

21 U.S. Code § 364

Definitions

In this subchapter:

(1) Adverse event

The term “adverse event” means any health-related event associated with the use of a cosmetic product that is adverse.

(2) Cosmetic product

The term “cosmetic product” means a preparation of cosmetic ingredients with a qualitatively and quantitatively set composition for use in a finished product.

(3) Facility

(A) In general.—

The term “facility” includes any establishment (including an establishment of an importer) that manufactures or processes cosmetic products distributed in the United States.

(B) Such term does not include any of the following:

- (i) Beauty shops and salons, unless such establishment manufactures or processes cosmetic products at that location.
- (ii) Cosmetic product retailers, including individual sales representatives, direct sellers (as defined in section 3508(b)(2) of title 26), retail distribution facilities, and pharmacies, unless such establishment manufactures or processes cosmetic products that are not sold directly to consumers at that location.
- (iii) Hospitals, physicians’ offices, and health care clinics.
- (iv) Public health agencies and other nonprofit entities that provide cosmetic products directly to the consumer.
- (v) Entities (such as hotels and airlines) that provide complimentary cosmetic products to customers incidental to other services.
- (vi) Trade shows and other venues where cosmetic product samples are provided free of charge.
- (vii) An establishment that manufactures or processes cosmetic products that are solely for use in research or evaluation, including for production testing and not offered for retail sale.
- (viii) An establishment that solely performs one or more of the following with respect to cosmetic products:
 - (I) Labeling.
 - (II) Relabeling.
 - (III) Packaging.
 - (IV) Repackaging.

(V) Holding.

(VI) Distributing.

(C)Clarification.—

For the purposes of subparagraph (B)(viii), the terms “packaging” and “repackaging” do not include filling a product container with a cosmetic product.

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