the condition.

Whatever their reason, consumers should be aware of the risks involved in order to make an informed decision.

### What Risks Are Involved in Tattooing?

The following are the primary complications that can result from tattooing:

- **Infection.** Unsterile tattooing equipment and needles can transmit infectious diseases, such as hepatitis. The risk of infection is the reason the American Association of Blood Banks requires a one-year wait between getting a tattoo and donating blood.

It is extremely important to make sure that all tattooing equipment is clean and sterilized before use. Even if the needles are sterilized or never have been used, it is important to understand that in some cases the equipment that holds the needles cannot be sterilized reliably due to its design. In addition, the person who receives a tattoo must be sure to care for the tattooed area properly during the first week or so after the pigments are injected.

- **Removal problems.** Despite advances in laser technology, removing a tattoo is a painstaking process,

usually involving several treatments and considerable expense. Complete removal without scarring may be impossible. See "The Most Common Problem: Dissatisfaction" and "Removal Techniques," below.

- **Allergic reactions.** Although allergic reactions to tattoo pigments are rare, when they happen they may be particularly troublesome because the pigments can be hard to remove. Occasionally, people may develop an allergic reaction to tattoos they have had for years.
- **Granulomas.** These are nodules that may form around material that the body perceives as foreign, such as particles of tattoo pigment.
- **Keloid formation.** If you are prone to developing keloids -- scars that grow beyond normal boundaries -- you are at risk of keloid formation from a tattoo. Keloids may form any time you injure or traumatize your skin, and according to Office of Cosmetics and Colors (OCAC) dermatologist Ella Toombs, M.D., tattooing or micropigmentation is a form of trauma. *Micropigmentation: State of the Art*, a book written by Charles Zwerling, M.D., Annette Walker, R.N., and Norman Goldstein, M.D., states that keloids occur more frequently as a consequence of tattoo removal.
- **MRI complications.** There have been reports of people with tattoos or permanent makeup who experienced swelling or burning in the affected areas when they underwent magnetic resonance imaging (MRI). This seems to occur only rarely and apparently without lasting effects.

There also have been reports of tattoo pigments interfering with the quality of the image. This seems to occur mainly when a person with permanent eyeliner undergoes MRI of the eyes. Mascara may produce a similar effect. The difference is that mascara is easily removable.

The cause of these complications is uncertain. Some have theorized that they result from an interaction with the metallic components of some pigments.

However, the risks of avoiding an MRI when your doctor has recommended one are likely to be much greater than the risks of complications from an interaction between the MRI and tattoo or permanent makeup. Instead of avoiding an MRI, individuals who have tattoos or permanent makeup should inform the radiologist or technician of this fact in order to take appropriate precautions, avoid complications, and assure the best results.

## The Most Common Problem: Dissatisfaction

According to Dr. Toombs, the most common problem that develops with tattoos is the desire to remove them. Removing tattoos and permanent makeup can be very difficult.

Skill levels vary widely among people who perform tattooing. According to an article by J.K. Chiang, S. Barsky, and D.M. Bronson in the June 1999 issue of the *Journal of the American Academy of Dermatology*, the main complication with eyelid tattooing is improperly placed pigment. You may want to ask the person performing the procedure for references and ask yourself how willing you are to risk permanently wearing someone else's mistake.

Although tattoos may be satisfactory at first, they sometimes fade. Also, if the tattooist injects the pigments too deeply into the skin, the pigments may migrate beyond the original sites, resulting in a blurred appearance.

Another cause of dissatisfaction is that the human body changes over time, and styles change with the season. The permanent makeup that may have looked flattering when first injected may later clash with changing skin tones and facial or body contours. People who plan to have facial cosmetic surgery are advised that the appearance of their

permanent makeup may become distorted. The tattoo that seemed stylish at first may become dated and embarrassing. And changing tattoos or permanent makeup is not as easy as changing your mind.

## Removal Techniques

Methods for removing tattoos include laser treatments, abrasion, scarification, and surgery. Some people attempt to camouflage an objectionable tattoo with a new one. Each approach has drawbacks:

- **Laser treatments** can lighten many tattoos, some more easily and effectively than others. Generally, several visits are necessary over a span of weeks or months, and the treatments can be expensive. Some individuals experience hypopigmentation -- a lightening of the natural skin coloring -- in the affected area. Laser treatments also can cause some tattoo pigments to change to a less desirable shade.

Unfortunately, knowing what pigments are in your tattoo or permanent makeup has always been difficult and has become more so as the variety of tattoo inks has multiplied. Inks are often sold by brand name only, not by chemical composition. Because the pigments are sold to tattoo parlors and salons, not on a retail basis to consumers, manufacturers are not required by law to list the ingredients on the labels. Furthermore, because manufacturers may consider the identity and grade of their pigments "proprietary," neither the tattooist nor the customer may be able to obtain this information.

There also have been reports of individuals suffering allergic reactions after laser treatments to remove tattoos, apparently because the laser caused allergenic substances in the tattoo ink to be released into the body.

- **Dermabrasion** involves abrading layers of skin with a wire brush or diamond fraise (a type of sanding disc). This process itself may leave a scar.
- **Salabrasion**, in which a salt solution is used to remove the pigment, is sometimes used in conjunction with dermabrasion, but has become less common.
- **Scarification** involves removing the tattoo with an acid solution and creating a scar in its place.
- **Surgical removal** sometimes involves the use of tissue expanders (balloons inserted under the skin, so that when the tattoo is cut away, there is less scarring). Larger tattoos may require repeated surgery for complete removal.
- **Camouflaging** a tattoo entails the injection of new pigments either to form a new pattern or cover a tattoo with skin-toned pigments. Dr. Toombs notes, however, that injected pigments tend not to look natural because they lack the skin's natural translucence.

## What About Temporary Tattoos?

Temporary tattoos, such as those applied to the skin with a moistened wad of cotton, fade several days after application. Most contain color additives approved for cosmetic use on the skin. However, the agency has issued an [import alert for several foreign-made temporary tattoos](#).

According to OCAC Consumer Safety Officer Allen Halper, the temporary tattoos subject to the import alert are not allowed into the United States because they don't carry the FDA-mandated ingredient labels or they contain colors not permitted by FDA for use in cosmetics applied to the skin. FDA has received reports of allergic reactions

to temporary tattoos.

In a similar action, FDA has issued an [import alert for henna intended for use on the skin](#). Henna is approved only for use as a hair dye, not for direct application to the skin. Also, henna typically produces a reddish brown tint, raising questions about what ingredients are added to produce the varieties of colors labeled as "henna," such as "black henna" and "blue henna."

## Reporting Adverse Reactions

FDA urges consumers and healthcare providers to report adverse reactions to tattoos and permanent makeup, problems with removal, or adverse reactions to temporary tattoos. The agency operates the **Cosmetics Adverse Reaction Monitoring (CARM)** system to monitor problems consumers experience with cosmetic products and ingredients, including color additives. Consumers and healthcare providers can register complaints by contacting their FDA district office (see the blue pages of your local phone directory) or by sending written reports of adverse reactions to:

Office of Cosmetics and Colors  
HFS-106  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740-3835

You also can contact CARM by telephone at (202) 401-9725.

In addition, healthcare professionals and consumers may submit information about adverse events to MedWatch, the FDA Medical Products Reporting Program, as follows:

- **By mail:** Use the postage-paid MedWatch Form ([PDF format](#))
- **By phone:** 1-800-FDA-1088
- **By fax:** 1-800-FDA-0178
- **By Internet:** [MedWatch](#)

Consumers may obtain MedWatch reporting forms by calling the following FDA toll-free number: (888) 463-6332 [888-INFO-FDA]

For more information, see [Temporary Tattoos and Henna/Mehndi](#) and [FDA's Import Alert on Tattoo Removers](#)

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