

# The Regulation of Cosmetics

Food Law

# FDCA Definition

- Articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body...for cleansing, beautifying, promoting attractiveness, or altering the appearance."

# FDCA Definition

- Included in this definition are products such as skin moisturizers, perfumes, lipsticks, fingernail polishes, eye and facial makeup preparations, shampoos, permanent waves, hair colors, toothpastes, and deodorants, as well as any material intended for use as a component of a cosmetic product

# Cosmetic Regulation

- FDA is only able to regulate cosmetics after products are released to the marketplace
- No cosmetic products or cosmetic ingredients are reviewed or approved by FDA before they are sold to the public

# Animal Testing

- Law does not specifically mandate animal testing for cosmetic safety
- FDA strongly urges cosmetic manufacturers to conduct whatever tests are appropriate to establish that their cosmetics are safe
- FDA believes that the use of animals remains necessary to ensure the safety of cosmetic ingredients and products.

# Cosmetics

- FDA cannot require companies to do safety testing of their cosmetic products before marketing
- If the safety of a cosmetic product has not been substantiated, the product's label must read:

*WARNING: The safety of this product has not been determined."*

# Cosmetics

- FDA does not have the authority to require manufacturers to register their cosmetic establishments, file data on ingredients, or report cosmetic-related injuries
- FDA maintains a voluntary data collection program
- Companies that wish to participate in the program forward data to FDA.

# Cosmetic Recalls

- FDA is not permitted to require recalls of cosmetics but does monitor companies that conduct a product recall
- If FDA wishes to remove a cosmetic product from the market, it must first prove in a court of law that the product may be injurious to users, improperly labeled, or otherwise violates the law

# Cosmetics

- FDA collects cosmetic product samples as part of its plant inspections, import inspections, and complaints of adverse reactions
- FDA acts through the **Department of Justice** to remove adulterated and misbranded cosmetics from the market
- **Domestic and foreign manufacturers must follow the same regulations**

# Labeling Cosmetics

- Regulations require ingredients to be listed on product labels in descending order by quantity
- Based on the amount used, an ingredient such as water is usually found at the beginning of the product's ingredient listing
- **Color additives** and fragrances, used in small amounts, are normally seen at the end of the ingredient listing.

# Labeling Cosmetics

- Cosmetic ingredient declaration regulations apply only to retail products intended for **home use**
- Products used exclusively by beauticians in beauty salons and labeled **“For Professional Use Only”**
- **Cosmetic samples** are not required to include the ingredient declaration. Must state the distributor, list the content's quantity, and include all necessary warning statements.

# Labeling Cosmetics

- FDA regulates only the labeling that appears on cosmetic products themselves
- Unfair and deceptive advertising that appears in magazines, in newspapers, or on television falls under the authority of the **Federal Trade Commission**

# "Puffery"

- Promotion of "gimmick" additives, combined with more sophisticated cosmetic ingredients
- Lotion contained bovine albumin and the label claimed it would give a "face lift without surgery
- Exaggerated claims of beauty or long-lasting effects

# “Puffery”

- Product claims should be based on skin care realities, promises banked on achievable benefits
- In the past, cosmetic manufacturers have depended upon mysterious **gimmick additives**, such as turtle oil to promote skin rejuvenation or tighten chin muscles, shark oil, queen bee royal jelly, chick embryo extract, horse blood serum, and pigskin extracts.

# "Puffery"

- Cosmetic claims, even those considered "puffery," are allowed **without scientific substantiation**
- But if a cosmetic makes a medical claim, such as removing dandruff, the product is regulated as a **drug** for which scientific studies demonstrating safety and efficacy must be submitted

# “Alcohol Free”

- In cosmetic labeling, the term “alcohol”, used by itself, refers to ethyl alcohol
- To prevent the ethyl alcohol in a cosmetic from being diverted illegally for use as an alcoholic beverage, it must contain an added “denaturant” that makes it undrinkable
- Cosmetic manufacturers market cosmetic products that do not contain ethyl alcohol as “alcohol free”

# “Hypoallergenic”

- Manufacturers claim produce fewer allergic reactions than other cosmetic product
- No regulations that govern the use of the term “hypoallergenic”
- Term means whatever a particular company wants it to mean
- Cosmetics labeled as hypoallergenic are not required to submit substantiation of their hypoallergenicity claims to FDA

# Cosemeceuticals

- *Products that are cosmetics but are also intended to treat or prevent disease, or affect the structure or functions of the human body*
- Considered to be drugs and must comply with **both** the drug and cosmetic provisions of the law
- Fluoride toothpaste, hormone creams, sun tanning preparations, antiperspirants that are also deodorants, and antidandruff shampoos.

# Summary

- FDA does not pre-approve cosmetic products or ingredients, with the important exception of color additives
- Cosmetic firms are responsible for marketing safe, properly labeled products; using no prohibited ingredients; and adhering to limits on restricted ingredients
- Considered good practice to follow industry safety guidelines and recommendations.

# Summary

- Must carry warning if safety not determined but can still market product
- FDA must “go to court” to remove a cosmetic from the market
- Different labeling requirements for different markets
  - *Does not include all labeling*
  - *FTC regulates ads (unfair and deceptive)*
- Puffery is OK