

Registration and Listing of Cosmetic Product Facilities and Products: Guidance for Industry

Draft Guidance

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Submit electronic comments to <https://www.regulations.gov>. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with docket number FDA-2023-D-1716 as listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact the Office of Cosmetics and Colors at 240-402-1130.

**U.S. Department of Health and Human Services
Food and Drug Administration
Office of the Chief Scientist**

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Table of Contents

I. Introduction.....	3
II. Background	3
III. Questions and Answers.....	4
Appendix A.....	12

Registration and Listing of Cosmetic Product Facilities and Products: Guidance for Industry¹

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance at the phone number listed on the title page.

I. Introduction

This guidance provides recommendations and instructions to assist persons submitting cosmetic product facility registrations and product listings to FDA. This guidance document explains, among other things:

- The statutory requirement to submit cosmetic product facility registrations and product listings;
- Definitions;
- Who is responsible for making the submissions;
- What information to include in the submissions;
- How to make the submissions; and
- When to make the submissions.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe our current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidances means that something is suggested or recommended, but not required.

II. Background

On December 29, 2022, the President signed the Consolidated Appropriations Act, 2023 (Pub. L. 117-328) into law, which included the Modernization of Cosmetics Regulation Act of 2022 (MoCRA). Among other provisions, MoCRA added section 607 to the Federal Food, Drug, and

¹ This guidance has been prepared by the Office of Cosmetics and Colors, in the Center for Food Safety and Applied Nutrition, and the Office of the Chief Scientist at the U.S. Food and Drug Administration.

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Cosmetic Act (FD&C Act), establishing requirements for cosmetic product facility registration and product listing.

Section 607(a) of the FD&C Act requires every person that owns or operates a facility that “engages in the manufacturing or processing of a cosmetic product for distribution in the United States” to register each facility with FDA.

Section 607(c) of the FD&C Act requires that for each cosmetic product, the responsible person must submit to FDA “a cosmetic product listing.”

FDA previously had a voluntary cosmetics registration program (see 21 CFR Parts 710 and 720). FDA ended its voluntary registration program as of March 27, 2023, while we work toward establishing a new system, including a submission portal for the cosmetic product facility registrations and product listings mandated by MoCRA.² Information in the voluntary cosmetics registration program will not be transferred to this new system. Because the information in the voluntary cosmetics registration program differs from the information required to be submitted under MoCRA, FDA does not consider previous submissions to the voluntary cosmetics registration program to satisfy the registration and listing requirements mandated by MoCRA.

FDA intends to make the new electronic submission portal available for submitting registration and product listing information under section 607 of the FD&C Act in October 2023. FDA is developing a paper form as an alternative submission tool. FDA strongly encourages electronic submissions to facilitate efficiency and timeliness of data submission and management for the agency.

Certain small businesses, as defined in section 612 of the FD&C Act, are not required to register facilities and list cosmetic product(s) (refer to Definitions section below and Question B. below).

Failure to register or submit listing information in accordance with section 607 of the FD&C Act is a prohibited act under section 301(hhh) of the FD&C Act (21 U.S.C. 331(hhh)).

III. Questions and Answers

A. What definitions apply?

We plan to use the following definitions in implementing the registration and product listing requirements of section 607 of the FD&C Act:

CONTRACT MANUFACTURER. — means a facility that engages in one or more steps in manufacturing or processing a cosmetic product on behalf of another company.

² For more information, refer to FDA’s Constituent Update “FDA Has Stopped Accepting Submissions to the Voluntary Cosmetic Registration Program (VCRP)” at: <https://www.fda.gov/food/cfsan-constituent-updates/fda-has-stopped-accepting-submissions-voluntary-cosmetic-registration-program-vcprp>.

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COSMETIC PRODUCT. — as defined in section 604(2) of the FD&C Act, means a preparation of cosmetic ingredients with a qualitatively and quantitatively set composition for use in a finished product.

DUNS NUMBER. — The Data Universal Numbering System (DUNS) number is a unique nine-digit identification number provided by Dun & Bradstreet (D&B). The DUNS Number is site-specific. Therefore, each distinct physical location of an entity (such as branches, divisions, and headquarters) may be assigned a DUNS number.

FACILITY. — as defined in section 604(3) of the FD&C Act, includes any establishment (including an establishment of an importer) that manufactures or processes cosmetic products distributed in the United States.

This 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 the Internal Revenue Code of 1986), 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:
 - Labeling,
 - Relabeling,
 - Packaging,
 - Repackaging,
 - Holding,
 - Distributing.

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For purposes of determining whether an establishment solely performs one or more of the activities listed under (viii), the terms ‘packaging’ and ‘repackaging’ do not include filling a product container with a cosmetic product.

MANUFACTURING OR PROCESSING OF A COSMETIC PRODUCT. — means engaging in one or more steps in the making of any cosmetic product by chemical, physical, biological, or other procedures, including manipulation, sampling, testing, or control procedures applied to the product.

OPERATOR. — means a person, as defined in section 201(e) of the FD&C Act (21 U.S.C 321(e)), who has management authority over an establishment.

OWNER. — means a person, as defined in section 201(e) of the FD&C Act (21 U.S.C. 321(e)), who has an ownership interest in an establishment.

RESPONSIBLE PERSON. — as defined in section 604(4) of the FD&C Act, means the manufacturer, packer, or distributor of a cosmetic product whose name appears on the label of such cosmetic product in accordance with section 609(a) of the FD&C Act or section 4(a) of the Fair Packaging and Labeling Act.

SMALL BUSINESSES. — as defined in section 612 of the FD&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, and who do not engage in the manufacturing or processing of certain cosmetic products described in section 612(b) of the FD&C Act. A small business is exempt from the registration and listing requirements.

Under section 612(b) of the FD&C Act, regardless of their average gross annual sales, businesses that engage in the manufacturing or processing of the following are not exempt from the registration and listing requirements:

- Cosmetic products that regularly come into contact with mucus membrane of the eye under conditions of use that are customary or usual;
- Cosmetic products that are injected;
- Cosmetic products that are intended for internal use; or
- 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.

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B. Who registers and submits product listing information under section 607 of the FD&C Act?

1. Registration

Section 607(a)(1) of the FD&C Act requires every person that owns or operates a facility that engages in the manufacturing or processing of a cosmetic product for distribution in the United States to register each facility, except in the following instances:

- A facility that is exempt from registration as a “small business” as described section III.A. above;
- A facility that is also subject to the requirements in chapter V of the FD&C Act (for drugs and devices) unless the facility also manufactures or processes cosmetic products that are not subject to the requirements of chapter V of the FD&C Act (see section 613 of the FD&C Act).

As provided under section 607(a)(3) of the FD&C Act, if a facility manufactures or processes cosmetic products on behalf of a responsible person (i.e., a contract manufacturer), only a single registration is required for such facility even if the facility is manufacturing or processing its own cosmetic products or cosmetic products on behalf of more than one responsible person. A responsible person whose products are manufactured or processed at such facility may submit the facility registration for such facility. Under this approach, an owner or operator of a contract manufacturing facility would not register such facility if the responsible person submitted the facility registration.

2. Product Listing

Section 607(c) of the FD&C Act requires that for each cosmetic product, the responsible person must submit a cosmetic product listing, except in the following instances:

- The responsible person that is exempt as a “small business” as described in section III.A. above;
- The cosmetic product that is also subject to the requirements in chapter V of the FD&C Act (for drugs and devices). For example, if the product is both a drug and a cosmetic product under the FD&C Act, a cosmetic product listing is not required to be submitted for such product (see section 613 of the FD&C Act).

C. What information is submitted as part of facility registration and product listing under section 607 of the FD&C Act?

1. Registration

Under sections 607(a) and 607(b)(2) of the FD&C Act, the following information must be submitted in a facility registration:

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- 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;³
- all brand names under which cosmetic products manufactured or processed in the facility are sold;
- the product category or categories (refer to Appendix A below) and responsible person for each cosmetic product manufactured or processed at the facility; and
- type of submission (initial, amended, biennial renewal, or abbreviated renewal, for further information see discussion in section III.F.1).

Obtaining the assigned facility registration number is the first step *before* starting the registration submission.

FDA also requests that the following additional optional information be submitted:

- parent company name (if applicable);
- facility DUNS Number; and
- additional contact information for individuals associated with the registration.

In addition, FDA requests that individuals submitting registration and listing information to attest to the accuracy and veracity of the information submitted.

2. Product Listing

Under section 607(c) of the FD&C Act, the following information must be submitted in a cosmetic product listing:

- the facility registration number of each facility where the cosmetic product is manufactured or processed;⁴
- 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 (refer to Appendix A below);

³ The facility registration number will be the FDA Establishment Identifier (FEI). To facilitate the registration process, the owner or operator of a facility will need to obtain an FEI number before submitting the facility registration. For more information, including how to request an FEI number or determine if an entity already has an FEI number, please refer to the webpage at:

<https://www.accessdata.fda.gov/scripts/feiportal/index.cfm?action=portal.login>.

⁴ The responsible person will need to obtain the relevant facility registration number(s) for each facility where its cosmetic products are manufactured or processed, because the facility registration number(s) is required for the product listing submission. If the facility is a small business that is exempt from registration and has no facility registration number, then facility name/address can be provided instead.

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- a list of ingredients in the cosmetic product, including any fragrances, flavors, or colors, with each ingredient identified by the name, as required under section 701.3 of title 21, Code of Federal Regulations (or any successor regulations), or by the common or usual name of the ingredient;
- the product listing number, if any previously assigned; and
- type of submission (initial, update to content (annual), abbreviated renewal).

Under section 607(c)(4)(B), 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.

FDA also requests that the following additional optional information be submitted:

- parent company name (if applicable);
- 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 (UNIIs)⁵; and
- additional contact information for individuals associated with the listing.

In addition, FDA requests that individuals submitting registration and listing information attest to the accuracy and veracity of the information submitted.

D. Is cosmetic product facility registration and cosmetic product listing information submitted under section 607 of the FD&C Act available for public disclosure?

The product listing number will not be available for public disclosure (section 607(d) of the FD&C Act). Further, under section 607(e) of the FD&C Act, FDA will not disclose information from a facility registration on the brand names under which cosmetic products manufactured or processed in the facility are sold, or from a product listing on the facility registration number of the facility where the cosmetic product is manufactured or processed, in response to a request under the Freedom of Information Act (FOIA) (5 U.S.C. 552). All other information from cosmetic product facility registration and listing would be available for public disclosure consistent with the FOIA, FDA's disclosure regulations under 21 CFR Part 20, and other applicable federal law. FDA intends to make relevant information from cosmetic product facility registration and listing available to the public to the extent permitted by law.

⁵ For more information and to search for UNIIs please refer to the webpage at: <https://precision.fda.gov/uniisearch>. For UNII requests contact: FDA-SRS@fda.hhs.gov.

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E. How do you submit registration and product listing information required under section 607 of the FD&C Act?

FDA is developing an electronic submission portal to streamline submission and receipt of registration and product listing information required by section 607 of the FD&C Act. While electronic submission is not required, FDA strongly encourages electronic submissions to facilitate efficiency and timeliness of data submission and management for the agency. Registration and listing data are submitted electronically using structured product labeling (SPL) format. Future updates to industry submissions are intended to be efficient to submit because information from a previous submission can be applied without re-entering all information.

FDA is developing a paper form as an alternative submission tool. Both the electronic submission portal and the paper form will be accessible at <https://www.fda.gov/>. Instructions for submission will also be provided on this webpage.

F. When must you register and list under section 607 of the FD&C Act?

1. Registration

a. Initial Registration

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 December 29, 2023 (section 607(a)(1)(A) of the FD&C Act).

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 first engaging in such activity or by February 27, 2024, whichever is later (section 607(a)(1)(B) of the FD&C Act).

b. Amended Registration

Every person who is required to register must update their registration within 60 days of any changes to the information required for registration (section 607(a)(4) of the FD&C Act) (an “amended” registration). This includes any changes that result in cancellation of the registration.

c. Renewal of Registration

Every person who is required to register a facility must renew such registration biennially (i.e., every two years) (section 607(a)(2) of the FD&C Act).

FDA is providing for an abbreviated renewal of registrations when there have not been any updates to the registration since the most recent facility registration submission, as required under section 607(a)(4) of the FD&C Act.

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2. Product Listing

a. Initial Listing

The responsible person of a cosmetic product that is marketed on December 29, 2022, must submit a cosmetic product listing not later than December 29, 2023, or for a cosmetic product that is first marketed after December 29, 2022, within 120 days of marketing such product in interstate commerce (section 607(c)(2) of the FD&C Act). Consistent with the approach for registration of a facility that starts manufacturing or processing cosmetic products after December 29, 2022 (section 607(a)(1)(B) of the FD&C Act), FDA expects the product listing for a cosmetic product first marketed after December 29, 2022 to be submitted within 120 days of marketing the product, or within 120 days of December 29, 2023, whichever is later.

b. Update to Content and Renewal

The responsible person must provide any updates to such listing annually (section 607(c)(5) of the FD&C Act). This includes an update that the product was discontinued.

FDA is providing for an abbreviated process for the renewal of any cosmetic product listing, as required under section 607(c)(3), for which there has been no change since the responsible person submitted the previous listing.

G. What if my product is both a drug and a cosmetic product? Do have I have to comply with cosmetic product facility registration and cosmetic product listing requirements under section 607 of the FD&C Act?

A cosmetic product that is also a drug is not subject to the listing requirements under section 607 of the FD&C Act. Likewise, a facility that manufactures or processes cosmetic products that are also drugs is not subject to the registration requirement under section 607 unless it also manufactures or processes cosmetic products that are not also drugs (see section 613 of the FD&C Act). Cosmetic product facility registration and product listing will be available using the same electronic submission process available to register an establishment and list a drug with FDA. This will help to streamline the process of submitting registration and listing information for cosmetics facilities and products for entities that also submit drug establishment and listing information.

H. Does FDA charge a fee to submit a registration or product listing under section 607 of the FD&C Act?

No. There is no fee to submit a registration or product listing to FDA under section 607 of the FD&C Act.

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APPENDIX A⁶

Cosmetic Product Categories and Codes

(01) *Baby products.*

- (a) Baby shampoos.
- (b) Lotions, oils, powders, and creams.
- (c) Baby wipes.
- (d) Other baby products.
 - 1. Leave-on.
 - 2. Rinse-off.

(02) *Bath preparations.*

- (a) Bath oils, tablets, and salts.
- (b) Bubble baths.
- (c) Bath capsules.
- (d) Other bath preparations.

(03) *Eye makeup preparations (other than children's eye makeup preparations).*

- (a) Eyebrow pencils.
- (b) Eyeliners.
- (c) Eye shadows.
- (d) Eye lotions.
- (e) Eye makeup removers.
- (f) False eyelashes.
- (g) Mascaras.
- (h) Eyelash and eyebrow adhesives, glues, and sealants.
- (i) Eyelash and eyebrow preparations (primers, conditioners, serums, fortifiers).
- (j) Eyelash cleansers.
- (k) Other eye makeup preparations.

(04) *Children's eye makeup preparations.*

- (a) Children's eyeshadows.
- (b) Other children's eye makeup.

(05) *Fragrance preparations.*

- (a) Colognes and toilet waters.
- (b) Perfumes.
- (c) Powders (dusting and talcum) (excluding aftershave talc).
- (d) Other fragrance preparations.

(06) *Hair preparations (non-coloring).*

- (a) Hair conditioners.
 - 1. Leave-on.
 - 2. Rinse-off.
- (b) Hair sprays (aerosol fixatives).

⁶ FDA has created this list of categories and codes and requests comment or additional categories/codes.

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- (c) Hair straighteners.
- (d) Permanent waves.
- (e) Rinses (non-coloring).
- (f) Shampoos (non-coloring).
 - 1. Leave-on.
 - 2. Rinse-off.
- (g) Tonics, dressings, and other hair grooming aids.
- (h) Wave sets.
- (i) Other hair preparations.
 - 1. Leave-on.
 - 2. Rinse-off.
- (07) *Hair coloring preparations.***
 - (a) Hair dyes and colors (all types requiring caution statement and patch test).
 - (b) Hair tints.
 - (c) Hair rinses (coloring).
 - 1. Leave-on.
 - 2. Rinse-off.
 - (d) Hair shampoos (coloring).
 - 1. Leave-on.
 - 2. Rinse-off.
 - (e) Hair color sprays (aerosol).
 - (f) Hair lighteners with color.
 - (g) Hair bleaches.
 - (h) Eyelash and eyebrow dyes.
 - (i) Other hair coloring preparations.
 - 1. Leave-on.
 - 2. Rinse-off.
- (08) *Makeup preparations (not eye)(other than makeup preparations for children).***
 - (a) Blushers and rouges (all types).
 - (b) Face powders.
 - (c) Foundations.
 - 1. Traditional applications.
 - 2. Airbrush applications.
 - (d) Leg and body paints.
 - 1. Traditional applications.
 - 2. Airbrush applications.
 - (e) Lipsticks and lip glosses.
 - (f) Makeup bases.
 - 1. Traditional applications.
 - 2. Airbrush applications.
 - (g) Makeup fixatives.
 - (h) Other makeup preparations.
 - 1. Traditional applications.
 - 2. Airbrush applications.
- (09) *Makeup preparations for children (not eye).***

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- (a) Children's blushers and rouges (all types).
- (b) Children's face paints.
- (c) Children's face powders.
- (d) Children's foundations.
- (e) Children's lipsticks and lip glosses.
- (f) Children's color hairsprays.
- (g) Other children's makeup.
- (10) ***Manicuring preparations.***
 - (a) Basecoats and undercoats.
 - (b) Cuticle softeners.
 - (c) Nail creams and lotions.
 - (d) Nail extenders.
 - (e) Nail polishes and enamels.
 - (f) Nail polish and enamel removers.
 - (g) Other manicuring preparations.
- (11) ***Oral products.***
 - (a) Dentifrices (aerosols, liquids, pastes, and powders).
 - (b) Mouthwashes and breath fresheners (liquids and sprays).
 - (c) Other oral products.
- (12) ***Personal cleanliness.***
 - (a) Bath soaps and body washes.
 - (b) Deodorants (underarm).
 - 1. Sticks, roll-ons, gels, creams, and wipes.
 - 2. Sprays.
 - (c) Douches.
 - (d) Feminine deodorants.
 - 1. Leave-on.
 - 2. Rinse-off.
 - (e) Disposable wipes.
 - (f) Other personal cleanliness products.
 - 1. Leave-on.
 - 2. Rinse-off.
- (13) ***Shaving preparations.***
 - (a) Aftershave lotions.
 - (b) Beard softeners.
 - (c) Men's talcum.
 - (d) Pre-shave lotions (all types).
 - (e) Shaving creams (aerosol, brushless, and lather).
 - (f) Shaving soaps (cakes, sticks, etc.).
 - (g) Other shaving preparation products.
- (14) ***Skin care preparations, (creams, lotions, powder, and sprays).***
 - (a) Cleansing (cold creams, cleansing lotions, liquids, and pads).
 - (b) Depilatories.
 - (c) Face and neck (excluding shaving preparations).
 - 1. Leave-on.

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- 2. Rinse-off.
- (d) Body and hand (excluding shaving preparations).
 - 1. Leave-on.
 - 2. Rinse-off.
- (e) Foot powders and sprays.
- (f) Moisturizing.
- (g) Night.
- (h) Paste masks (mud packs).
- (i) Skin fresheners.
- (j) Other skin care preparations.
 - 1. Leave-on.
 - 2. Rinse-off.
- (15) ***Suntan preparations.***
 - (a) Suntan gels, creams, and liquids.
 - (b) Indoor tanning preparations.
 - 1. Traditional applications (creams, lotions, etc.).
 - 2. Airbrush applications.
 - 3. Spray applications.
 - 4. Professional airbrush tanning applications.
 - 5. Professional spray tanning applications.
 - (c) Other suntan preparations.
- (16) ***Tattoo preparations.***
 - (a) Permanent tattoo inks.
 - (b) Temporary tattoo inks.
 - (c) Other tattoo preparations.
- (17) ***Other preparations*** (*i.e., those preparations that do not fit another category*).