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1. Is it a Cosmetic, a Drug, or Both?

Products that beautify and cleanse are generally regulated as cosmetics, while products that are used or intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, or that affect the structure or any function of the body are drugs.

Some products can be both cosmetics and drugs. These products must meet the requirements for both cosmetics and drugs:

- Anti-Dandruff Shampoo
- Toothpaste
- Sunscreen
- Makeup with SPF (Sun Protection Factor) numbers

California Health and Safety Code (CA H&S), Section 109900 defines cosmetics as:

- Any article, or its components, intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to, the human body, or any part of the human body, for cleansing, beautifying, promoting attractiveness, or altering the appearance. The term “cosmetic” does not include soap.

CA H&S Section 109925 defines a drug as:

- Any of the following:
 - a) Any article recognized in an official compendium.
 - b) Any article used or intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or any other animal.
 - c) Any article other than food, that is used or intended to affect the structure or any function of the body of human beings or any other animal.
 - d) Any article used or intended for use as a component of any article designated in subdivision (a), (b), or (c) of this section.

The term “drug” does not include any device.

- Businesses are considered manufacturers pursuant to CA H&S 109970 if they are engaged in the preparation, compounding, propagation, processing, or fabrication of any food, drug, device, or cosmetic. The term “manufacture” includes repackaging or otherwise changing the container, wrapper, or labeling of any food, drug, device, or cosmetic in furtherance of the distribution of the food,

drug, device, or cosmetic. The term “manufacture” does not include repackaging from a bulk container by a retailer at the time of sale to its ultimate consumer.

2. How does the California Department of Public Health (CDPH), Food and Drug Branch (FDB) regulate cosmetic products?

Although registration with the Department as a cosmetic manufacturer is voluntary, the Department’s authority over cosmetics is similar to other products we regulate, such as drugs and medical devices. Under state and federal law, cosmetics must not be “adulterated” or “misbranded.” Cosmetics must be safe for consumers when used as directed in their labeling and must be properly labeled.

Cosmetics could be considered adulterated if,

- CA H&S 111670 – it bears or contains any poisonous or deleterious substance that may render it injurious to users under the conditions of use prescribed in the labeling or advertisement of the cosmetic, or under conditions of use as are customary or usual.
- CA H&S 111680 – it consists in whole or in part of any filthy, putrid, or decomposed substance.
- CA H&S 111685 – it has been produced, prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.
- CA H&S 111690 – its container is composed, in whole or in part, of any poisonous or deleterious substance that may render the contents injurious to health.

Cosmetics could be considered misbranded if,

- CA H&S 111730 – its labeling is false or misleading in any particular.
- CA H&S 111735 – its labeling or packaging does not conform to the requirements of Chapter 4 (commencing with Section 110290).
- CA H&S 111740 – it is in package form and it does not bear a label containing all of the following information:
 - a) The name and place of business of the manufacturer, packer, or distributor.
 - b) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count.

The Department can take action against any cosmetic marketed in California if there is evidence that it is adulterated or misbranded.

The Department may also, pursuant to CA H&S Section 110140, inspect any factory, warehouse, or establishment in which any cosmetic is manufactured, packed, or held; enter any vehicle that is being used to transport or hold the cosmetic; or enter any place

where any cosmetic is suspected of being held in violation of state law for purposes of enforcement of this part. Such inspections will be conducted at a reasonable time and staff will always present credentials at the onset of the inspection.

3. What should I do if I have an adverse reaction to a cosmetic product?

You should consult with your health care provider, the cosmetic manufacturer, and the California Department of Public Health, Food and Drug Branch. The Department's consumer complaint line is 1-800-495-3232.