

# KELLER AND HECKMAN LLP

*Serving Business through Law and Science®*

1001 G STREET, N.W.  
SUITE 500 WEST  
WASHINGTON, D.C. 20001  
TELEPHONE 202.434.4100  
FACSIMILE 202.434.4646  
WWW.KHLAW.COM

## KELLER AND HECKMAN LLP MEMORANDUM

Via Email

**TO:** Health Professionals

**March 16, 2005**

**FROM:** Frederick A. Stearns, Esq.

**(202) 434-4288**  
**stearns@khlaw.com**

**RE:** Use of Topical Anesthetics in Permanent Cosmetic Procedures

---

---

An issue that arises surprisingly often is, “What topical anesthetics are ‘approved’ for use in permanent cosmetic procedures?” As you probably know, however, this is a trick question - there are no over-the-counter (OTC) topical anesthetic drug products authorized to be labeled for use specifically in connection with permanent makeup and tattoo procedures.

The Food and Drug Administration (FDA) does not formally “approve” the vast majority of OTC drug products. Instead, topical anesthetics for OTC use are governed by two “monographs” (essentially regulations) established by FDA. One of these monographs is in final form; the other is not yet final but serves as a guide to industry (at this stage it is known as a “tentative final monograph” (TFM)).

These monographs identify the active ingredients that may be used in the products and establish specific labeling requirements. The two anesthetic monographs establish identical permitted concentration for several of the same active ingredients, including benzocaine, dibucaine, dibucaine HCl, and dyclonine HCl. In other cases, however, the monographs have different permitted dosage levels even though the same ingredients are allowed. Ingredients with different acceptable levels include benzyl alcohol, lidocaine, tetracaine, and tetracaine HCl. Compliance with the terms of an applicable monograph allows a party to market an OTC drug without seeking review by or authorization from FDA.<sup>1</sup>

While FDA regulates product formulation and labeling, the Agency does not oversee the end-use of a specific OTC product. Users of OTC drugs (whether health care professionals or the general public) necessarily take on (and presumably accept) the obligation of making appropriate use decisions.

---

<sup>1</sup> “Manufacturers desiring to market an OTC drug covered by an OTC drug monograph need not seek FDA clearance before marketing.” 67 *Fed. Reg.* 3060, 3060 (January 23, 2002).

Health Professionals  
March 16, 2005  
Page 2

Despite the absence of specific labeling for permanent makeup use, FDA is clearly aware that topical anesthetics are used during these procedures. For example, in an article that first appeared in April 1993 (and which remains valid today), the Agency noted the following:

Introduced to this country from the Orient more than 10 years ago, permanent eyelining is now offered in many beauty salons. Using disposable needles, pigment is implanted into the skin at the base of the upper or lower eyelashes. The pigments used are derived from vegetable products. A local anesthetic is often given to relieve pain during the tattooing, which takes from 20 minutes to an hour. Some swelling may follow the procedure. Scabs that form in the treated area fall off within a week. [Underlining added.]<sup>2</sup>

This statement is consistent with the view that product end-users are entitled to make, and are responsible for, their own decisions about the proper use of OTC drug products.

\* \* \*

**NOTE:** This document is intended for information purposes only and is not offered as, and does not constitute, legal advice for particularized facts. Counsel should be consulted for advice on specific compliance issues.

---

<sup>2</sup> FDA, "Hair Dye Dilemmas" (*see* the discussion under the heading "Permanent Eyeliner" near the end), available at: <http://www.cfsan.fda.gov/~dms/cos-818.html>. (The original text is available at: <http://www.fda.gov/bbs/topics/CONSUMER/CON00205.html>.) (last accessed March 15, 2005).