



4 KEY STEPS TO COMPLIANCE

PREPARING FOR THE MODERNIZATION OF COSMETICS REGULATION ACT (MOCRA)

GUIDANCE TO BRAND OWNERS & FACILITIES SELLING
IN THE USA | VERSION 1.1 (NOVEMBER 2023)

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1. Understand the requirements

MoCRA Requirement	2023	2024	2025	2026
Adverse Events	Prepare systems to receive and respond to adverse events	Brand owners retain adverse event records and report SAEs		
Safety Substantiation	Collaborate to prepare safety substantiation of products	Retain records, respond to enquiries from FDA		
Product Registration	Brand owners register product listing and ingredients	Maintain and keep up to date		
Facility Registration	Manufacturers register facilities and products made	Maintain and keep up to date		
Product Labelling	Prepare labeling to include contact details for adverse events	Ensure labelling is compliant, note FDA fragrance allergen proposal	Ensure updated labelling compliance	
Fragrance Allergens		FDA proposal of fragrance allergens	Ensure compliance	
Asbestos in Talc		FDA proposal of a method for detecting asbestos in talc	Ensure compliance	
GMPs			FDA proposal of Good Manufacturing Practices	Ensure compliance
PFAS				FDA reports on PFAs in cosmetics



BRAND OWNERS AND FACILITIES OWNERS REQUIREMENTS

OBELIS USA LLC

The following action steps are required by December 29, 2023.

Brand owners must:

Establish a system for consumers who purchase a product in the US, and have an adverse event, for example hair loss, a skin rash or other reaction, to be able to contact the brand owner and send details of the product and the event. The system must include the following functions:

- Provide contact details to the consumer
- Receive and evaluate reports of adverse events
- Report serious adverse events to the FDA within 15 business days of being notified
- Retain records for 6 years (3 years for brand owners with annual sales <1 million)
- Hold records available for examination by the FDA

Brand owners must:

- Maintain records of safety substantiation of all products on sale in the US
- Ensure that safety substantiation files are up-to-date and complete

Our recommendation, in line with industry best practice, is to adopt the European Cosmetic Product Safety Report as the model for products you sell on the US market.

Brand Owners must:

Register product details with the FDA. The following data needs to be collected for each product on sale in the US market:

- Facility registration number where the product is made
- Name and contact number of responsible person, details also to be included on the product label
- Product category
- List of ingredients identified by name, including fragrances, flavors or colors
- Families of products may be grouped together if they differ only in color, fragrance, flavor or quantity of contents

Note that the responsible person is defined in MoCRA as: “the manufacturer, packer, or distributor of a cosmetic product whose name appears on the label of such cosmetic product”. This means that the owner of the brand name on the cosmetic product is the responsible person.

The product listing will be kept up to date after initial registration.

Facility owners must:

Register product details with the FDA. The following data needs to be collected for each facility making product on sale in the US market:

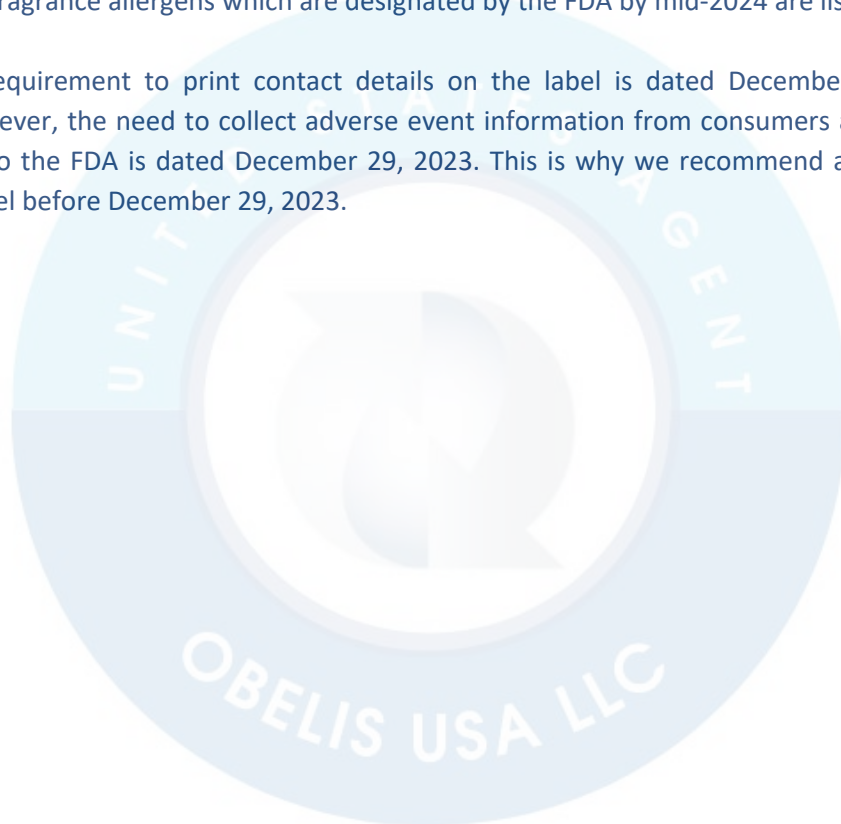
- Facility name, address, email and telephone number
- Foreign sites need to be registered, with contact details for a US based agent
- Brand name, product category and responsible person for each product manufactured
- Contract manufacturers only need one registration number to serve multiple brand owners

We anticipate a very high demand for registering both products and facilities when the FDA makes the registration web address available. To avoid business interruptions, we advise collecting the information now so that it is available to upload at the first opportunity.

Brand owners must:

- Ensure that labeling includes contact details for consumers to notify them of adverse events
- Ensure that fragrance allergens which are designated by the FDA by mid-2024 are listed on the label

Note that the requirement to print contact details on the label is dated December 29, 2024 in the regulations. However, the need to collect adverse event information from consumers and report serious adverse events to the FDA is dated December 29, 2023. This is why we recommend adding the contact details to the label before December 29, 2023.



4 KEY STEPS TO COMPLIANCE

OBELIS USA LLC



1. Designate a US Agent / US Consultant

Facilities which are manufacturing or processing cosmetic products for the US market and are located outside the US, are required to appoint a US Agent before December 29, 2023.

The contact details for the US Agent must be included when the facility registers. When the facility appoints Obelis USA as the US Agent, then these details can be registered at the same time as Obelis registers the facility with the FDA.

Brand owners who do not have a US office are required to put on the label of each cosmetic product, the US address, US phone number, or electronic contact information, including website, to receive adverse event reports. Obelis USA are available for this purpose, and to provide a service to review reports of adverse events, notify serious adverse events to the FDA, co-ordinate investigations between the brand owner, manufacturing facility and the FDA, and retain records for the necessary period of time.

Brand owners who do have a US office may prefer to appoint Obelis USA to review reports of adverse events, report serious adverse events to the FDA, co-ordinate investigations between the brand owner, manufacturing facility and the FDA, and retain records for the necessary period of time, as a service provider. This solution may be more cost-effective for you as the brand owner, than creating the capability in-house.

2. Work on your Substantiation

MoCRA includes the following definition: “Adequate substantiation of safety means tests or studies, research, analyses, or other evidence or information that is considered, among experts qualified by scientific training and experience to evaluate the safety of cosmetic products and their ingredients, sufficient to support a reasonable certainty that a cosmetic product is safe.”

The FDA is directed by MoCRA to adopt international standards wherever practicable, consistent with meeting its responsibilities for public health in the US market. The European Cosmetic Product Safety Report is widely accepted. We recommend the following two steps:

- If you have a CPSR supporting a European variant of the product you are placing on the US market, review the CPSR to ensure that it is up-to-date, accurate, complete and applies also to the US variant
- If you do not have a CPSR for one of your products, begin immediately the process of creating a file, using the European CPSR as a model

3. Prepare your Product Listing

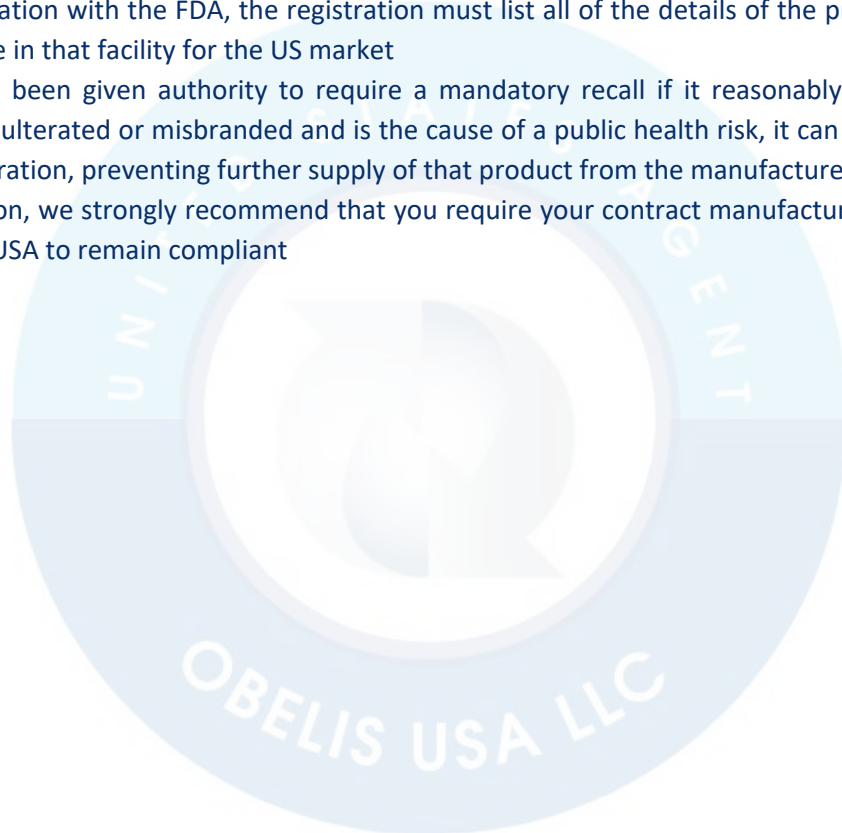
We anticipate a very high demand once the FDA launch their registration website, possibly overwhelming the available bandwidth. In order to ensure that we are able to be at the front of the line when registering, we highly recommend collecting the data now in a machine-readable format – e.g. Excel spreadsheet.

- See item number 1, above for details of the information to be provided to Obelis so that we can register your products at the earliest available opportunity

4. Contact your Facilities

Given that the manufacturing facility for each of your products must be registered with the FDA, we strongly suggest that you ensure that contract manufacturers you use are fully compliant. Obelis USA is ready to train your contract manufacturers and to act as US Agent or Consultant, as outlined in point 2 above.

- Note that a contract manufacturer which manufactures for more than one brand owner needs a single registration with the FDA, the registration must list all of the details of the products and brand owners made in that facility for the US market
- The FDA has been given authority to require a mandatory recall if it reasonably believes that the product is adulterated or misbranded and is the cause of a public health risk, it can also withdraw the facility registration, preventing further supply of that product from the manufacturer
- For this reason, we strongly recommend that you require your contract manufacturers to seek advice from Obelis USA to remain compliant





APPENDIX 1 MOCRA CHECKLIST

OBELIS USA LLC

Creating a System for Recording Adverse Events and Reporting Serious Adverse Events:

Identify who will be nominated on the label so that consumers can notify the brand owner of adverse events (AE). Identify who will evaluate the AE for – 1) level of frequency of reaction consistent with exposure levels in the population of target users; 2) out-of-trend result which requires investigation; 3) level of reaction which raises the AE to Serious. Identify the communication flow between brand owner, responsible formulator, manufacturer, representative (Obelis) and the FDA.

Products	Contact Name for Adverse Events (AEs)	Contact Phone Number for AEs	Contact Address for AEs	Contact Web Address for AEs	Name of Person who will evaluate AEs	Name of Key Technical Contact in Brand Owner for Investigations	Name of Person Who will Report Serious AEs to FDA	Location of Records of AEs	Contact Details to get Access to Records if Needed

Maintain Records of Safety Substantiation:

Identify who will collect the data. List the products on sale in the USA, grouping families together. Product families are a group of product which contain the same ingredients, but vary by color, flavour or fragrance eg shades of foundation. Review existing safety substantiation file eg European Cosmetic Product Safety Report (CPSR) and whether or not it is fully up-to-date with the current formula. Review whether or not the USA variant(s) of the product is/are covered by the file. Identify who will lead additional work on safety substantiation, with target dates, track progress and identify where the records will be held in case of a request by the FDA to review them.

Products	Family Y/N	Current Safety Substantiation Exists Y/N	Current Safety Substantiation Up-to-date Y/N	USA Variant(s) Covered Y/N	Additional Safety Substantiation Required Y/N	Name of Person who will Lead Safety Substantiation	Target Date for Safety Substantiation Report	Safety Substantiation Complete Y/N	Contact Details to get Access to Safety Substantiation Report

Product Listing:

Identify who will gather your information. Gather the following for each product. Add more rows as needed.

Product Name	Manufacturing Facility Registration Number	Name of Responsible Person (Brand Owning Company)	Phone Number of Responsible Person (Brand Owning Company)	Product Category	List of Ingredients by Name – in Label Order (Largest Quantity to Smallest)	Number of variants if the Product is a Family (shades, odors, etc)

Facility Registration:

Identify who will gather your information. Engage your manufacturing location, which will need to collect the following information for each product they make, to be registered with the FDA. Ensure that your manufacturing location gathers all of the data below for each product, or let Obelis do work with the manufacturer as the appointed US Agent (for locations outside the US).

Note that the manufacturing registration number is given to the manufacturing location as the time of registration with the FDA. A contract manufacturer, who makes for multiple brand owners needs only one registration number. Add more rows as needed.

Product Name	Manufacturing Facility Name	Manufacturing Facility Address	Manufacturing Facility Email Address	Manufacturing Facility Phone Number	US Agent Name	US Agent Address	US Agent Phone Number	US Agent Email Address	Product Category	Responsible Person

Labelling:

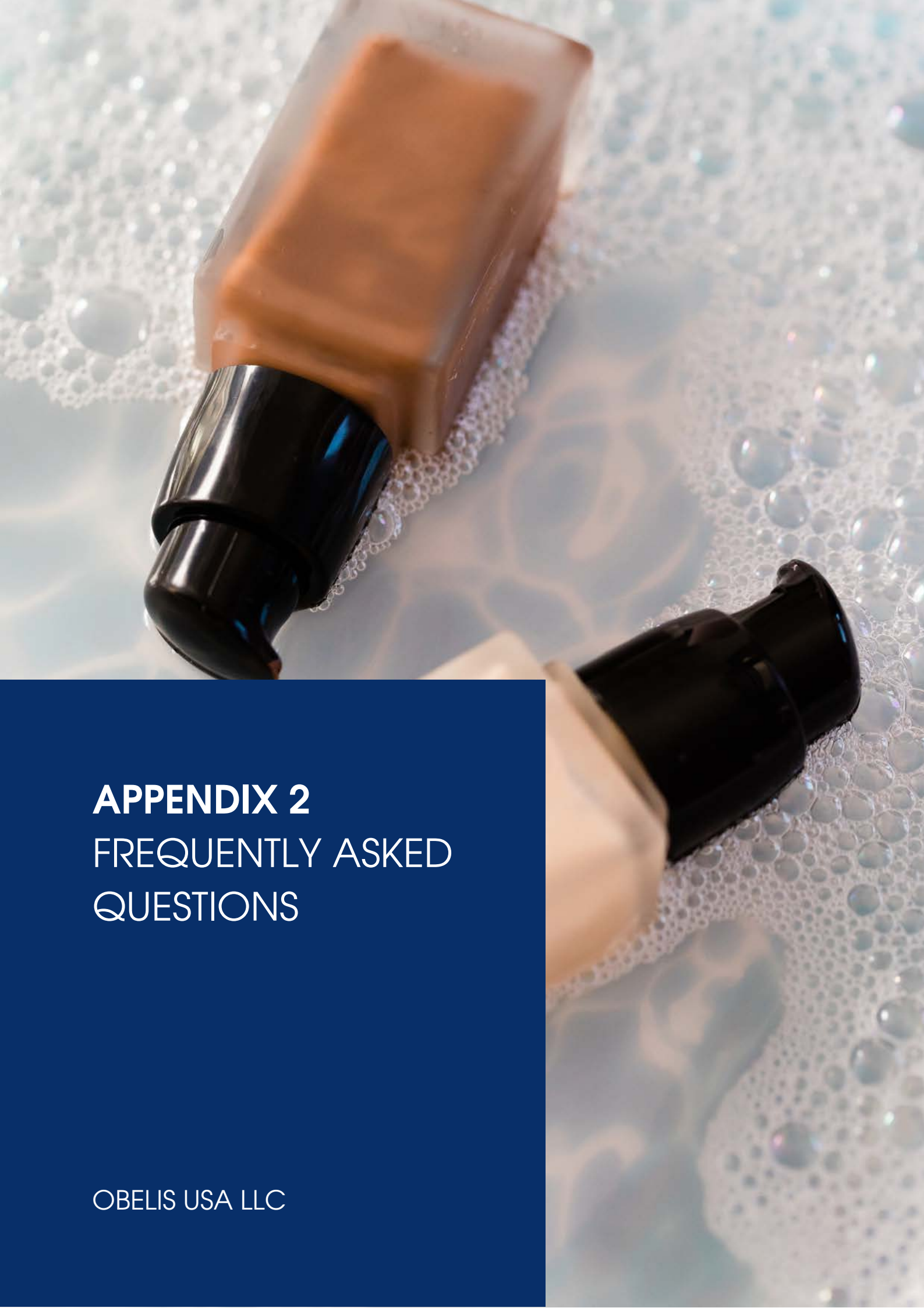
Identify who will lead the effort to make labels compliant for receiving Adverse Events (AEs). Identify the US address and telephone number or electronic contact information (web URL address) to receive AEs, refer to the table for handling AEs for the next steps in this process. Identify who will take responsibility for modifying the label artwork and/or developing a sticker, and track progress.

Products	US Address to Receive Adverse Events (AEs)	US Phone Number to Receive Adverse Events (AEs)	Electronic Contact Details to Receive Adverse Events (AEs)	Contact Name for Adverse Events (AEs)	See Adverse Event Handling Table	Name of Person who will Modify Label Artwork	Target Date for New Label Artwork or Sticker	Label Artwork Reviewed and at Printers Y/N	Label Artwork On Current Production

Identify who you want Obelis to communicate with when the FDA proposes and then finalizes the list of fragrance allergens. Identify who will review formulations and highlight any that contain ingredients on the list of fragrance allergens. Identify who will follow the process in the second half of the labelling table above to modify product labels to keep them compliant.

Products	Name of Person to be informed About Fragrance Allergens	Name of Person to Review Ingredients for Fragrance Allergens	Name of Person to Review Ingredients for Fragrance Allergens	See Second Part of Labelling Table Above

Finally, translate the above work processes into SOPs which include the requirement to keep registration, adverse event reporting, safety substantiation and labeling up to date with new product launches, range extensions, sourcing location changes etc.



APPENDIX 2
FREQUENTLY ASKED
QUESTIONS

OBELIS USA LLC

I don't believe that the FDA have time to create the registration website in time to give industry the opportunity to register all of their products and facilities, and that this will delay the deadlines in MoCRA, what do you think?

Like you, I'm aware that many large changes similar to this one, suffer from delays to the original deadlines, and I certainly can't say to you that the FDA will definitely create the registration website and process in time for all of the data to be entered by all of the companies around the world before December 29, 2023. However, I do know that the number of companies which have to register is huge, and potentially overwhelming to the website when the FDA launch it. The data which we have to enter on your behalf is already defined by MoCRA, so to avoid a business interruption for you when the deadline arrives, we want to make sure that we have all of your information in a format which can easily be uploaded as early as possible so that when the FDA release the details of registration, we can serve you best by being at the front of the queue to load data and get the facility registration number which is needed on both product and facility registration.

I'm going to wait for the FDA to give more information before we start working on compliance with MoCRA, what do you think?

The FDA has created a special Office of Cosmetics, reporting to the Chief Scientist. It is a much smaller group of people than the number of FDA people dedicated to drugs or foods for example. They will have their hands full over the next couple of years getting the registration process up and running, deciding what to do about Good Manufacturing Procedures, which they have to propose and finalize, and handling (serious) adverse event reporting as well as enforcing the new regulations. I believe that we will have to operate with what we know from the FDA today, and in fact, we already know a lot about what information has to be registered, what we have data we have to collect about adverse events and report to the FDA if those events are serious, how to substantiate the safety of products. Our strong recommendation is to get started, because there are a lot of different parts of the regulation, all coming into effect over the next few years, which we need to stay ahead of to prevent any business interruption caused by non-compliance.

I've never heard of MoCRA before you started talking to me about it, and I know my contract manufacturer isn't aware, what should we do?

Every company in the world which is responsible for a cosmetic product which is on sale in the US is now covered by this new regulation, so I'm not surprised if it takes time for the news to spread. We suggest that you give us contact details of your manufacturing locations so that we can talk to them and educate them about their responsibilities. By December 29, 2023 all manufacturing locations will need to be registered with the FDA and have a registration number. As a brand owner, you will have to register your product details including the facility number of the manufacturing locations you use. We can help you to avoid any problems of non-compliance by working with you and your supply chain. That way we can make sure that you can continue to sell your products in the US.

The FDA hasn't said what we have to do to substantiate the safety of our products, what do you suggest?

MoCRA directs the FDA to make use of existing international standards wherever possible provided these standards protect the public health of the American consumers. It also says that safety substantiation means that “tests or studies, research, analyses, or other evidence or information that is considered, among experts qualified by scientific training and experience to evaluate the safety of cosmetic products and their ingredients, sufficient to support a reasonable certainty that the product is safe.” They have not defined what data has to be held in the file. They only say that recognized experts will have enough data to reach a conclusion that the product is safe. It is clear to us that large parts of industry will be extending the European CPSR to cover their USA products, and we advise our clients to do the same.





What do we ensure?

Product compliance and sales in the EU, UK and US markets



What are we going to do?

We will ensure your cosmetic products meet the regulatory requirements



We will review your product documentation, formulas, laboratory tests and labels

We will complete products registration (CPNP, SCPN, FDA listing) and assume the role of your RP/US Agent – This will allow your products to be made available on the respective markets



**ANY COMPLIANCE
CHALLENGE (EU/UK/USA)?**

TALK TO US

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