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A Certified Group Company

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Facility Registration and Product Listing of Cosmetics

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Respected • Experts • Ethical • with Integrity

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John Bailey
EAS Independent Consultant

Dr. Bailey is currently an Independent Advisor for EAS Consulting Group specializing in cosmetics and color additives. Prior to this position, Dr. Bailey worked for the Personal Care Products Council as Executive Vice President for Science. Previously, Dr. Bailey served as the director of FDAs Office of Cosmetics and Colors which is the organization responsible for the regulation of cosmetics and color additives. Before retiring from FDA, he established FDA's Office of Applied Research and Safety Assessment where he formed the organization of the office and was responsible for research into the safety of foods and cosmetics.

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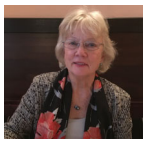
Speaker



Catherine Bailey
EAS Independent Consultant

After an established career at the FDA retiring as the Director, Division of Cosmetics and Compliance, Office of Cosmetics and Colors, Ms. Bailey joined the Personal Care Products Council (PCPC) as staff scientist. PCPC is the leading U.S. trade association representing 600 global cosmetics and personal care products companies. Ms. Bailey is an independent consultant with EAS Consulting Group, assisting clients with cosmetic labeling issues and color additives.

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Speaker

Victoria Pankovich
Manager, Regulatory Services

Victoria Pankovich supports clients through assembling and processing FDA submissions including Drug Master Files, Abbreviated New Drug Applications and New Drug Applications. Serve as the primary US Agent for all required communications with FDA on behalf of clients, including Establishment Inspection coordination with FDA, Drug, Medical Device and Food facilities registration; Drug and Medical Device product listings; Color Certification requests; FDA Inspection Notifications; FOI and FDA Controlled Correspondence requests.

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PART I : MoCRA Introduction

- Background
- Where are we now?
- What's coming soon?
- What's coming later?

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Why?

Part of FDA's mission is to protect public health.
Information helps agency with activities related to:

- Identifying companies involved in cosmetic manufacturing and distributing
- Safety Substantiation
- Post-market surveillance of adverse reactions
- Adding mandatory recall authority
- Monitoring of cosmetic products imported into USA

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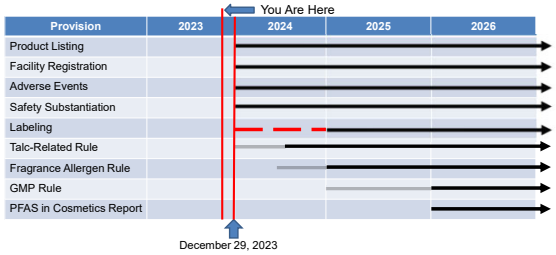
MoCRA Implementation Timeline



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PART 2 – Overview of FDA Guidance [FDA-2023-D-1716] August 2023

- https://www.fda.gov/cosmetics/cosmetics-news-events/fda-issues-draft-guidance-registration-and-listing-cosmetic-product-facilities-and-products
- https://www.regulations.gov/docket/FDA-2023-D-1716

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DEFINITIONS

- Contract Manufacturer
- Cosmetic Product
- Facility
- Manufacturing or Processing of a Cosmetic Product
- Operator
- Owner
- Responsible Person
- Small Businesses

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Q. WHO must register and submit a product listing?....

A. EVERYONE…. *With the following exceptions*

- A "Small Business"
- A Facility also subject to Drugs and Devices

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SUBMISSION OF WHAT?, HOW?, AND WHEN? WILL BE COVERED IN PART 3

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GUIDANCE – APPENDIX A
Cosmetic Product Categories and Codes (i.e. intended use)

- 21 CFR 720.4(c) lists the 12 that were used for the VCRP, e.g. Baby products, Bath preparations, Eye make-up preparations, etc..
- The new guidance lists 17 and includes much more elaboration
- New categories include makeup preparations for children, suntan preparations, and tattoo preparations, as well as "other"

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A sampling of issues raised in comments to the GUIDANCE

- Extension of Dec 2023 deadline
- Categories of Products
- FOIA concerns
- U.S. Agent

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PART 3 – Specifics of Registration and Product Listing

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Terminology

CDER Direct
Free on-line tool that allows drug firms to create and submit SPL files.

Cosmetics Direct
Free on-line tool that allows cosmetic firms to create and submit SPL files.

FDA Direct
Free on-line tool that allows firms to create and submit both drug and cosmetic SPL files.

ESG: Electronic Systems Gateway
An agency-wide solution and central transmission point for accepting secure electronic regulatory submissions over the internet. It's a conduit that automatically routes submissions to the appropriate FDA Center office.

SPL: Structured Product Labeling
A document mark-up standard adopted by the FDA as a mechanism for exchanging facility and product information.

XML: Extensible Markup Language
A markup language that defines a set of rules for encoding documents in a format which is both human-readable and machine-readable.

XForm
Authoring tool used for almost all SPL documents; requires ESG Webtrader Account.

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Unique Facility Identifier

DUNS (DATA UNIVERSAL NUMBERING SYSTEM)

- A unique, 9-digit identifier that verifies the existence of a business entity globally.
- Number assigned by Dun & Bradstreet for each physical location of business.
- Easy to obtain: Dun & Bradstreet support for FDA Registrants
- **Required** for CDER Direct and FDA Direct (combination CDER /Cosmetic Direct) accounts. **OPTIONAL** for Cosmetic Direct only accounts

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FEI (FDA ESTABLISHMENT IDENTIFIER)

- Number assigned to a facility by the FDA.
- You can search the FDA's FEI portal to see if your facility already has one assigned. If you do not find your company in this database, you can request an FEI by contacting feiportal@fda.hhs.gov and providing the required information.

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FEI (FDA ESTABLISHMENT IDENTIFIER)

Cont.

- Information required to request an FEI:
  - The legal name of the firm being registered.
  - Are you representing the firm as an Agent (third party)?
  - Any alternate firm names, including those used for "doing business as" purposes.
  - The physical address of the firm being registered.
  - The designated mailing address for the firm being registered.

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FEI (FDA ESTABLISHMENT IDENTIFIER)

Cont.

- Information required to request an FEI continued:
  - The name and contact information of the designated contact person at the facility being registered.
  - A comprehensive list of activities conducted at this specific location (e.g., drug manufacturing, food packaging, etc.).
  - Any registration numbers associated with other FDA Centers, if applicable.
  - Any former names the firm was known by.
  - Any previous addresses linked to the firm.

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Who must register?

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" (section III.A) **Exception to the exemption for the following types of cosmetic products:**
  - Cosmetic products that regularly come into contact with mucus membrane of the eye under conditions of use that are customary
  - 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
- 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).

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Information required for Establishment 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 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 (refer to Appendix A of the guidance document) 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 of the guidance document).

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Optional Information for Establishment Registration (requested but not required)

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

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Establishment Registration

Cosmetics Direct Sections

- Document Type Details
- Registration Details
- Confirmation Statement
- Additional Contact Information for Authorized Agent

- Cosmetics Direct online draft (Registration begins slide 8)

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Registration timing

Initial Registration

For establishments that were engaged in manufacturing or processing cosmetics on 29 December 2022, registration submission is required no later than 29 December 2023. For establishments that began operation after 29 December 2022, submission is required within 60 days of first engaging, or by 27 February 2024, whichever date is later.

Amended Registration

Changes to a registration must be updated in the system within 60 days of such change. This includes changes that result in cancellation of the registration.

Renewal of Registration

Registrations must be submitted biennially. (every two years)

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Who must list what?

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.

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" (section III.A)
- 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).

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Product Listing Required Information

- the facility registration number of each facility where the cosmetic product is manufactured or processed;
- 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;

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Product Listing Required Information cont.

- 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).

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Product Listing Optional Information (Requested but not required)

- 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); and
- additional contact information for individuals associated with the listing.

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Product Listing Number

(this number is autogenerated for each product)

- Required for all cosmetics
- Unique 12 digit, 3 section number per the program draft. Example:

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.

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Product Listing Number Cont.

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.

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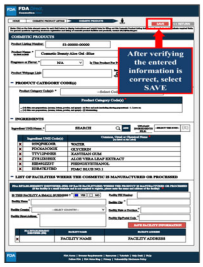
Example of a Complete Listing



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Product Listing

Cosmetics Direct Sections

- Document Type Details
- Cosmetic Products
- Confirmation Statement
- Additional Contact Information for Authorized Agent

- Cosmetics Direct online draft (Product Listing begins slide 42)

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Submission

SUBMISSION FAILED

- Response received within 20 minutes generally.
- Response provides feedback showing where error exists.
- Errors have codes; difficult to decipher sometimes.
- Self-Help section of Cosmetics Direct

SUBMISSION ACCEPTED

- Response received within 20 minutes generally.
- **Acceptance into the system is NOT THE SAME as "Approval" or "License"!**

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What's next?

Link to Cosmetics Direct draft screen shots

It is anticipated that the FDA will provide a training webinar after the programs for registration and listing have been released.

Firms can:

- Use Xforms and a Web Trader Account
- Try out Cosmetics Direct
- Hire a consultant!
  - For program training
  - To process on company's behalf

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Questions?

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Thank you