
This content is from the eCFR and is authoritative but unofficial.

Title 21 —Food and Drugs

Chapter I —Food and Drug Administration, Department of Health and Human Services

Subchapter G —Cosmetics

Part 700 —General

Authority: 21 U.S.C. 321, 331, 352, 355, 361, 362, 371, 374.

Source: 39 FR 10054, Mar. 15, 1974, unless otherwise noted.

Subpart A General Provisions

§ 700.3 Definitions.

Subpart A—General Provisions

§ 700.3 Definitions.

As used in this subchapter:

- (a) The term *act* means the Federal Food, Drug, and Cosmetic Act.
- (b) The term *cosmetic product* means a finished cosmetic the manufacture of which has been completed. Any cosmetic product which is also a drug or device or component thereof is also subject to the requirements of Chapter V of the act.
- (c) The term *flavor* means any natural or synthetic substance or substances used solely to impart a taste to a cosmetic product.
- (d) The term *fragrance* means any natural or synthetic substance or substances used solely to impart an odor to a cosmetic product.
- (e) The term *ingredient* means any single chemical entity or mixture used as a component in the manufacture of a cosmetic product.
- (f) The term *proprietary ingredient* means any cosmetic product ingredient whose name, composition, or manufacturing process is protected from competition by secrecy, patent, or copyright.
- (g) The term *chemical description* means a concise definition of the chemical composition using standard chemical nomenclature so that the chemical structure or structures of the components of the ingredient would be clear to a practicing chemist. When the composition cannot be described chemically, the substance shall be described in terms of its source and processing.
- (h) The term *cosmetic raw material* means any ingredient, including an ingredient that is a mixture, which is used in the manufacture of a cosmetic product for commercial distribution and is supplied to a cosmetic product manufacturer, packer, or distributor by a cosmetic raw material manufacturer or supplier.
- (i) The term *commercial distribution* of a cosmetic product means annual gross sales in excess of \$1,000 for that product.
- (j) ***Establishment*** means a place of business where cosmetic products are manufactured or packaged.

- (k) The term *manufacture* of a cosmetic product means the making of any cosmetic product by chemical, physical, biological, or other procedures, including manipulation, sampling, testing, or control procedures applied to the product.
- (l) The term *packaging* of a cosmetic product means filling or labeling the product container, including changing the immediate container or label (but excluding changing other labeling) at any point in the distribution of the cosmetic product from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer.
- (m) The term *all business trading names used by the establishment* means any name which is used on a cosmetic product label and owned by the cosmetic product manufacturer or packer, but is different from the principal name under which the cosmetic product manufacturer or packer is registered.
- (n) The definitions and interpretations contained in sections 201, 601, and 602 of the act shall be applicable to such terms when used in the regulations in this subchapter.
- (o) **System of commercial distribution** of a cosmetic product means any distribution outside the establishment manufacturing the product, whether for sale, to promote future sales (including free samples of the product), or to gage consumer acceptance through market testing, in excess of \$1,000 in cost of goods.
- (p) **Filed screening procedure** means a procedure that is:
 - (1) On file with the Food and Drug Administration and subject to public inspection;
 - (2) Designed to determine that there is a reasonable basis for concluding that an alleged injury did not occur in conjunction with the use of the cosmetic product; and
 - (3) Which is subject, upon request by the Food and Drug Administration, to an audit conducted by the Food and Drug Administration at reasonable times and, where an audit is conducted, such audit shows that the procedure is consistently being applied and that the procedure is not disregarding reportable information.
- (q) **Reportable experience** means an experience involving any allergic reaction, or other bodily injury, alleged to be the result of the use of a cosmetic product under the conditions of use prescribed in the labeling of the product, under such conditions of use as are customary or reasonably foreseeable for the product or under conditions of misuse, that has been reported to the manufacturer, packer, or distributor of the product by the affected person or any other person having factual knowledge of the incident, other than an alleged experience which has been determined to be unfounded or spurious when evaluated by a filed screening procedure.

[39 FR 10054, Mar. 15, 1974, as amended at 46 FR 38073, July 24, 1981]