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HOW DOES MOCRA AFFECT THE COSMETICS INDUSTRY?

February Webinar - 2024

U.S. COMMERCIAL SERVICE
United States of America Department of Commerce

wit ORANGE COUNTY

EDC | ECONOMIC DEVELOPMENT COLLABORATIVE

AMERICA'S SBDC CALIFORNIA
LOS ANGELES NETWORK

EDC SBDC
GO GLOBAL TRADE PROGRAM

AMERICA'S SBDC CALIFORNIA
LOS ANGELES NETWORK

EDC ECONOMIC DEVELOPMENT COLLABORATIVE

EDC GGTP
Go Global Trade Program

The Economic Development Collaborative hosts the Small Business Development Center and is funded in part through a cooperative agreement with the U.S. Small Business Administration, a Grant with the California Office of the Small Business Advocate and by the Workforce Development Board of Ventura County.

AMERICA'S SBDC CALIFORNIA
LOS ANGELES NETWORK

POWERED BY SBA
U.S. Small Business Administration

WORKFORCE DEVELOPMENT BOARD of Ventura County

CALIFORNIA OFFICE OF THE SMALL BUSINESS ADVOCATE

EDC SBDC GO GLOBAL TRADE PROGRAM

The EDC SBDC Go Global Trade Program is part of the LA SBDC Network, is hosted by EDC SBDC, serves Los Angeles, Ventura, and Santa Barbara counties, and **provides no-cost focused one-on-one technical advising** to businesses interested in accessing international trade opportunities **in the following areas:**

- Developing an Export Plan
- Developing a Global Marketing Strategy
- Export/Import Regulations
- Export/Import Documentation (eUCP/eURC)
- International Financing
- International Distribution and Logistics
- International Market Research and Digital Marketing
- E-commerce Digital Tools that help you go Global
- Manufacturing Consulting
- Foreign Direct Investment Consulting

This program is **no-cost** to businesses interested in accessing international trade opportunities and includes focused **one-on-one technical advising**. To connect with an LA SBDC international trade specialist, call **1.805.409.9159** or email **info@edcollaborative.com**.
For more information visit **www.edcollaborative.com**.

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EDC SBDC GO GLOBAL TRADE PROGRAM - Business Assistance

EXPORT ASSESMT. & INT'L MKT

ECOMMERCE STRATEGY

International Marketing Strategy

Marketing Research

Low Budget Marketing Plan

EXPORT CAPACITY

Export Capital

Team Dynamics

Production Capacity & Processes

Your Why, Scope, Scale

Decision Making

Supply Chain

Bus. Culture

DOMESTIC PRESENCE

Marketing Research & Strategy

Price Strategy

Legal – Regs & IP

Accounting

Production Capacity & Processes

Operating Capital

SBA Export Loans

Export Market Plan & Implementation Plan

Export Assessment

Production Capacity for Export

Develop Trade Assistance Network

Export Success

Omnichannel eCommerce

Designated Export Staff

Amazon & Digital Mkt.

Cross Border Ecommerce

STEP/ICEP Grant

Other Gov. Grants

WUSATA

U.S. Regs Compliance

Export Legal Services

Foreign Regs Compliance

IP & Trademark

Customs, Logistics, Freight Forwarding

Shipping Documents for U.S. & Foreign

TRADE REGULATIONS

VC Financing

PO Financing

EXIM Bank Export Credit Insurance & Loans

EXPORT FINANCING

AMERICA'S SBDC CALIFORNIA LOS ANGELES NETWORK

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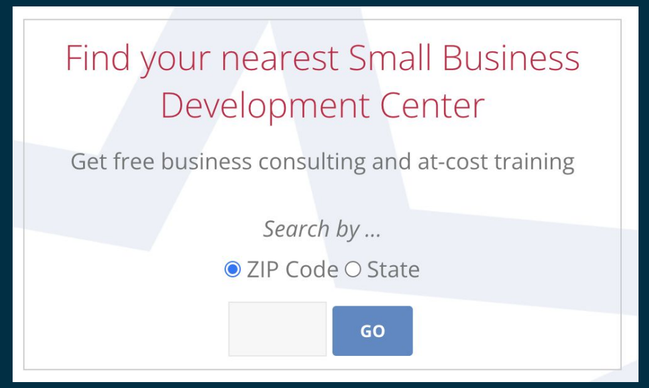
https://americassbdc.org/find-your-sbdc/



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Thank You

WOMEN IN INTERNATIONAL TRADE ORANGE COUNTY (WITOC)

owit ORANGE COUNTY

WITOC is a non-profit organization founded in 1985 and an affiliate chapter of the Organization of Women in International Trade (OWIT). Our mission is to foster international trade and the advancement of women in business. For over 35 years we have served the Southern California trade community as an educational resource providing our members and their guests with a variety of opportunities to learn about current international trade issues and to make valuable contacts with other professionals involved in the field of international trade.

OWIT Chapters host programs and events enabling their members to learn, network, and forge professional relationships in their business communities. Once you are a member of the local OC chapter (WITOC), you will automatically become a member of OWIT's international global network, which is comprised of individual members in chapters located throughout the world - over 3000 global members across 27 chapters.

www.witoc.org

www.owit.org

www.linkedin.com/in/witoc

outreach@witoc.org

WITOC MEMBERSHIP BENEFITS

- OWIT Membership
- Access to OWIT Events
- Discounted Rate to WITOC Events

- Network With Trade Professionals
- Enhance Leadership Skills Via Committee & Board Participation

WHAT IS MoCRA?

The Modernization of Cosmetics Regulation Act of 2022 gives the FDA expanded power to regulate cosmetics. The aim of MoCRA is to improve the safety of cosmetics products for US consumers.

NEW REQUIREMENTS

- **Adverse Event Reporting**
- **Facility Registration**
- **Product Listing**
- **Safety Substantiation**

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FDA'S DEFINITION OF A COSMETIC

The Federal Food, Drug & Cosmetic Act (FD&C Act) defines cosmetics as "articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body…for cleansing, beautifying, promoting attractiveness, or altering the appearance."

A product's directions for customary use, ingredients, and formulation impact whether it is considered a cosmetic.

EXAMPLES OF COSMETICS:

- Perfume and cologne
- Fingernail polish
- Manicure preparations such as cuticle creams
- Hair dyes and colors
- Facial moisturizers
- Face creams
- Foundations and powders
- Blush and rouges
- Lipstick
- Eye shadows and liner
- Mascara
- Children’s makeup, including face paint, lipsticks and lip glosses, colored hairsprays, face powders, eye shadows, and blushes

Surprising Products the FDA Considers Cosmetics

Although not an all-inclusive list, you may be surprised to learn that the below items are considered a cosmetic product by the FDA.

Baby Products

Baby wipes, shampoos, lotions, creams, and powders

Bath and Shower

Bath salts, oils, tablets, bubble baths, and bath capsules

Dental Products

Toothpastes and mouth rinses

Personal Cleanliness

Bath soaps and body washes, underarm deodorants, disposable wipes, douches, and talcum powders

Shaving Preparations

Bath salts, oils, tablets, bubble baths, and bath capsules

Tattoo Products

Both permanent and temporary tattoo inks and other preparations

How Will the FDA Regulate These Products?

- Requires cosmetic companies to register with the FDA and list their ingredients
- Gives FDA the authority to order recalls of unsafe products
- Sets new standards for good manufacturing practices for cosmetic manufacturers
- Requires cosmetic companies to submit safety data to the FDA

RESPONSIBLE PERSON

WHAT IS A RESPONSIBLE PERSON?

A manufacturer, packer, importer, or distributor of a cosmetic must designate a “responsible person” as a point of contact with FDA.

A “responsible person” is the name of the manufacturer, packer, or distributor whose contact name, US address, telephone number, or electronic information appears on the label of the product.

WHAT IS THEIR PURPOSE?

The responsible person serves as the central point of accountability, ensuring the product adheres to safety and labeling regulations from its entry into the US market to its post-market monitoring and reporting.

COMPLIANCE RESPONSIBILITY

IMPORTANT

- Product registration and ingredient listing
- Facility registration
- Adverse event management
- Adverse event documentation
- Regulatory interactions and market control

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WHAT IS AN ADVERSE EVENT?

MoCRA defines an adverse event as any health-related event associated with the use of a cosmetic product that is harmful or negative.

Serious adverse events must be reported to the FDA within 15 business days.

Serious Adverse Events can include:

- Infection
- Hospitalization
- Disability or incapacity
- Congenital anomaly or birth defect
- Significant disfigurement including rashes, burns, or hair loss
- A life-threatening experience
- Death
- Medical interventions to prevent any of the above from happening

Adverse Event Reporting implementation began December 29, 2023.

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FACILITY REGISTRATION

Manufacturers and processors must register their facilities, whether domestic or foreign, with the FDA and renew their registration every two years.

MoCRA grants the FDA the ability to suspend the registration of facilities if it is determined that the products manufactured or processed there have a reasonable probability of producing serious adverse events.

Owners or operators of facilities must register by July 1, 2024.

PRODUCT LISTING

The information to be submitted in a cosmetic product listing can include:

- The facility registration number where the cosmetic product is manufactured or processed
- The name and contact number of the responsible person
- The name of the cosmetic product
- The cosmetic category
- A list of ingredients for the cosmetic product, including any fragrances, flavors, or colors, with each ingredient identified by name
- The product listing number, if previously assigned

Ingredient updates must be reported annually. Product listings must be submitted by July 1, 2024.

SAFETY SUBSTANTIATION

A responsible person is required to keep documentation that demonstrates evidence that the cosmetic products are safe for consumers.

Additionally, MoCRA requires compliance with:

- Fragrance allergen labeling requirements
- The FDA will assess the use of PFAS in cosmetic products, the safety of their use in cosmetic products, and any risks associated with their use
- Standardized testing methods for detecting and identifying asbestos in talc-containing cosmetic products

SAFETY SUBSTANTIATION TIMELINES

The responsible person must document and maintain safety substantiation records of their products starting **December 29, 2023.**

Mandatory fragrance allergen labeling requirements are **expected to be proposed by July 1, 2024**, with implementation expected in **early 2025**.

The FDA is expected to publish a report summarizing the results of the safety assessment on PFAS in cosmetic products by **December 29, 2025.**

The FDA is still working on developing a proposed rule for standardized testing to identify asbestos in talc-containing cosmetic products under MoCRA.

GOOD MANUFACTURING PRACTICES (GMP)

Good manufacturing practices cover a variety of best practices:

- Records and documentation
- Buildings and facilities
- Equipment and utensils
- Personnel experience and education
- Raw materials
- Written manufacturing and control SOPs
- Laboratory controls
- Effective procedures and internal audits
- Product complaints and consumer adverse event reporting

GOOD MANUFACTURING PRACTICES TIMELINE

Current: Nonbinding, voluntary guidance designed for manufacturers and distributors to self-assess their cosmetics operations

December 29, 2024: FDA is expected to release draft guidance on binding guidance on Good Manufacturing Practices

December 29, 2025: FDA is expected to release final decisions on binding Good Manufacturing Practices

POTENTIAL EXEMPTIONS

Small Businesses

A small business is defined as responsible persons, 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).

What is Exempt?

- Good Manufacturing Practices (GMP)
- Registration
- Product listing requirements

NOT Exempt

- Products that regularly come into contact with the mucus membrane of the eye
- Products that are injected or designed for internal use
- Products that alter the appearance for over 24 hours

PRODUCT SAFETY RESPONSIBILITY

MoCRA emphasizes manufacturer and distributor responsibility. The FDA has no authority for pre-market approval of cosmetic ingredients or products beyond already existing regulations for color additives.

MoCRA empowers manufacturers to ensure safety while granting the FDA tools for post-market monitoring and intervention when necessary.

Under MoCRA's framework, consumer safety is a shared goal between manufactures and the FDA.

HOW DOES MOCRA AFFECT THE COSMETICS INDUSTRY?

MoCRA grants the FDA increased regulatory oversight, resulting in enhanced consumer protection, transparency, and cosmetoviligence.

Industry challenges and adaptations:

- Some products may need reformulation or new packaging and marketing materials to meet stricter safety standards or labeling requirements

- Cosmetic companies may see increased costs as they implement MoCRA requirements and guidance, such as facility upgrades, personnel training, product testing, and robust safety and reporting documentation

- The industry will find new ways to innovate and market amid increasing consumer demand for safety and transparency

Benefits of MoCRA For Sellers

Increased Consumer Trust

Increased transparency and product safety measures can build trust and loyalty among customers seeking safe and regulated cosmetics

Product Safety

MoCRA marks a significant step towards data-driven accountability to protect US consumers. Safe products can enhance brand reputation and minimize the risks of product recalls.

Operational Excellence

By complying with MoCRA safety substantiation processes and GMPs, sellers can potentially increase their operational efficiency.

Innovation

Through MoCRA, the FDA continues to be a strong advocate to refine, reduce, and replace animal testing with alternative methodologies. This incentivizes research and adoption of alternative methods, opening doors for new safety assessments, technologies, and efficient use of data.

Recommendations for Importers

The FDA will continue to release guidance and documentation as they finalize MoCRA procedures, particularly for how to submit needed documentation. All shareholders should stay aware of the evolving guidance.

Potential increased documentation requirements for shipments destined for the United States could possibly impact shipping times and costs.

Under MoCRA, the FDA can refuse entry of cosmetic products from suspended facilities, which may cause delays and potential economic losses.

MoCRA aligns more closely to international cosmetic standards, which could potentially streamline and harmonize import-export processes.

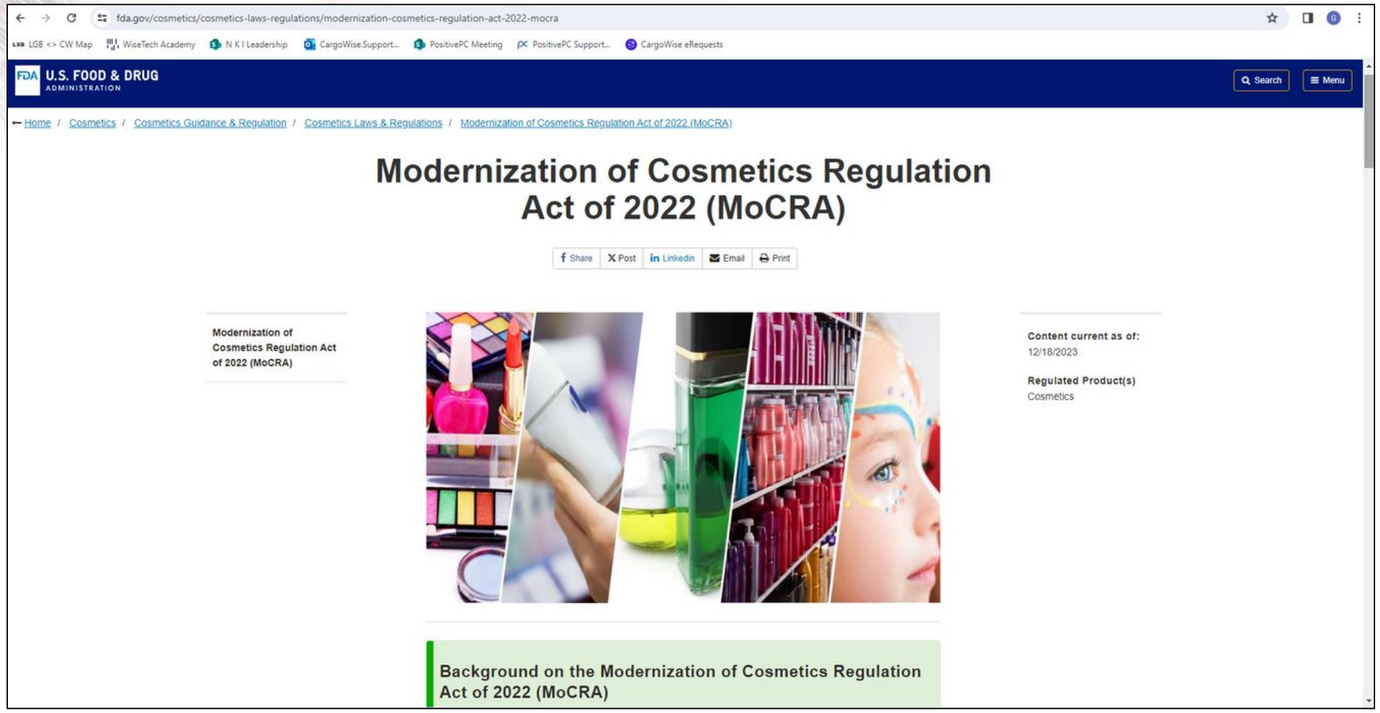
Confer with consultants or legal professionals specializing in product regulations who can offer further guidance.

Visit the FDA Website

Visit the FDA's website for MoCRA for more information and details, updates, portals, and documents.

- *Explore the FDA electronic submission portal*:
  : the electronic submission portal for registration and listing of cosmetic facilities and products

- *Monitor when current hard-copy forms become available on an electronic submission portal*:
  - Currently, the Serious Adverse Event Report form is only available as a PDF on the website
  - The FDA is developing a process for submitting electronic



HAVE OTHER QUESTIONS?
GET IN TOUCH WITH US!

We understand the complexities of cosmetic distribution, such as handling and tracking high volumes of product, understanding temperature and flammable components restrictions, and ensuring on-time delivery at a competitive cost.

Contact Marquis Blanc, Director of Client Services
mblanc@nkinc.com

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www.nkinc.com

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Finding New Export Markets

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U.S. Commercial Service Domestic Footprint

We have over **106** Export Assistance Offices in the United States.

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HERE TO SUPPORT YOUR EXPORT BUSINESS.

Export Counseling

- Develop effective market entry and sales strategies.
- Understand export documentation requirements and import regulations of foreign markets.

Market Intelligence

- Analyze market potential and foreign competitors.
- Obtain useful information on best prospects, financing, laws, and cultural issues.
- Conduct background checks on potential buyers and distributors.

Business Matchmaking

- Promote your product or service to prospective buyers at trade events worldwide.
- Meet with international industry and government decision makers in your target markets.

Commercial Diplomacy

- Overcome trade obstacles to successfully enter international markets.
- Benefit from coordinated U.S. government engagement with foreign governments to protect U.S. business interests.

Foreign Direct Investment Attraction

- Advise local EDOs on investment promotion strategies

Common Export Challenges and Issues

“How Tos”	Int’l Customs	Export Documentation	Certificates of Free Sale/Origin
Getting Paid & Finance Tools to Leverage	Regulatory Processes	Find Customers / Distributors	Due Diligence on Partners
Market Research	Government Procurements	Market Access Issues / Standards	In-Country Advice
Protocol / Business Norms	Data	Scam Avoidance	Intellectual Property

Q&A
PLEASE SUBMIT YOUR QUESTIONS

THANK YOU!

Comments or Suggestions?

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