FDA Food Facility Registration and Unique Facility Identifiers (DUNS)

Mary Hancock
Director of Food Facility Registration

June 1st, 2023

Registrar Corp

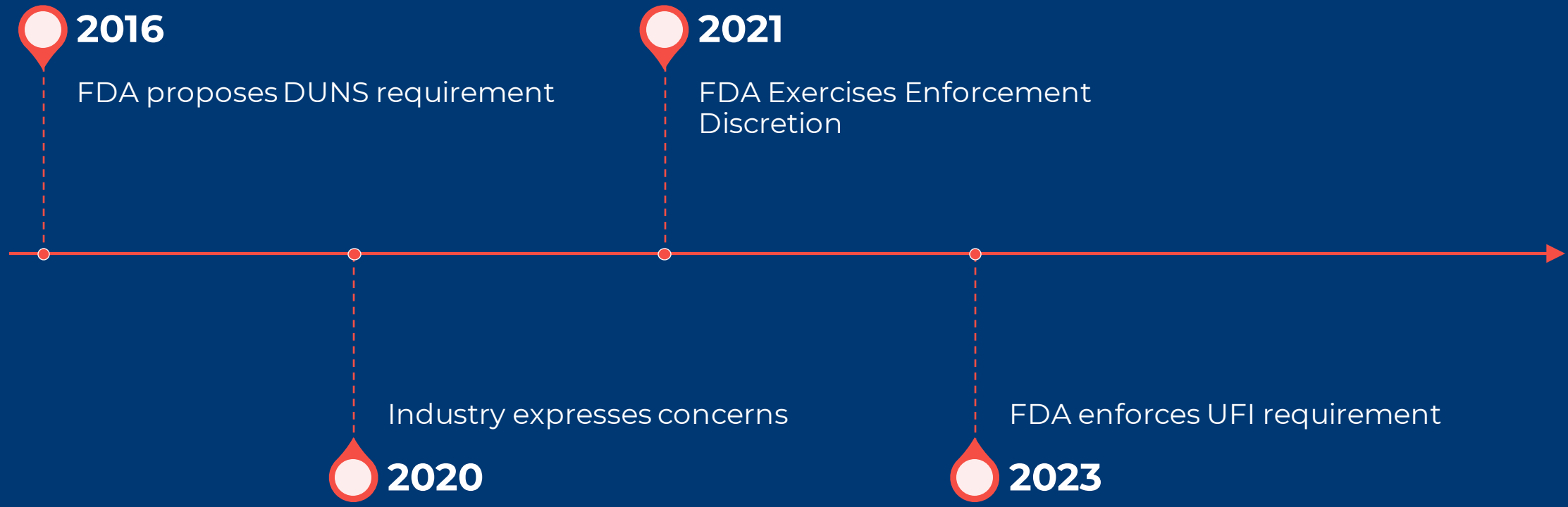
Background

1938
Federal Food, Drug and Cosmetic Act (FD&C)

2002
The Public Health Security and Bioterrorism Preparedness and Response Act

2011
The FDA Food Safety Modernization Act (FSMA)

FDA's Unique Facility Identifier: A Timeline



2022 Biennial Registration Renewal

FDA's Biennial Food Facility Registration period began on October 1, 2022 and ended on December 31, 2022.

Just like any of the previous 5 renewal periods, the DUNS number was not a required field.

What about DUNS?

Food Facility Registration Statistics

September 21, 2022

Valid Food Facility Registrations:

220,586

Domestic (U.S.) registrations:	99,451
Foreign registrations:	138,865

March 2, 2023

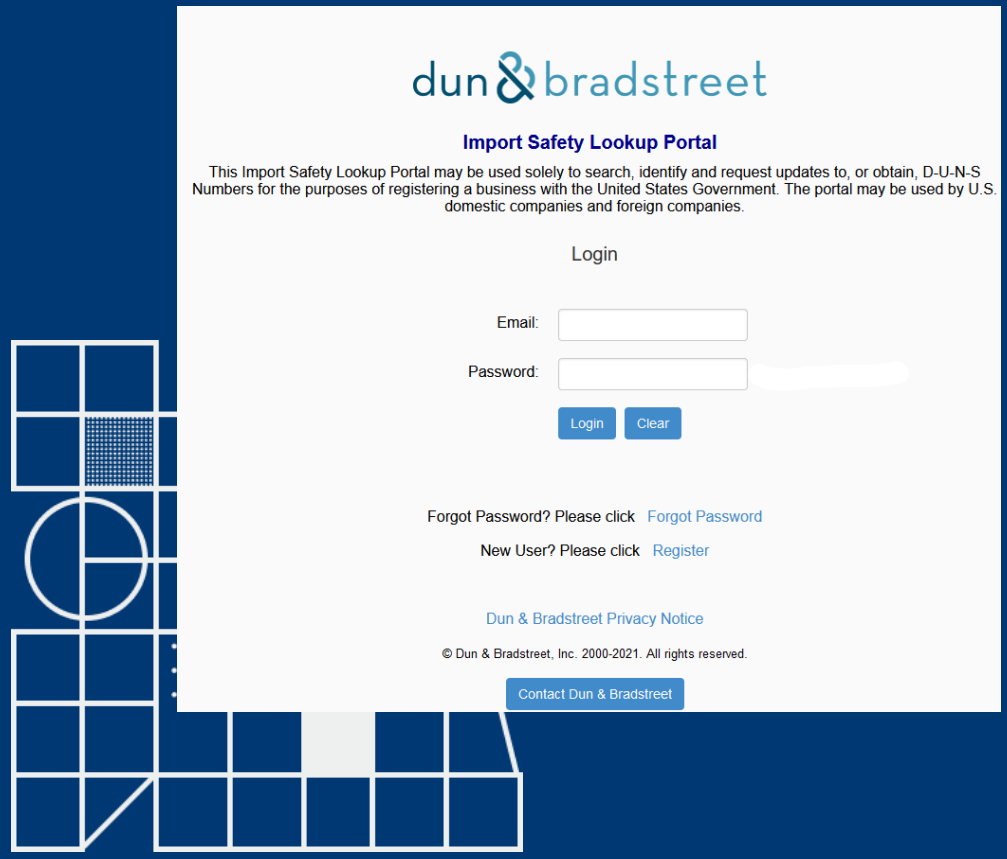
Valid Food Facility Registrations:

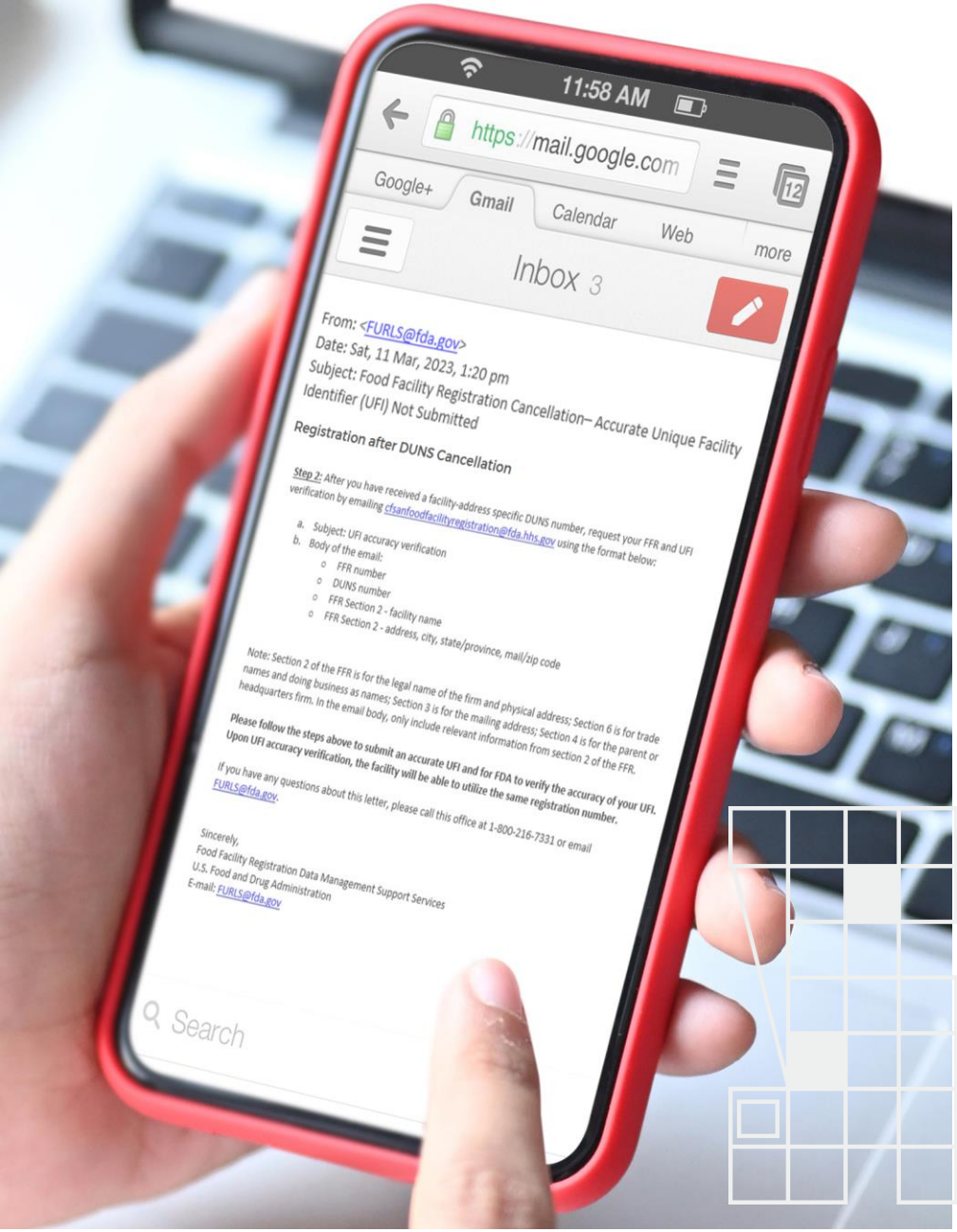
208,034

Domestic (U.S.) registrations:	87,729
Foreign registrations:	120,305

DUNS No Longer Optional for New Registrants

- FDAs proposed rule
- The comment period
- The Final Rule
- What is DUNS?

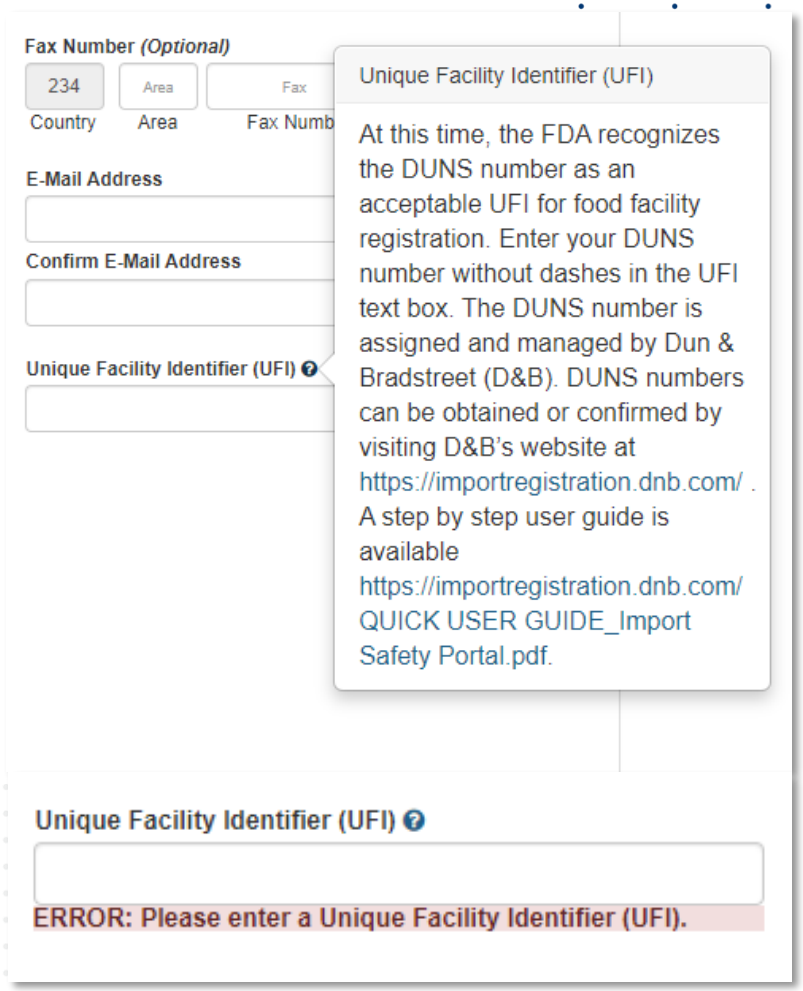




DUNS Enforcement; Reinstatement Process

FDA is *DONE* waiting for *DUNS*...

DUNS No Longer Optional for New Registrants



2020 Coronavirus Aid, Relief, and Economic Security Act or CARES ACT

New Requirements for Drug Manufacturers

Marco Theobald, Ph.D.
Director Drug and Medical Device Department

Melissa Sayers, M.S.
Senior Regulatory Specialist and Team Leader

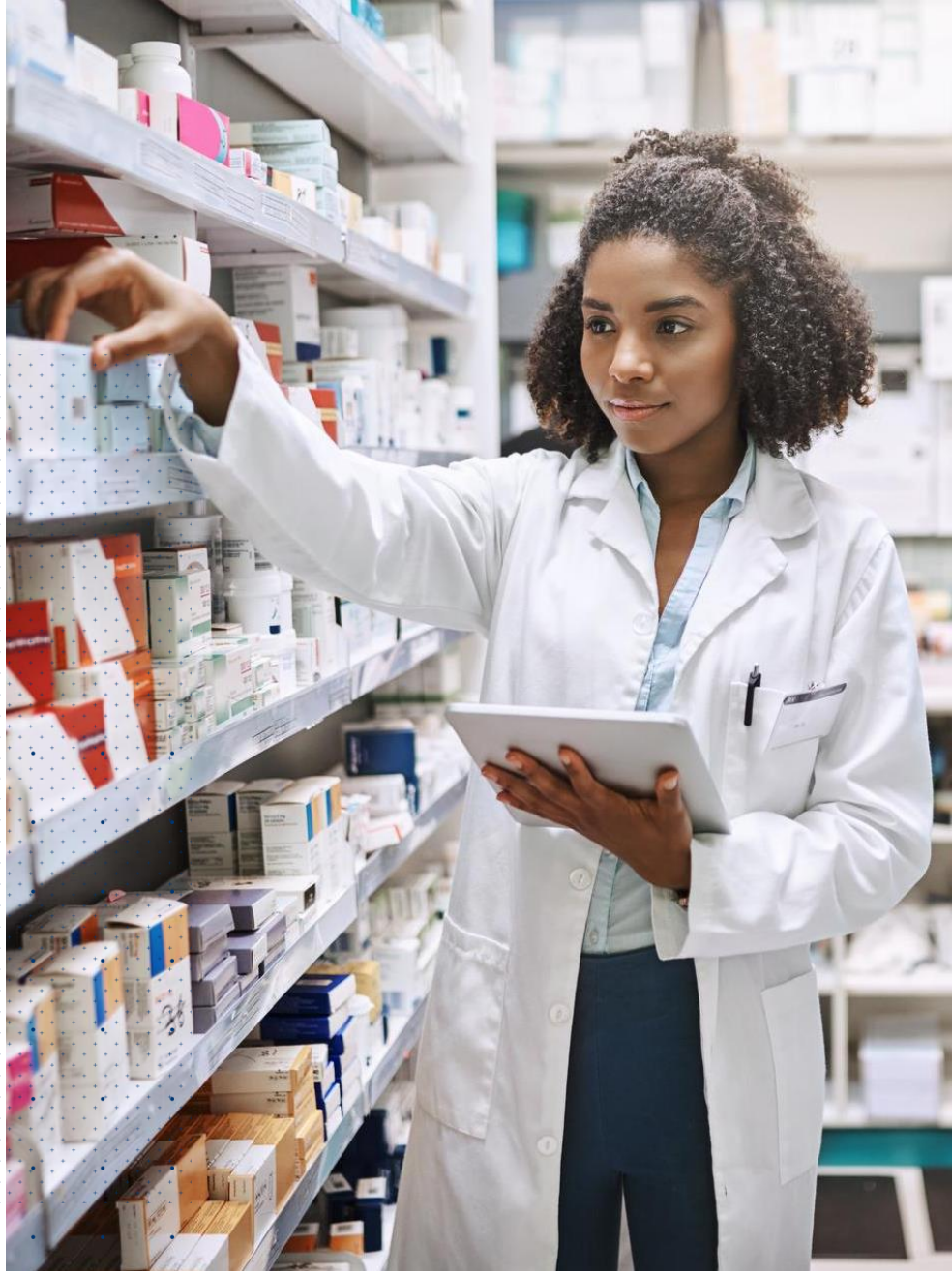
June 1st, 2023

Registrar Corp

What is a Drug?

A drug (medical product) is:

- Intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease or disease related condition;
- Intended to affect the structure or function of the body; and
- Achieves its primary function through chemical action.



Coronavirus Aid, Relief, and Economic Security (CARES) Act

- $2.2 trillion economic stimulus bill
- Signed into law on **March 27, 2020**, in response to the economic fallout of the COVID-19 pandemic in the United States

- Enhanced FDA's ability to identify, prevent, and mitigate possible drug shortages by improving FDA's visibility into drug supply chains:
    1. Reporting of the yearly manufactured amounts
    2. Over-The-Counter Monograph Drug User Fee Program (OMUFA) Fee

CARES Reporting

Each registrant that lists a drug must report to FDA annually on the amount of such drug for commercial distribution that it either:

- Manufactured
- Prepared
- Propagated
- Compounded
- Processed (Including re-packing and re-labeling)

The report should provide:

- The amount of each listed drug,
- identified by National Drug Code (NDC),
- that was released by each registered establishment during the reported year,
- organized by the amount of drug released in each month

Re-packers and re-labelers should also include in their reports, if available:

- The source NDC
  (i.e., the full three-segment NDC assigned to the drug received by the re-packer/re-labeler for re-packing or re-labeling)

Over-The-Counter Monograph Drug User Fee Program (OMUFA) Fee

What is a monograph?

What is a monograph drug?

An **OTC monograph** is a "recipe book" for each therapeutic category establishing conditions, such as active ingredients, uses (indications), doses, route of administration, labeling, and testing under which an OTC drug is generally recognized as safe and effective (GRASE).

An **OTC monograph drug** is a nonprescription, over-the-counter (OTC) drug that may be marketed without an approved drug application.

Who Pays the OMUFA Facility Fee?

The facility fee will be assessed for qualifying persons who own an OTC monograph drug facility, including contract manufacturing organization facilities.

The OTC Monograph User Fee program does ***not*** assess a facility fee for human OTC drug products that are produced under an approved drug application.

When is the facility fee due?

The facility fee is due annually on **June 1st**.

Will the Facility Fee be Assessed per Product Listing Submitted (Label), One Fee Per Formula, or One Per Facility?

The annual facility fee is assessed "**per facility**," in accordance with the definition of an OTC monograph drug facility.

OTC monograph drug facilities can include a contract manufacturing organization (CMO) facility.

A CMO facility is an OTC monograph drug facility where neither the owner nor any affiliate of the owner or facility sells the OTC monograph drug produced at such facility directly to wholesalers, retailers, or consumers in the United States.

OMUFA Fees for Fiscal Year 2023

$26,153

Monograph Drug Facility (MDF)

$17,435

Contract Manufacturing Organization (CMO) Facility

How Can a Product be Both a Cosmetic and a Drug?

Some products meet the definitions of both cosmetics and drugs. This may happen when a product has two intended uses.

For Example: Shampoo

Shampoo is a cosmetic: Its intended use is to cleanse the hair
Antidandruff treatment is a drug: Its intended use is to treat dandruff

Consequently, an antidandruff shampoo is both a cosmetic and a drug.

Other common cosmetic/drug combinations:

- Toothpastes that contain fluoride
- Deodorants that are also antiperspirants
- Moisturizers and makeup marketed with sun-protection claims

Such products ***must*** comply with the requirements for ***both*** cosmetics and drugs.

FDCA Section 613

For OTC Drug-Cosmetic Clarity for products that are both a drug and a cosmetic under the FDCA and related operations.

Newly-added section 613 makes clear that the drug requirements of chapter V of the FDCA apply instead of the cosmetic requirements of chapter VI.

Exception: Fragrance allergen disclosure and professional use labeling.

What's to Come for FDA Medical Device Regulations in 2023?

Mirna Calero

Manager, Medical Devices

June 1st, 2023

Registrar Corp

What We'll Discuss

FDA Establishment User Fee

Certificate of Foreign Government
Not Exported from United States (CFG-NE)

Changes in FURLS

COVID 19- Enforcement Policy

GUDID/UDI

FDA Establishment Fee

All establishments must pay the establishment registration fee.

There are no waivers or reductions for small establishments, businesses, or groups.

2023 Annual Establishment Registration Fee: $6,493

2021 User Fee	$5,546
2022 User Fee	$5,672
2024 Estimated User Fee	$6,875

Changes in FURLS/DRLM

Registration and listing information is submitted by using FDA's Unified Registration and Listing System (FURLS)/ Device Registration and Listing Module (DRLM).

The Device Listing section has added a column for Premarket Submission Number. Previously, it was Premarket Submission Number/Type in one column. See below.

Device Listings

Listing Number	Premarket Submission Number	Premarket Submission Type	Product Code(s)	Device Name(s)	Activities
A00001		510(k) exempt	NZH	Collector, urine, powered, non indwelling catheter	Repackager/Relabeler
B00001	K032575		DJG	Enzyme immunoassay, opiates	Manufacturer Repackager/Relabeler
			DKZ	Enzyme immunoassay, amphetamine	
			LCM	Enzyme immunoassay, phencyclidine	

Certificate of Foreign Government

A Certificate to Foreign Government is issued for legally marketed devices in the United States that are in compliance with the requirements of the Federal Food, Drug, and Cosmetic Act (FD&C).

Eligibility Note:

- Are cleared or approved by FDA for marketing in the U.S.
- May be legally commercially distributed in the U.S.
- May be a Class I, II, or III device
- Are listed with the FDA
- All devices must be exported from the United States

Certificate of Foreign Government—Not Exported from United States (CFG-NE) Continued...

Establishments requesting a CFG-NE should provide the following information on Form 3613g, including certifying that:

- Each device that appears on the certificate is manufactured by a device establishment located outside of the United States
- Each establishment that appears on the certificate is currently registered under section 510 of the FD&C Act
- Each establishment has listed each of the medical devices that appear on the certificate, as required by Section 510(j) of the Act and 21 CFR Part 807
- Each device(s) identified herein is authorized to be marketed within the United States and

Certificate of Foreign Government—Not Exported from United States (CFG-NE) Continued...

Establishments requesting a CFG-NE should provide the following information on Form 3613g, including certifying that:

- Each device is imported or offered for import into the United States;
- Each device(s) identified is not subject of an open import alert, recall, seizure, injunction, or the subject of any other open enforcement action initiated by the FDA;
- Manufacturers, contract manufacturers, and contract sterilizers involved in the manufacturing process, if applicable, have been identified;
- The requesting establishment and all establishments involved in the manufacturing process are operating in substantial compliance with the Current Good Manufacturing Practices Requirements (Section 520(f) of the FD&C Act) for the identified device(s).

Certificate of Foreign Government—Not Exported from United States (CFG-NE) Continued...

Fees

Section 801(e)(4)(B) of the FD&C Act authorizes the FDA to charge a fee for each certification that is issued within 20 government working days.

Fees for each certificate issued by the FDA:

- First certificate: $175
- Each subsequent certificate: $85.00

Certificates are provided on anti-counterfeit paper with an embossed gold seal.

Note: Be mindful of page limits for certificates.

COVID-19 Enforcement Policy

Based on current COVID-19 trends, the Department of Health and Human Services (HHS) is planning for the federal Public Health Emergency (PHE) for COVID-19, declared under Section 319 of the Public Health Service (PHS) Act, to expire at the end of the day on **May 11, 2023**.

FDA recognizes that it will take time for device manufacturers, device distributors, healthcare facilities, healthcare providers, patients, consumers, and FDA to adjust from policies adopted and operations implemented during the COVID-19 public health emergency (PHE) to “normal operations.”

After **May 11**, the FDA granted companies 180 days to comply with FDA regulations. The new deadline will be **November 7, 2023**.

It is the FDA's recommendation that companies begin the transition process as soon as possible.

COVID-19 Enforcement Policy Continued...

List of most common EUAs:

- Enforcement Policy for **Face Shields, Surgical Masks, and Respirators** During the Coronavirus Disease (COVID-19) Public Health Emergency. https://www.fda.gov/media/166100/download
- Enforcement Policy for **Gowns, Other Apparel, and Gloves** During the Coronavirus Disease (COVID-19) Public Health Emergency. https://www.fda.gov/media/136540/download
- Enforcement Policy for **Sterilizers, Disinfectant Devices, and Air Purifiers** During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency. https://www.fda.gov/media/136533/download
- Enforcement Policy for **Ventilators and Accessories and Other Respiratory Devices** During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency. https://www.fda.gov/media/136318/download
- Enforcement Policy for **Viral Transport Media** During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency. https://www.fda.gov/media/140300/download

The FDA continues to reach out to companies affected by this new regulation to bring them into compliance with it.

A final order was issued by the FDA on November 21, 2021, regarding the reclassification of the following product codes for Blood Lancets devices from Class I exempt to Class II 510K required:

- FMK - Single use only blood lancet with an integral sharps injury prevention feature
- QRK – Single use only blood lancet with an integral sharps injury prevention feature
- QRL – Multiple use blood lancet for single patient use only
- QRM – Multiple use blood lancet for multiple patient use

Reference: https://www.federalregister.gov/documents/2021/11/22/2021-25376/medical-devices-general-and-plastic-surgery-devices-reclassification-of-blood-lancets

GUDID / UDI – Consumer Health Products

The UDI compliance date for class I devices was December 8, 2022. This compliance date, however, did not affect all Class I devices.

While FDA is not enforcing GUDID submissions for Consumer Heath Products, we have noticed that some companies are submitting devices, such as sunglasses, to FDA's GUDID system.

Please reference FDA's UDI public database, AccessGUDID: https://accessgudid.nlm.nih.gov/

"Based on an analysis, FDA generally does not intend to enforce the GUDID submission requirements under 21 CFR 830.300 for class I consumer health product devices."

A consumer health product is defined as follows:

"510(k)-exempt class I devices that are exclusively sold directly to consumers over-the-counter in both brick-and-mortar and online stores. These devices are typically labeled with a UPC, which may serve as the UDI for class I devices (21 CFR 801.40(d))."

The Modernization of Cosmetics Regulation Act of 2022 (MoCRA)

Jaclyn Bellomo

Director, Cosmetics Services and Software

June 1st, 2023

Registrar Corp

AGENDA

Path to MoCRA

Industry Trade Organizations and beauty brands have been lobbying Congress for a cosmetic regulatory reform for over a decade to get regulations for cosmetic products in the United States.

FDA updates & Legislative Summary

VCRP updates, FDA reorganization, and an overview of how MoCRA will transform cosmetic regulations and the significant changes that require action as early as this year.

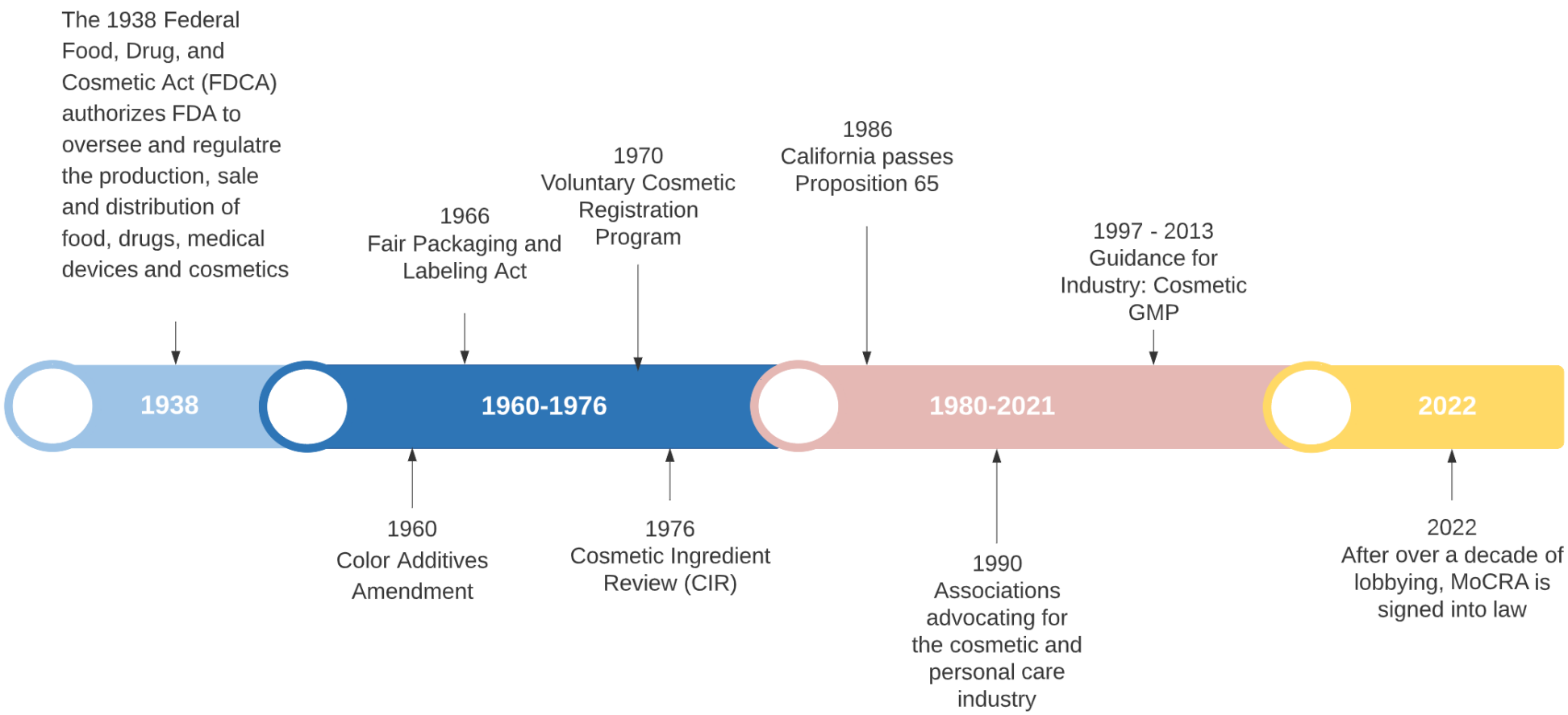
What's Next?

Who is responsible for key regulations and what does implementation look like in the coming months and years.

Q & A

Answer questions asked from our cosmetic community. These questions can help educate and prepare for the upcoming regulations.

PATH TO MoCRA



Key MoCRA Definitions

Responsible Person

Facility

Safe Cosmetic

Serious Adverse Event

Key MoCRA Definitions

Responsible Person

The term **“responsible person”** 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.

In terms of MoCRA, the “responsible person” will be responsible for the cosmetic product listing, adverse events, safety substantiation, labeling, and fragrance allergen disclosures and records.

Key MoCRA Definitions

Facility

The term **“facility”** includes any establishment (including an establishment of an importer) that manufactures or processes cosmetic products distributed in the United States.

A facility will be responsible for facility registration and GMP compliance issued by FDA.

There are exclusions and exemptions to some facilities that need registration.

Key MoCRA Definitions

Safe Cosmetic

The term **“safe”** means the cosmetic product and its ingredients are not injurious to users under the conditions of use prescribed in the labeling or when used in a customary or usual manner.

FDA will not consider a cosmetic ingredient or product injurious to users solely because it can cause minor and transient reactions or minor and transient skin irritations in some users.

Key MoCRA Definitions

Serious Adverse Event

The term **“serious adverse event”** means an adverse event that results in or requires medical intervention to prevent:

- Death or life-threatening experience
- An infection or in-patient hospitalization
- A persistent or significant disability or incapacity
- Congenital anomaly or birth defect
- Significant disfigurement other than as intended, under conditions of use that are customary or usual, such as:
  - Serious, persistent rashes or infections;
  - Second- or third-degree burns;
  - Significant hair loss; or
  - Persistent or significant alteration of appearance

FDA Updates & Legislative Summary

VOLUNTARY COSMETIC REGISTRATION PROGRAM

- The Voluntary Cosmetic Registration Program (VCRP) is no longer accessible for new submissions as of March 27, 2023
- FDA is working on a brand-new software solution to submit facility registrations and product listings
- Data from VCRP will not be migrated over to the new system
- All registrations and product listings will need to be done regardless of whether they were entered into VCRP previously

FDA OFFICE OF COSMETICS AND COLORS REORGANIZATION

- The Office of Cosmetics and Colors (OCAC) is currently under the Center for Food Safety and Applied Nutrition (CFSAN)
- OCAC will move to the FDA Office of the Chief Scientist which sits within the FDA Office of the Commissioner
- FDA's Chief Scientist, Dr. Bumpus will be leading MoCRA implementation
- FDA has launched a dedicated MoCRA website to support the industry during the rulemaking process

Cosmetic Facility Registration and Renewal

- Mandatory FDA registration for owners and operators of facilities that manufacture or process cosmetic products for U.S. distribution.
- Existing facilities will have **1 year** from the date of enactment to register their facility with FDA.
- New facilities must register within 60 days of marketing a product or 60 days after the deadline for registration, whichever is later.
- Foreign facilities will need a U.S. Agent for registration
- Renewal with updates every **2 years**

Cosmetic Product Listing and Renewal

- The responsible person must submit a mandatory product listing to FDA for each cosmetic product.
- Flexible listings will allow for a single submission for multiple cosmetic products.
- The responsible person must renew a product listing **annually** with any updates.

New Cosmetic Labeling Requirements

- Product labels must be updated to include:
  - **A U.S.** address,
  - **A U.S.** phone number, or
  - Electronic contact information in which a responsible person can receive adverse event reports.
- For professional cosmetic products, labels must indicate a clear and prominent statement that the product is administered or used only by licensed professionals and is in conformity with the existing cosmetic labeling requirements.
- Cosmetic products that contain fragrance allergens ***must*** update their label to list those allergens.

FRAGRANCE ALLERGENS

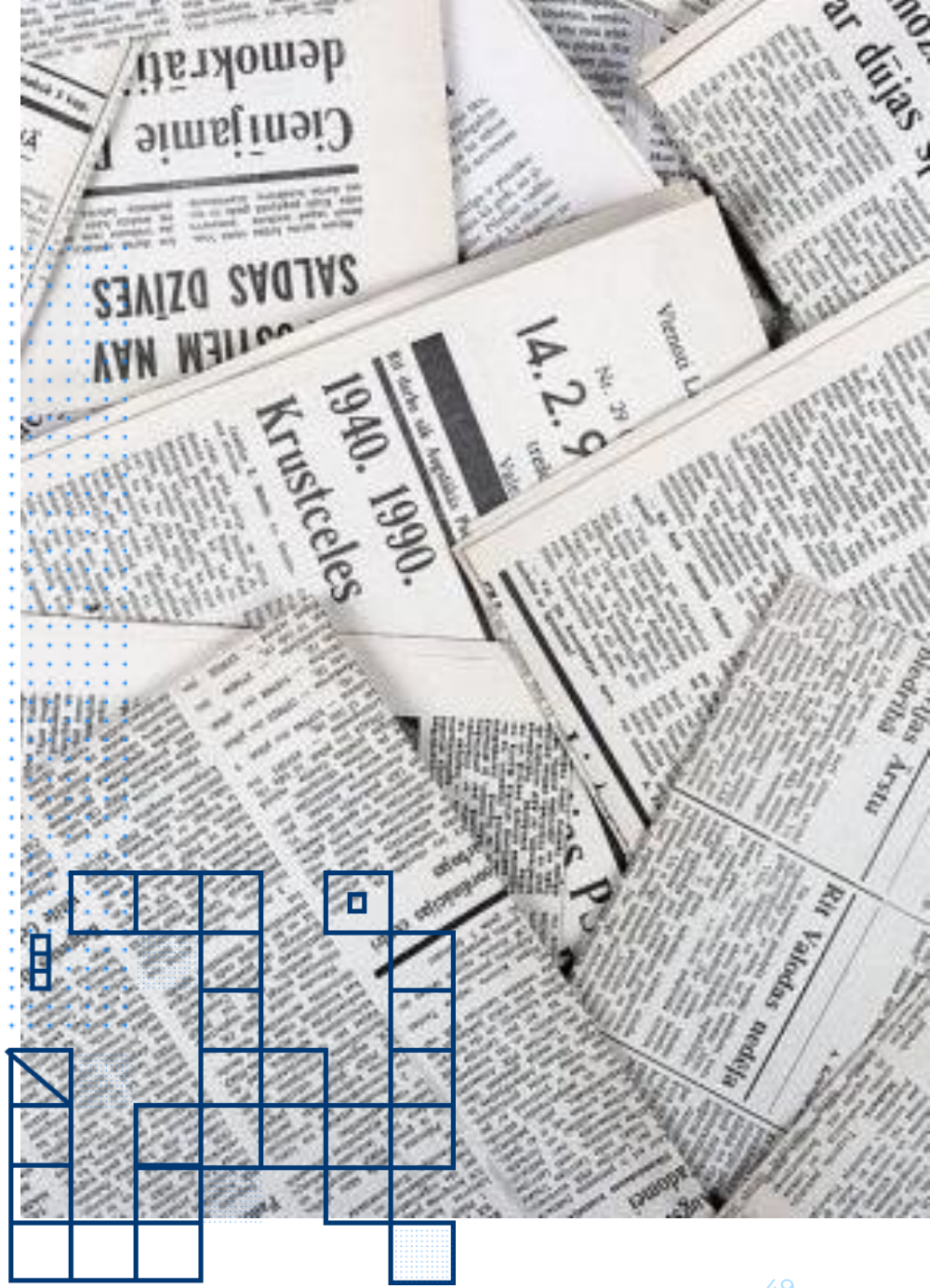
- Fragrance Allergens will be determined by FDA and will need to be identified on the label of a cosmetic product
- The cosmetic product will be deemed misbranded if it does not list required allergen information
- FDA must consider international, State, and local requirements, including EU requirements
- Responsible Persons will need fragrance allergen disclosures and provide record access if deemed necessary by the Secretary

Talc-containing Cosmetics and PFAS in Cosmetics

- All talc-containing cosmetics will be required to adhere to an established standardized testing method for detecting and identifying asbestos.
- Using scientific evidence, all PFAS substances will be assessed for safety of use in cosmetic products, including associated risks.
- Toxicological research can be included in this assessment.

Adverse Event Reporting

- In the event of a serious adverse event associated with a cosmetic product, the responsible person must submit a report, accompanied by a copy of the label on or within the retail packaging.
- MoCRA broadens the scope of what constitutes a serious adverse event to account for considerations relevant to the cosmetics sector.
- Serious adverse events include those that result in or require medical intervention to prevent death, infection, disfigurement, disability and other significant negative effects.



Adverse Event Record Keeping

- Records of adverse event reports must be maintained for 6 years, and FDA must be able to access them during inspections.
- If considered a small business, the responsible person is required to maintain records for 3 years.
- FDA may request a written list of all ingredients in the product's fragrances or flavors if it believes an ingredient or combination of ingredients has caused serious adverse events.

Good Manufacturing Practices (GMP)

- MoCRA requires FDA to establish Good Manufacturing Practices (GMPs) that are intended to protect the public's health and ensure that cosmetic products are not adulterated.
- Such regulation will allow FDA to inspect facilities and review all records that it deems necessary to verify compliance with GMP as prescribed by FDA.
- MoCRA also includes provisions for a “simplified” (less stringent) GMP for smaller businesses.
- Products deemed adulterated if not manufactured consistent with GMP requirements.

Cosmetic Safety Substantiation

- Companies must maintain records supporting adequate safety substantiation for their cosmetic products.
- FDA cannot consider a product unsafe solely because of minor and short-term reactions in some users.
- A product will be deemed adulterated if this requirement is not met

Inspections and Records Access

- FDA has long had the authority to inspect cosmetic facilities under section 704 of the FD&C Act
- MoCRA adds specific records access provisions for FDA's inspections:
    - FDA has the authority to access records relating to a cosmetic product under certain circumstances
    - FDA may request a list of ingredients in a product's fragrances or flavors if they may have contributed to a serious adverse event
    - Record access does not include Cosmetic formulas and recipes, administrative, or research data
    - FDA does not have inspection authority to access financial data or sales data

Mandatory Recall Authority

- FDA may issue a Mandatory Recall if the secretary determines that there is:
    - A reasonable probability that a cosmetic is adulterated or misbranded
    - The use or exposure to such cosmetic will cause serious adverse health consequences or death
- The Secretary shall provide the Responsible Person with an opportunity to voluntarily cease distribution and recall such article
- If the responsible person refuses to or does not voluntarily cease distribution or recall such cosmetic, FDA may issue a mandatory recall

Facility Suspension

- FDA may suspend a facility's registration requiring the facility to cease distribution of all cosmetic products if FDA:
    - Determines that a cosmetic product manufactured or processed by a registered facility and distributed in the United States has a "reasonable probability" of causing serious adverse health consequences
    - There is reasonable belief that other products manufactured or processed by the facility may be similarly affected because of failure that cannot be isolated to a product or products manufactured by the facility
- Before suspending a facility's registration, FDA will provide notice and an opportunity for the facility to be heard at an informal hearing

STATE LAW UNIFORMITY

- MoCRA prevents any state or local laws that differ on:
  - Registration
  - Product listing
  - Good Manufacturing Practice
  - Records
  - Recalls
  - Adverse Event Reporting
  - Safety substantiation
- States may continue to limit or ban use of cosmetic ingredients in cosmetic products and may continue ingredient reporting requirements that predate MoCRA

Small Business Exemptions

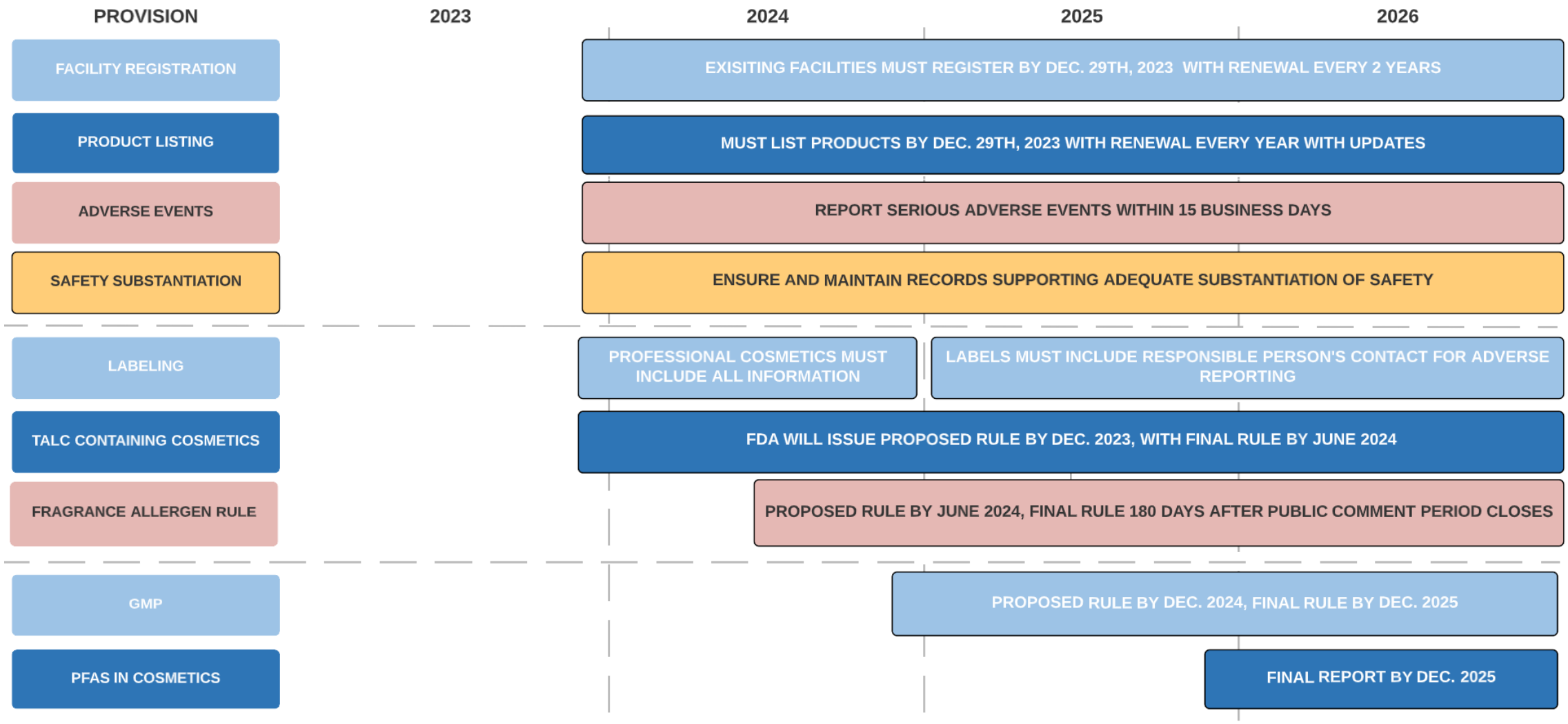
- FDA defines small businesses as:
  - Those with average gross annual sales for the previous 3-year period totaling less than $1,000,000.
- Small businesses are exempt from certain regulations:
  - Not subject to the requirements of sections 606 (GMP) or 607 (Registration and Listing).
  - Adverse event record keeping for 3 years.

WHAT'S NEXT?

Who is Responsible?

- Facilities will be responsible for registration, Good Manufacturing Practices, Inspections, Recalls, and Records Access
- The Responsible Person will be responsible for product listings, adverse event reporting, safety substantiation, labeling, and fragrance allergen disclosures
- Suppliers of cosmetic ingredients may be required to supply safety substantiation testing or analysis on ingredients, fragrance allergen disclosures, animal testing declarations, testing for asbestos in Talc, and toxicological data on PFAS

WHAT'S NEXT TIMELINE



TIME FOR SOME Q&A

HOW REGISTRAR CORP CAN HELP

Cosmetic Product Listings with Annual Update

Facility Registration, U.S. Agent, and Renewal

Label Review

Adverse Event Reporting

Cosmetri Product Manager Software

Cosmetri GMP Software – ISO 22716

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