



## Cosmetics Regulatory Requirements in US

**Cosmetics 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; except that such term shall not include soap.

### Product Classification:

- Products intended to cleanse or beautify are generally regulated as cosmetics. Some examples are skin moisturizers, perfumes, lipsticks, fingernail polishes, makeup, shampoos, permanent waves, hair colors, toothpastes, and deodorants.
- Products intended to treat or prevent disease, or affect the structure or function of the body, are drugs. This is true even if a product affects how you look. Some examples are treatments for dandruff or acne, sunscreen products, antiperspirants, and diaper ointments.
- Some are both cosmetics and drugs. Examples include anti-dandruff shampoos and antiperspirant-deodorants, as well as moisturizers and makeup with SPF (sun protection factor) numbers. They must meet the requirements for both cosmetics and drugs.

**Regulatory Authority:** Food and Drug Administration (FDA) ; Office of Cosmetic and Colors (OCC)



## Compliance Requirements:

- **Cosmetics:** Facility registration and product listing are required. FDA has ended its VCRP, while launching the new electronic submission portal Cosmetics Directive available in December 2023.
- **Drug and products regulated as "cosmetics-drugs" :** If strictly complies with the requirements in the OTC monograph regarding active ingredients, labeling, etc., it does not require specific FDA approval. An OTC drug product with active ingredient(s), dosage form, dosage strength, or route of administration new to the OTC marketplace is regulated under the new drug application (NDA) process.

## Post-market Surveillance:

- **FDA regulatory inspections:** Focused on "information standards" and "post-market enforcement", with an emphasis on "adulterated" and "misbranded".
- **Reporting of adverse reactions.**

## Compliance Step 1: Facility Registration

**1) Registration Subjects:** The owner or operator of the facility

### 2) Registration Dossier Requirements:

- The name of the owner and/or operator of the facility ;
- The facility's name, physical address, email address, and telephone number ;
- with respect to any foreign facility, the contact for the United States agent of the facility (name and phone number), and, if available, the electronic contact information (email) ;
- The facility registration number, if any, previously assigned;
- All brand names under which cosmetic products manufactured or processed in the facility are sold;
- The product category or categories and responsible person for each cosmetic product manufactured or processed at the facility;
- Type of submission (initial, amended, biennial renewal, or abbreviated renewal);
- The following additional optional information be submitted: parent company name, facility DUNS Number and additional contact information for individuals associated with the registration.

### 3) Facility registration is not available to the following locations:

- Beauty shops and salons, unless such establishment manufactures or processes cosmetic products at that location;
- Cosmetic product retailers, including individual sales representatives, direct sellers, retail distribution facilities, and pharmacies, unless such establishment manufactures or processes cosmetic products that are not sold directly to consumers at that location;
- Hospitals, physicians' offices, and health care clinics ;
- Public health agencies and other nonprofit entities that provide cosmetic products directly to the consumer;
- Entities (such as hotels and airlines) that provide complimentary cosmetic products to customers incidental to other services;
- Trade shows and other venues where cosmetic product samples are provided free of charge;
- 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;
- An establishment that solely performs one or more of the following with respect to cosmetic products: Labeling, Relabeling, Packaging, Repackaging, Holding and Distributing.

## Compliance Step 2: Product Listing

### 1) Registration Subjects: Responsible Person of Products\*

**Responsible Person:** The manufacturer, packer, or distributor of a cosmetic product whose name appears on the label of the cosmetic product.

### 2) Registration Dossier Requirements :

- The facility registration number FEI of each facility where the cosmetic product is manufactured or processed. If the facility is exempt from registration and does not have an FEI number, the company name and address be provided;
- The name and contact number of the responsible person and the name for the cosmetic product, as such name appears on the label;
- The applicable cosmetic category or categories for the cosmetic product;
- A list of ingredients in the cosmetic product, including any fragrances, flavors, or colors
- The product listing number, if any previously assigned;
- Type of submission (initial, update to content (annual), abbreviated renewal)
- The following additional optional information be submitted, including parent company name; type of business (as listed on the label), i.e., manufacturer, packer, or distributor; image of the label; product webpage link; whether the cosmetic product is for professional use only; responsible person DUNS Number for address listed on product label; Unique Ingredient Identifiers (UNIs); additional contact information for individuals associated with the listing.

**Note:** A single listing submission for a cosmetic product may include multiple cosmetic products with identical formulations, or formulations that differ only with respect to colors, fragrances or flavors, or quantity of contents.

|                            | Facility Registration                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Product Listing                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|----------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Registration /Listing date | <ul style="list-style-type: none"> <li>● <b>Initial Registration</b><br/>Every person that, on December 29, 2022, owns or operates a facility that engages in the manufacturing or processing of a cosmetic product for distribution in the United States must register each facility no later than July 1, 2024.<br/>Every person that owns or operates a facility that first engages, after December 29, 2022, in manufacturing or processing of a cosmetic product for distribution in the United States, must register such facility within 60 days of engaging in such activity for first time or by July 1, 2024, whichever is later.</li> <li>● <b>Amended Registration</b><br/>Every person who is required to register must update their registration within 60 days of any changes to the information required for registration.</li> <li>● <b>Renewal of Registration</b><br/>Every person who is required to register a facility must renew such registration biennially. FDA is providing for an abbreviated renewal of registrations when there have not been any updates to the registration.</li> </ul> | <ul style="list-style-type: none"> <li>● <b>Initial Listing</b><br/>The responsible person of a cosmetic product that is marketed on December 29, 2022, must submit a cosmetic product listing not later than July 1, 2024.<br/>The product listing for a cosmetic product first marketed after December 29, 2022 to be submitted within 120 days of marketing the product, or by July 1, 2024, whichever is later.</li> <li>● <b>Update to Content and Renewal</b><br/>The responsible person must provide any updates to such listing annually, including an update that the product was discontinued.</li> </ul> |

|                                      | Facility Registration                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Product Listing                                                                                                                                                                                                                                                   |
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| Exempt from registration and listing | <ul style="list-style-type: none"> <li>● Complying with small business requirements* (excluding the businesses engaged in the manufacturing or processing of the following products)               <ul style="list-style-type: none"> <li>a) Cosmetic products that regularly come into contact with mucus membrane of the eye under conditions of use that are customary or usual;</li> <li>b) Cosmetic products that are injected;</li> <li>c) Cosmetic products that are intended for internal use;</li> <li>d) Cosmetic products that are intended to alter appearance for more than 24 hours under conditions of use that are customary or usual and removal by the consumer is not part of such conditions of use that are customary or usual</li> </ul> </li> </ul> |                                                                                                                                                                                                                                                                   |
|                                      | <ul style="list-style-type: none"> <li>● The facility complying with drugs or devices management requirements (Excluding the facility that also manufacture products intended solely for cosmetic)</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <ul style="list-style-type: none"> <li>● The cosmetic product that is also subject to the requirements in chapter V of the FD&amp;C Act (for drugs and devices). For example, the product is both a drug and a cosmetic product under the FD&amp;C Act</li> </ul> |
|                                      | <p><b>Small Business:</b> As defined in section 612 of the FD&amp;C Act, means responsible persons, and owners and operators of facilities, whose average gross annual sales in the U.S. of cosmetic products for the previous 3-year period is less than \$1,000,000, adjusted for inflation.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                   |

## ↘ The United States agent

- Assisting FDA in communications with the foreign establishment, responsible for communication regarding emergencies and daily affairs;
- Responsible for receiving FDA documents or information;
- Assisting FDA in scheduling inspections of the foreign establishment;
- No responsibility related to reporting of adverse events

## ↘ Our services:

- The United States agent
- The United States FDA Cosmetic Facility Registration
- The United States FDA Cosmetic Product Listing
- The United States FDA OTC Drug Registration
- The United States Color Additive Batch Certification
- The United States Cosmetic/OTC Drug Label Review
- International Cosmetic Ingredient Name(INCI) Application



## HEADQUARTER



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