

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

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<https://www.fda.gov/cosmetics/cosmetics-guidance-regulation/cosmetics-guidance-documents>

Appendix B of this guidance describes frequently asked questions and answers. A portion of Appendix B, Q20 to Q22, is being distributed for comment purposes only.

Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that FDA considers your comment on Q20-Q22 in Appendix B before we begin work on the final version of Q20-Q22 in Appendix B, submit either electronic or written comments on this document within 30 days of publication in the Federal Register of the notice announcing the availability of the guidance.

Submit electronic comments to <http://www.regulations.gov>. Submit written comments on the guidance 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 the docket number FDA-2023-D-1716 as listed in the notice of availability that publishes in the *Federal Register*.

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

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

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) 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 office responsible for this guidance as 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 Cosmetic Act (FD&C Act), establishing requirements for cosmetic product facility registration and product listing.

¹ This guidance has been prepared by the Office of Cosmetics and Colors in the Office of the Chief Scientist at the U.S. Food and Drug Administration.

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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 cosmetic registration program (see 21 CFR Parts 710 and 720). FDA ended its voluntary registration program as of March 27, 2023, while we worked 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 cosmetic registration program will not be transferred to this new system. Because the information in the voluntary cosmetic registration program differs from the information required to be submitted under MoCRA, FDA does not consider previous submissions to the voluntary cosmetic registration program to satisfy the registration and listing requirements mandated by MoCRA.

FDA has developed an electronic submission portal, Cosmetics Direct, to help streamline submission and receipt of registration and product listing information under section 607 of the FD&C Act. FDA has developed paper forms (FDA Form 5066 and 5067) as an alternative submission tool. As an additional alternative, users may transmit submissions through FDA’s Electronic Submissions Gateway (ESG) as described in section III.E. below. FDA strongly encourages electronic submissions to facilitate efficiency and timeliness of data submission and management for the agency. Cosmetics Direct, technical assistance documents and paper submission forms can be accessed at: <https://www.fda.gov/cosmetics/registration-listing-cosmetic-product-facilities-and-products>.

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 section III.A. and III.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:

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-vcpr>.

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CONTRACT MANUFACTURER. — means a facility that manufactures or processes a cosmetic product on behalf of another entity.

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.

FEI. — is an acronym which stands for FDA Establishment Identifier. It is also known as the Firm or Facility Establishment Identifier. The FEI number is a unique identifier assigned by the FDA to identify firms associated with FDA-regulated products. FDA intends to use a facility’s FEI number as the cosmetic product facility’s registration number.

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,³ 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

³ We recommend using the Implicit Price Deflator for GDP, updated annually by the Bureau of Economic Analysis, when adjusting for inflation. Please refer to: <https://apps.bea.gov/iTable/?reqid=19&step=3&isuri=1&1921=survey&1903=13>.

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- 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.

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

1. Registration of a Facility

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 because the responsible person, owner or operator meets the definition of a “small business” as defined by section 612 of the FD&C Act and described in section III.A. above;
- A facility that is subject to the requirements of chapter V of the FD&C Act (for drugs and devices) (see section 613(a) of the FD&C Act). The exception from the facility registration requirements of section 607 of the FD&C Act does not apply if that same 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(b) 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, or ensure such submission is made, 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 of 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), but the listed product should be identified as both a drug and a cosmetic in the drug listing submission.

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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:

- 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 agent⁴ of the facility (name and phone number), and, if available, the electronic contact information (email);
- the facility registration number, if any, previously assigned by FDA;⁵
- 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:

⁴ With respect to a foreign facility, a United States agent ("U.S. agent") is required for registration purposes. The U.S. agent is the person, which includes an individual or business entity, that resides in the U.S. or maintains a U.S. place of business and is physically present in the U.S. A U.S. agent should not be a mailbox, answering machine or service, or other place where an individual acting as the foreign facility's agent is not physically present.

⁵ The facility registration number is 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. Request for issuance of FEI numbers associated with registration for cosmetic product facilities are typically processed in 7-10 business days. A facility that was previously assigned an FEI number in connection with other business with FDA should use the same FEI number and should not request a new FEI. For more information, including how to determine if an entity already has an FEI number, refer to the webpage at: <https://www.accessdata.fda.gov/scripts/feiportal/index.cfm?action=portal.login>. If your entity does not have an FEI number assigned by FDA, send a request to feiportal@fda.hhs.gov and provide the following information:

- Legal firm name
- Any alternate firm names, including those used for "doing business as" purposes
- Physical address
- Designated mailing address
- Name and contact information of the designated contact person
- A comprehensive list of activities conducted at this specific location (e.g., drug manufacturing, food packaging, etc.)
- Any registration numbers associated with other FDA Center(s), if applicable
- Any former names the firm was known by
- Any previous addresses linked to the firm

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- 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;⁶
- 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);
- 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) of the FD&C Act, 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 (currently jpg files are accepted);
- 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 (UNII)s⁷; and

⁶ 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 exempt from registration, for example because it is a small business, and has no facility registration number, then facility name/address can be provided instead.

⁷ 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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- 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.

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

Cosmetics Direct⁸ is an electronic submission portal designed to help 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)⁹ 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. Technical assistance will be available for users by contacting a help desk for Cosmetics Direct.

As an alternative, users may transmit SPL-formatted submissions through FDA's Electronic Submissions Gateway (ESG),¹⁰ or any SPL authoring software including Xforms.¹¹ The FDA ESG system requires users to apply for a free account before submitting data, a process which can take one to three weeks. FDA therefore urges those who are planning to use the ESG to

⁸ For link to Cosmetics Direct see: <https://direct.fda.gov/>

⁹ The Structured Product Labeling (SPL) is a document markup standard approved by Health Level Seven (HL7) and adopted by FDA as a mechanism for exchanging product and facility information.

¹⁰ For more information on FDA's Electronic Submissions Gateway, please refer to the webpage at <https://www.fda.gov/industry/electronic-submissions-gateway>

¹¹ For more information on Xforms, please refer to the webpage at <https://www.fda.gov/industry/structured-product-labeling-resources/spl-xforms> In addition, the technical details on using SPL for registration and listing are available in the FDA's SPL Implementation Guide available at <https://www.fda.gov/media/84201/download>.

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apply for ESG accounts well in advance of the deadline for data submission. Technical assistance is available for users by contacting the ESG at ESGHelpDesk@fda.hhs.gov.

FDA developed paper forms (FDA Form 5066 and 5067) as another alternative submission tool. Both the Cosmetics Direct and the paper forms are accessible at <https://www.fda.gov/cosmetics/registration-listing-cosmetic-product-facilities-and-products>.

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).

Note: On November 8, 2023, FDA issued a guidance for industry titled “Compliance Policy for Cosmetic Product Facility Registration and Cosmetic Product Listing.” This guidance explains that FDA does not intend to enforce the requirements under section 607 of the FD&C Act related to cosmetic product facility registration until **July 1, 2024**.

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)(5) of the FD&C Act.

Note: In the case of a contract manufacturer, a facility registration may be submitted by the contract manufacturer or any responsible person whose products are manufactured or processed at such facility (section 607(a)(3) of the FD&C Act). Also, note that the renewal period and timeframe to submit updates for a cosmetics product facility registration may be different than for other FDA-regulated products for which the facility may also be required to register.

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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, or ensure such submission is made, 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 (which is April 27, 2024), whichever is later.

Note: On November 8, 2023, FDA issued a guidance for industry titled “Compliance Policy for Cosmetic Product Facility Registration and Cosmetic Product Listing.” This guidance explains that FDA does not intend to enforce the requirements under section 607 of the FD&C Act related to cosmetic product listing until **July 1, 2024**.

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 are 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.

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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.

APPENDIX A

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).
- (c) Hair straighteners.
- (d) Permanent waves.
- (e) Rinses (non-coloring).
- (f) Shampoos (non-coloring).

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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).***
- (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.

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- (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.
 - 2. Rinse-off.
 - (d) Body and hand (excluding shaving preparations).
 - 1. Leave-on.
 - 2. Rinse-off.
 - (e) Foot powders and sprays.
 - (f) Moisturizing.

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- (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*).

APPENDIX B¹²

Frequently Asked Questions and Answers

Q1. Do owners and operators of facilities that only manufacture or process cosmetic ingredients need to register their facilities? Does a responsible person need to submit a product listing for cosmetic ingredients?

A. At this time, FDA expects owners or operators to register their facilities if the facilities manufacture or process the final formulation of cosmetic ingredients (including a final formulation that includes a single ingredient). This includes final formulations that have not yet been packaged. FDA expects responsible persons to list cosmetic products that are marketed for users (e.g., consumers or professional use).

Q2. Can a consultant be a “responsible person” under section 607 of the FD&C Act?

A. A consultant can only be a responsible person if they meet the definition of “responsible person” in section 604(4) of the FD&C Act. A “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.

Q3. Can a company located outside of the U.S. be the “responsible person”?

A. “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. A company located outside of the U.S. could be a “responsible person” so long as they are the manufacturer, packer, or distributor of the cosmetic product whose name appears on the label, consistent with the definition of “responsible person” in section 604(4) of the FD&C Act. However, we note that, under section 609(a) of the FD&C Act, each cosmetic product shall bear a label that includes a domestic address, domestic phone number, or electronic contact information, which may be a website, through which the responsible person can receive adverse event reports with respect to such cosmetic product. We recommend that firms consider when selecting electronic contact information, such as an email address or a website (whether foreign or domestic), how they can best facilitate reporting and responding to these reports, and meeting maintenance, inspection, and reporting requirements under section 605 of the FD&C Act. For example, a fax number or QR code is unlikely to facilitate reporting due to potential limitations in accessibility for all consumers.

Q4. Is the brand name the same as the product name?

A. No. FDA does not consider the brand name and product name to be the same.

¹² A portion of the section of the guidance, Q20-Q22 in Appendix B (designated with a shaded background), is being distributed for comment purposes only.

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The product name is generally considered the statement of identity, as required under 21 CFR 701.11. The statement of identity provides information about the type or kind of cosmetic product in the package to help the consumer understand the functional use of the product.

The brand name is the distinguishing name used by a company to identify a commercial product on the product label. The brand name may be proprietary and/or registered as a trademark.

Q5. What are examples of products whose manufacture does not qualify the responsible person or facility for the small business exemptions under section 612 of the FD&C Act?

A. Section 612 of the FD&C Act provides exemptions for certain small businesses from the requirements of sections 606 (Good Manufacturing Practice) and 607 (Registration and Product Listing). However, such exemptions from the requirements of sections 606 and 607 of the FD&C Act do not apply to any responsible person or facility engaged in the manufacturing or processing of any of the following products listed in section 612(b) of the FD&C Act:

(1) Cosmetic products that regularly come into contact with mucus membrane of the eye under conditions of use that are customary or usual.

(2) Cosmetic products that are injected.

(3) Cosmetic products that are intended for internal use.

(4) 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.

Q6. What are examples of products that regularly come into contact with the mucus membrane of the eye as described in section 612(b)(1) of the FD&C Act?

A. While there may be certain exceptions, we expect that products that are intended to be applied in the proximity of the eye such as eye shadow, an eye makeup remover, a liquid or mucosal eyeliner, or a false eyelash adhesive would regularly come into contact with the mucous membrane of the eye under conditions of use that are customary or usual. A responsible person or facility engaged in the manufacturing or processing of such products would not qualify for the small business exemption (see section 612(b)(1) of the FD&C Act). However, facial cleansers, facial moisturizers, and facial serums generally would not be expected to regularly come into contact with the mucous membrane of the eye under conditions of use that are customary or usual.

Q7. What are examples of products that are intended to alter appearance for more than 24 hours?

A. Examples of cosmetic products that are intended to alter the appearance for more than 24 hours and removal by the consumer is not part of such conditions of use that are customary or usual, as described in section 612(b)(4) of the FD&C Act, may include certain nail polishes, some hair dye products, some eyebrow dyes, tattoo inks, and certain leave-on skin

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preparations. To determine if a product falls under section 612(b)(4) of the FD&C Act one should consider product labeling, including directions for use, as well as the uses of the product that are not indicated in the labeling but are customary or usual.

Q8. If the owner or operator of a facility meets the criteria for being a small business in section 612(a) of the FD&C Act, but the facility engages in the manufacturing or processing of cosmetic products listed in section 612(b) of the FD&C Act, does the facility registration need to include information required under section 607(b)(2)(D) and (E) for only the cosmetic products listed in section 612(b), or for all of the cosmetic products manufactured or processed by the facility?

A. In the context of facility registration under section 607(b) of the FD&C Act, the exemptions in section 612 of the FD&C Act apply to the owners and operators of facilities if the owners and operators meet the definition of a small business in section 612(a). However, such an owner or operator will need to register a facility and include the information under section 607(b)(2)(D) and (E) of the FD&C Act for all cosmetic products that the facility manufactures or processes if the facility manufactures or processes any of the following cosmetic products:

(1) Cosmetic products that regularly come into contact with mucus membrane of the eye under conditions of use that are customary or usual.

(2) Cosmetic products that are injected.

(3) Cosmetic products that are intended for internal use.

(4) 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.

Q9. Where can I submit documentation that my business meets the small business exemption in order to receive an exemption certificate from FDA?

A. FDA is not generally asking companies to submit this information nor does FDA provide small business exemption certificates for cosmetic product facilities or responsible persons.

Q10. Does an importer need to register and/or list under 607 of the FD&C Act?

A. If an importer meets the definition of a facility and/or a responsible person in section 604 of the FD&C Act, and does not meet any exemption, then they must comply with any applicable registration or listing requirements. Otherwise, the importer is not required to register or list.

Q11. Does a laboratory that only performs testing on cosmetic products used for research and development need to register?

A. No. If a laboratory tests cosmetic products that are solely for use in research, development, or evaluation, and that are not offered for retail sale, it does not need to register because it is an

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establishment that is not included in the definition of facility in section III.B. above (see section 604(3)(B)(vii) of the FD&C Act).

Q12. Does a laboratory that performs cosmetic product batch release testing need to register?

- A. Yes. Cosmetic product batch release testing is part of manufacturing and processing. Laboratories conducting this testing are considered facilities subject to the registration requirements.

Q13. My company owns 2 buildings with 2 addresses, and 1 of the buildings is for storage only. Do we need to register the building used only for storage?

- A. No. An establishment that solely performs storage (holding) with respect to cosmetic products is not required to register under section 607 of the FD&C Act.

Q14. If a contract manufacturer of cosmetic products is located outside of the United States, are they required to be registered with the FDA under section 607 of the FD&C Act? Is there an exemption from registration if the contract manufacturer follows ISO22716?

- A. If a contract manufacturer manufactures or processes cosmetic product(s) distributed in the United States, then the contract manufacturing facility must be registered with the FDA, even if the contract manufacturer is located outside of the United States. More information, including on exemptions, are described in section III above. There is not an exemption from registration for following ISO22716.

Q15. Do hair coloring preparations (including hair dyes) need to be listed?

- A. Yes. Hair coloring preparations, including hair dyes, are cosmetic products and therefore need to be listed, unless an exemption applies.

Q16. Do hairbrushes and wigs need to be listed?

- A. No. We do not expect hairbrushes and wigs to be listed.

Q17. My cosmetic products don't fit into any of the product categories provided in Appendix A. Therefore, what product category and code should be used?

- A. We recommend that you select the product category and code in Appendix A (above) that match most closely and use the "other" category and code if another category and code does not appear to fit. Keep in mind that products intended for use in the eye area should be entered into an eye area product category.

FDA intends to periodically update the product categories and codes. We intend to publish any proposed updates to the product categories and codes as draft guidance on our website, with a notice in the Federal Register announcing that the draft guidance document is available. After providing an opportunity for public comment on the draft guidance, FDA will:

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- (A) Review any comments received and prepare the final version of the guidance document that incorporates suggested changes, when appropriate;*
- (B) Publish a notice in the Federal Register announcing that the guidance document is available;*
- (C) Post the guidance document on the Internet and make it available in hard copy; and*
- (D) Implement the guidance document.*

Q18. What is the receipt date for registrations and listings submitted via paper form?

- A. When FDA receives a paper submission, the submission is assigned a receipt date. The receipt date for a paper submission is the date on which the submission physically arrives at the appropriate receiving unit (the address specified on the paper form) during business hours. If paper registration and listing forms are mailed, we recommend using a method that includes tracking.

FDA encourages electronic submission of registration and listing for cosmetic product facilities and products.

Q19. The cosmetic establishment registration is to be renewed biennially. Does this mean the biennial renewal has to be done every two years from the date of initial registration?

- A. Yes, a cosmetic product facility needs to renew its registration every two years from the date of initial registration.

Q20. What are the responsibilities of a U.S. Agent?

- A. The responsibilities of the U.S. agent are limited and generally include:

- assisting FDA in communications with the foreign establishment;
- responding to questions concerning the foreign establishment's products that are imported or offered for import into the United States;
- assisting FDA in scheduling inspections of the foreign establishment; and
- receiving information or documents from FDA on behalf of the foreign establishment when FDA is unable to contact the foreign establishment directly or expeditiously. FDA providing such information or documents to the U.S. Agent will be considered equivalent to providing the same information or documents to the foreign establishment.

We also note that FDA does not recommend or endorse any particular U.S. agent.

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Q21. Can multiple buildings that are in close proximity (within 3 miles of each other) be associated with one FEI number, or are two FEI numbers needed?

A. A cosmetic product facility may include multiple buildings that are part of the same establishment. Under certain circumstances, one FEI number may be associated with multiple buildings that manufacture or process cosmetic products. Multiple buildings with different physical addresses that are within three miles of one another are generally considered one establishment with one FEI number if their activities are closely related to the same business enterprise; are under the supervision of the same local management; and are capable of being inspected by FDA during a single inspection. The cosmetic product facility registration and listing system allows only one cosmetic facility registration to be associated with a single FEI number. A cosmetic product facility registration may be submitted for multiple buildings that are associated with the same FEI number, and the physical address listed with the cosmetic product facility registration needs to match the “Physical Address” that is listed in the FEI Search Portal.

Note: FEI registration and cosmetic product facility registration are two separate registration processes. Registering for and obtaining the FEI number must be completed before starting the cosmetic product facility registration submission.

Q22. Does a product listing need to be submitted for free samples or gifts?

A. Generally, yes.

Under section 607(c) of the FD&C Act the responsible person must submit to FDA a cosmetic product listing for each cosmetic product. While, under section 604(3) of the FD&C Act, the definition of facility includes exemptions for trade shows and other venues where cosmetic product samples are provided free of charge and entities that provide complimentary cosmetic products to customers incidental to other services, which are relevant for cosmetic product facility registration, the requirement to submit a cosmetic product listing still applies to these types of cosmetic products. Thus, the responsible person for each cosmetic product, even those provided as free samples or gifts, must submit a cosmetic product listing in accordance with section 607(c) of the FD&C Act, unless another exemption applies (see, e.g., section 612 of the FD&C Act). However, FDA does not expect this requirement to apply for samples that are provided within the industry for purposes of research and development or product development and not intended for consumption by the consumer, for example, free finished product samples to hand out to industry participants (see Q1 and section 607(c) of the FD&C Act).