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1:00 pm - 3:00 pm

# Tattoo Ink Labeling

ASSOCIATION OF FOOD AND DRUG OFFICIALS

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# Why Label Tattoo Ink?

- ▶ Tattoo ink is by law classified as a cosmetic. Under the FD&C Act cosmetics that are offered for sale in interstate commerce must be labelled
- ▶ Proper labeling helps consumers make informed decisions
- ▶ Helps public health officials investigate outbreaks

# Costs of Improper Labeling

- ▶ Considerable increase to cost of recalling contaminated tattoo ink
- ▶ Product may be confused with another suppliers product
- ▶ Product could be pulled from market by regulatory authorities

# What is Interstate Commerce

- ▶ Tattoo inks that are sold across state lines, and
- ▶ Tattoo inks that contain ingredients that have been sold across state lines
- ▶ The only way to avoid “interstate commerce” designation is to manufacture ink that contains only ingredients that originated within a specific state or territory and only offer that ink for sale within the same state.
- ▶ Essentially all tattoo inks are in “interstate commerce”

# Retail Sales vs. Professional Use

- ▶ Tattoo ink that is sold to retail customers is required to meet all of the requirements for cosmetic labeling provided for under the FD&C Act, including an ingredient statement.
- ▶ Tattoo ink that is sold to professional tattoo artist solely for use by the artist are exempt from including an ingredient statement. However, all other labeling requirements must be complied with. (Fair Packaging and Labeling Act)

# State and Local Health Authority

- ▶ State and local health authorities may enforce federal standards and they may also adopt additional labeling requirements (example California prop 65)
- ▶ Federal action not required for states or local government to take action.
- ▶ States may adopt laws in addition to Federal

# Resources for Tattoo Ink Labeling

- ▶ FDA's Cosmetic Labeling Guide (<http://www.fda.gov/Cosmetics/Labeling/Regulations/ucm126444.htm>)
  - ▶ Everything you need to know about labeling

# Key elements of a Tattoo Ink Label

- ▶ The common or usual name must be on label
  - ▶ “Tattoo Ink” is an acceptable name
  - ▶ Just having the brand name without a description of the product is not acceptable
  - ▶ “Old Black Cat” without “tattoo Ink” is not acceptable
- ▶ The net quantity in Fluid Ounces must be visible and parallel to the bottom of container.



# Key Elements (continued)

- ▶ Manufacturer, Packer or Distributor?
  - ▶ Consumers must be able to identify and communicate with at least one of the three.
  - ▶ A web address by itself is not acceptable
- ▶ Country of origin must be declared on the label for imported tattoo ink

# Key Elements (continued)

- ▶ Adequate directions for safe use must be included in labeling (examples)
  - ▶ Sterilized Ink intended for single use should state “not to be reused – discard any leftover ink” and “Dilute with sterile liquids only”
  - ▶ Ink in reusable bottles should state “Sterilize before use and after diluting with any liquid”

# English Only

- ▶ All labeling must be in English
- ▶ In Puerto Rico labels may also be in Spanish, but English is acceptable.
- ▶ If any foreign language is on a label, including Asian characters, all required language must be present in that language and in English.

# Professional Use Labeling

- ▶ Must state “for professional use only”
- ▶ Common or usual name “tattoo ink” must be on the principle display panel
- ▶ Net weight must be on the principle display panel
- ▶ Directions for safe use must be on the label
- ▶ Cannot sell professional use product in a retail environment unless ingredient statement is included

# Lot/Batch Numbering

- ▶ Federal laws do not require identification of a lot or batch
- ▶ If a container does not contain a lot or batch identification then the entire production of that product would be considered to be a lot.
- ▶ In a recall involving a specific tattoo ink the entire lot would be subject to recall

# Lot/Batch Numbering (continued)

- ▶ Identifying by batch will allow linking adverse event records to specific batches thereby improving investigation of AE's
- ▶ It is advisable to limit the size of lots by assigning a batch code on a routine basis

# Date Coding

- ▶ Date coding, use by dates, etc. are not required under Federal law
- ▶ They can serve as a batch ID
- ▶ Use by date is recommended if the product deteriorates over time creating a possible safety issue.
- ▶ Stability testing is recommended to establish use by dates.
- ▶ Use by date will decrease the fraudulent use of used containers by scrupulous individuals.

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- ▶ Acknowledgments
  - ▶ Questions
  - ▶ Discussion