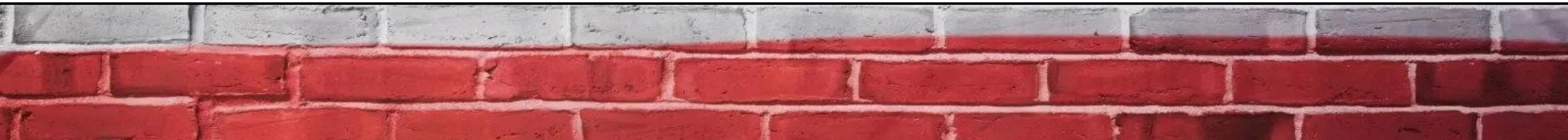
COSMETICA ITALIA SERVIZI

MoCRA e FDA Cosmetics Direct. Come presidiare correttamente i nuovi requisiti regolatori USA

22 marzo 2024



- *MoCRA: modalità e tempistiche della conformità ai nuovi requisiti della cosmetica negli USA*

- *le principali novità:*
  - *registrazione stabilimento*
  - *listing dei prodotti*
  - *Good Manufacturing Practices (GMP)*
  - *Valutazione della sicurezza*
  - *nuovi requisiti di etichettatura*
  - *reporting degli eventi avversi*
  - *tenuta dei registri*

- *In pratica!*

I riferimenti normativi

approvata dal Congresso degli Stati Uniti il 23 dicembre 2022

Gli emendamenti MoCRA al capitolo VI del *Federal Food, Drug, and Cosmetic Act* (FDCA) costituiscono la prima importante modifica sui cosmetici dal 1938 ed introducono 10 nuove sezioni in aggiunta alle 3 già presenti

La nuova legge consente ora alla FDA di esercitare maggiore autorità sulle aziende cosmetiche.

Records Access: l'FDA può avere accesso alla documentazione (Safety Substantiation).

Mandatory Recall Authority: l'FDA può richiedere il ritiro dal mercato di un prodotto ritenuto non sicuro o provvedere essa stessa al richiamo.

MoCRA
MODERNIZATION OF COSMETIC REGULATION ACT

H. R. 2617—1389

Subtitle E—Cosmetics

SEC. 3501. SHORT TITLE.

This subtitle may be cited as the "Modernization of Cosmetics Regulation Act of 2022".

https://www.fda.gov/cosmetics/cosmetics-laws-regulations/modernization-cosmetics-regulation-act-2022

Why MoCRA?

… 1938 !!!

normativa frammentata

scarsa protezione per i consumatori

sicurezza del prodotto non dimostrata e non documentata

FDA: limitato potere d'azione

… 1938 !!!

normativa frammentata

scarsa protezione per i consumatori

sicurezza del prodotto non dimostrata e non documentata

FDA: limitato potere d'azione

COSMETICA ITALIA SERVIZI

Un impatto di rilievo per la filiera

Chi?

- ✓ Produttori
- ✓ Confezionatori
- ✓ Distributori
- ✓ Importatori

Cosa?

- ✓ US Responsible Person
- ✓ Registrazione di prodotti (listing), produttori e attori della filiera
- ✓ Adverse Effects (Cosmetic Survey)
- ✓ Safety Substantiation (*documentata!*)
- ✓ Etichettatura (obbligo di indicare gli allergeni)
- ✓ Ispezioni dell'FDA

Un impatto di rilievo per la filiera

Come?

- ✓ Federal Food, Drug, and Cosmetic Act:
  10 nuove sezioni e aggiornamenti alle 3 già presenti
- ✓ FDA: maggiore autorità sulle aziende cosmetiche

Quando?

- ✓ tutti gli obblighi: 29 Dicembre 2023
- ✓ etichettatura: 29 Dicembre 2024
- ✓ Registrazione: 30 Giugno 2024


U.S.
Responsible
Person

U.S. Responsible Person

- referente unico delle autorità
- registrazioni: *product listing*, *facility registration*
- gestione dei *Serious Adverse Events*
- Safety Substantiation
- competenze specifiche in ambito regolatorio
- deve avere un referente locale! (US Agent)

<u>Valutare con attenzione la nomina di un distributore locale per</u>:

- confidenzialità delle informazioni sui prodotti/fornitori
- affidabilità delle sue competenze regolatorie e scientifiche
- esperienza e capacità nel rapporto con le autorità e nella conservazione dei dati

ARE YOU READY FOR

REGISTRATION?

Registrazioni: non solo brand

Facility Registration

- ✓ produttori e attori della filiera produttiva
- ✓ da rinnovare ogni 2 anni

Esistenti	**Nuove**
registrarsi entro il 30 giugno 2024	registrarsi entro 60gg dalla messa in funzione

Aggiornamenti entro 60gg

Informazioni necessarie

- nome, indirizzo, e-mail e numero di telefono
- contatto della U.S. RP alla quale i prodotti fanno riferimento
- categorie cosmetiche dei prodotti realizzati e riferimento delle U.S. RP per ogni prodotto
- eventuale numero di registrazione pregresso
- nomi dei brand realizzati

Registrazioni: prodotti e ingredienti

Product Listing

- ✓ U.S. *Responsible Person*
- ✓ info su prodotti e ingredienti
- ✓ da aggiornare ogni anno

Informazioni necessarie

- Facility Registration Number
- Nome e contatto della U.S. RP, come appare sul prodotto
- Categoria cosmetica
- Elenco degli ingredienti
- Product listing number eventualmente pregresso

Una premessa: registrarsi è facile?

Chi fa cosa e come?

COSMETIC FACILITIES

FEI number e registrazione

FEI Number e Registrazione

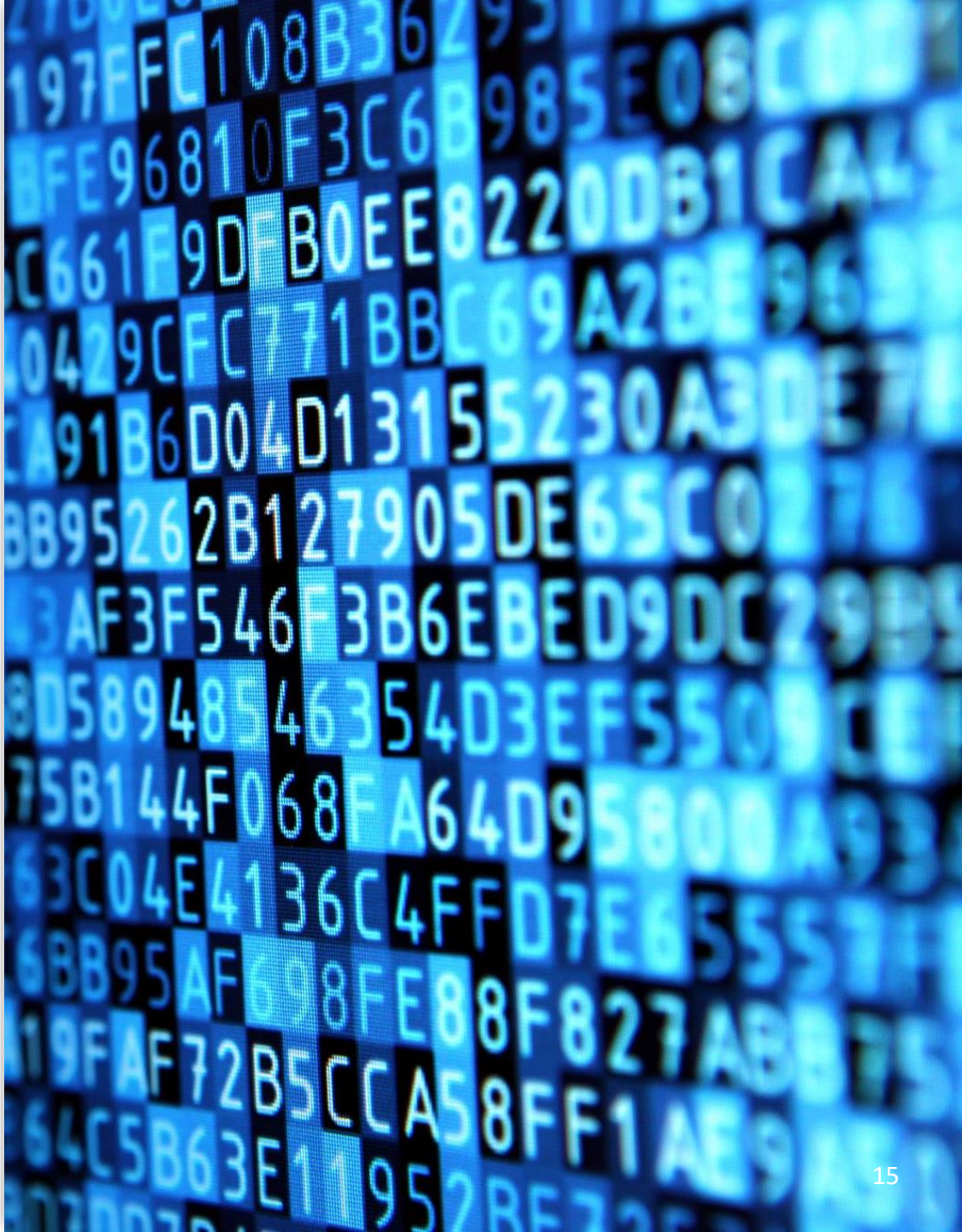
- FEI Number → FDA Establishment Identifier number

→Va richiesto all'FEI portal con una mail a feiportal@fda.hhs.gov

Informazioni richieste:

1 Ragione Sociale
2. US Agent
3. Eventuale nome alternativo dell'impresa
4. Indirizzo Fisico
5. Indirizzo email
6. Nome e contatti della persona di riferimento

7. Descrizione delle attività (breve)
8. Eventuali registrazioni pregresse



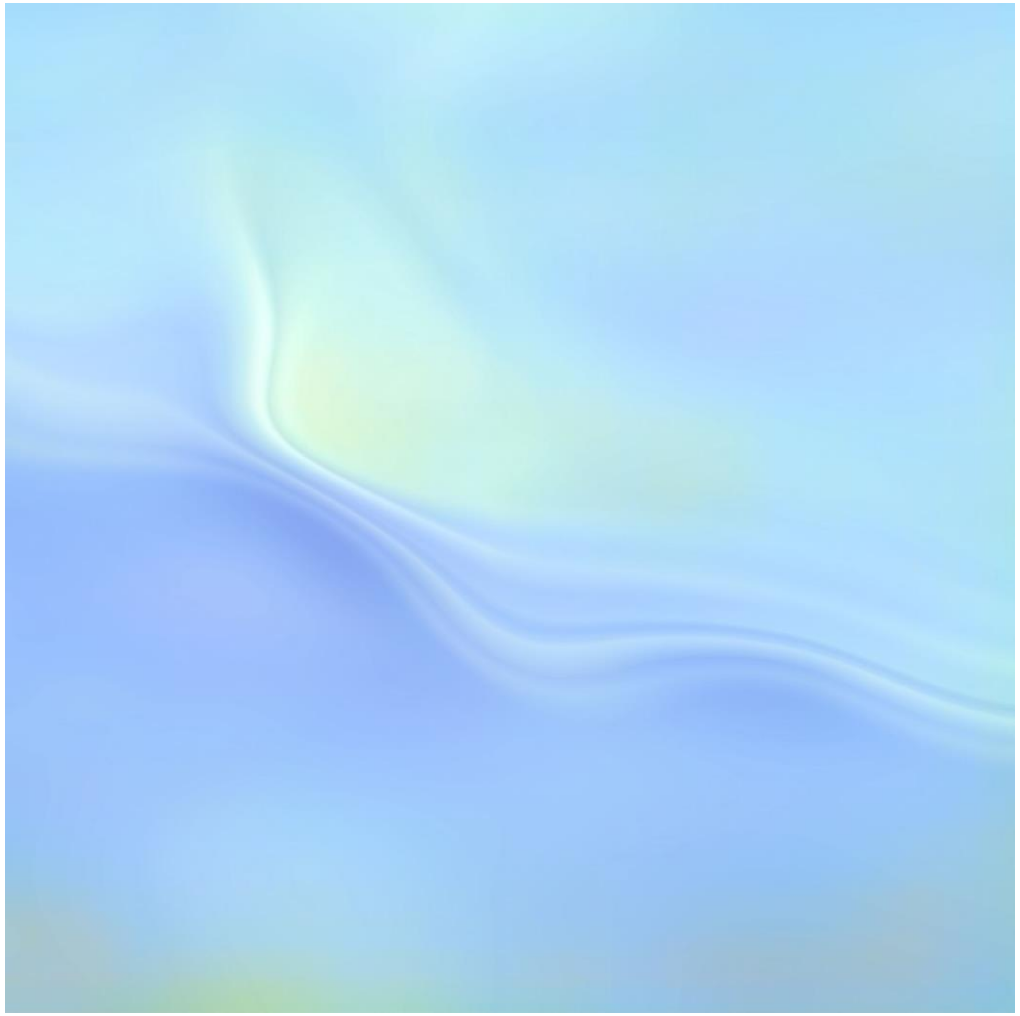
FEI Number e Registrazione

Preliminare e necessario per l'ottenimento del numero di registrazione

La Facility «non USA» deve essere rappresentata uno US Agent!

Se in fase di richiesta dell'FEI number **non** indico il nome dello US Agent, spesso mi viene assegnato ugualmente il numero (ma rischia di essere irregolare!)

Se in fase di richiesta **non** è stato indicato lo US Agent (e si è ottenuto il numero) è consigliabile **ricontattare l'FEI portal e comunicare l'identità dello US Agent**



Il Portale

FDA Direct

LOGIN

Username:

Password:

Forgot your password?

I accept the Terms of Service

LOGIN

OR

CREATE NEW ACCOUNT

Quick Links: Resources | Tutorials | FAQs | CDER Direct Help Desk | Cosmetic Direct Help Desk

WELCOME TO FDA DIRECT

FDA Direct is U.S. Food and Drug Administration's web-based and free structured product labeling (SPL) authoring tool. Previously CDER Direct, FDA Direct now includes CDER Direct and Cosmetics Direct. Users can create separate accounts, depending on drugs or cosmetics submissions, or a single account that includes both CDER Direct submissions as well as Cosmetics Direct submissions.

CDER Direct

CDER Direct allows users to easily create and submit data directly to the FDA. This system will provide information to FDA/CDER about drug manufacturers and private label distributors, outsourcing facilities, wholesale drug distributors and third-party logistics, and generic drug facilities, along with their drugs in U.S. commercial distribution. CDER Direct has several sections which allows submission of the following data to the FDA: Establishment Registration and Drug Listing, including NDC Labeler Code Requests and NDC Reservations, Outsourcing Facility and Product Reporting, DSCSA Annual Reporting, and Generic Drug Self-Identification.

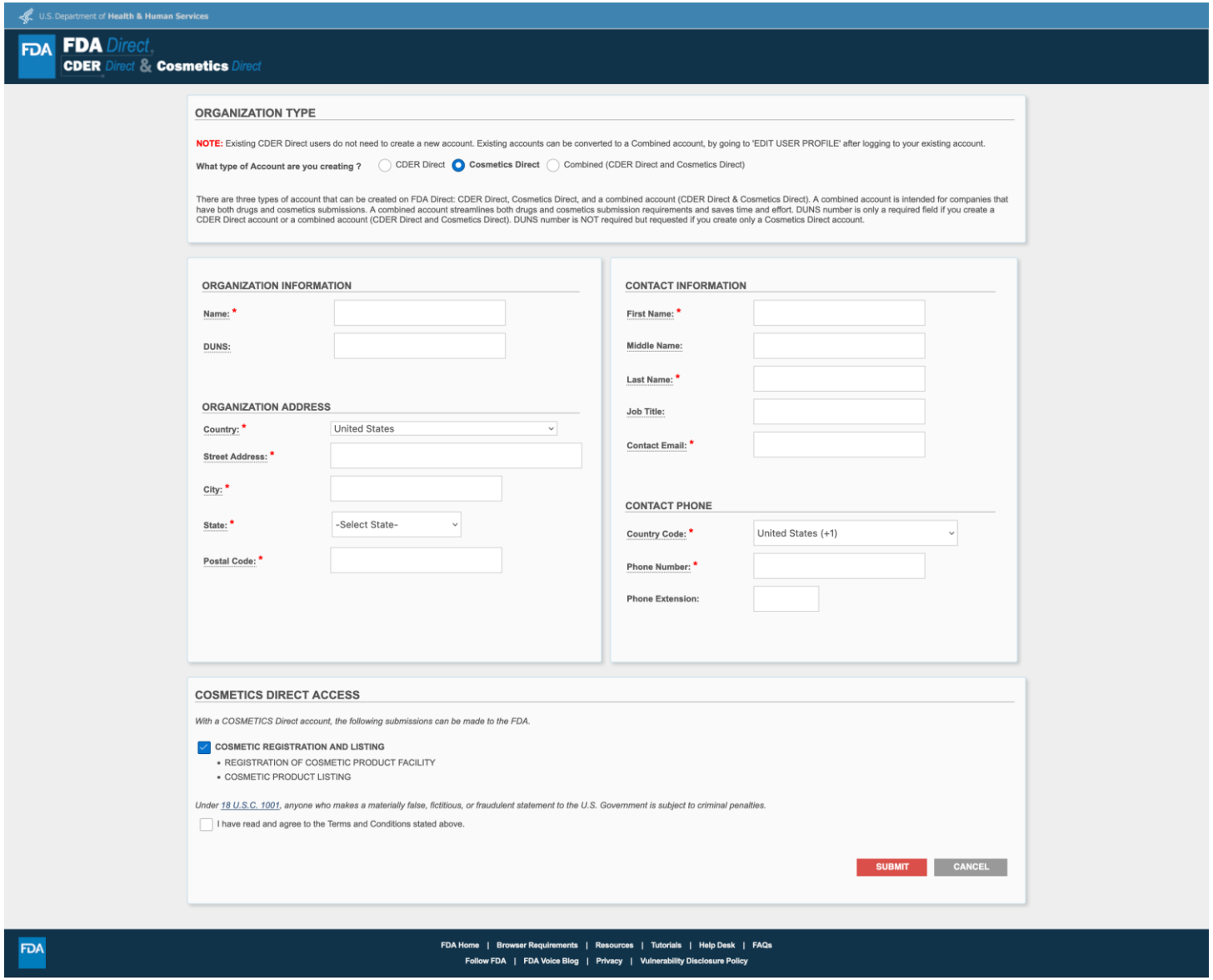
Cosmetics Direct

On December 29, 2022, the President signed the Consolidated Appropriations Act, 2023 (Pub. L. 117-328) into law, which included the Modernization of Cosmetics Registration 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 cosmetic product listing.

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 submit to FDA “a cosmetic product listing.” Certain small businesses, as defined in section 612 of the FD&C Act, are exempt from the registration and listing requirements.Click here to learn more about MoCRA.

This free tool allows you to create and submit the following types of data directly to the FDA: Registration of Cosmetic Product Facility and Cosmetic Product Listing. This system will provide information to FDA/Office of Cosmetics and Colors (OCAC) about cosmetic product manufacturers/processors and cosmetic products on the market.

Note: Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1993, requires that all electronic and information technology (EIT) products and services developed, acquired, maintained, or used under this contract/order must comply with the “Electronic and Information Technology Accessibility Provisions” set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the “Access Board”) in 36 CFR part 1194. Information about Section 508 is available at http://www.section508.gov/.


U.S. Department of Health & Human Services
FDA Direct,
CDER Direct & Cosmetics Direct
ORGANIZATION TYPE
NOTE: Existing CDER Direct users do not need to create a new account. Existing accounts can be converted to a Combined account, by going to 'EDIT USER PROFILE' after logging to your existing account.
What type of Account are you creating ?
CDER Direct
Cosmetics Direct
Combined (CDER Direct and Cosmetics Direct)
There are three types of account that can be created on FDA Direct: CDER Direct, Cosmetics Direct, and a combined account (CDER Direct & Cosmetics Direct). A combined account is intended for companies that have both drugs and cosmetics submissions. A combined account streamlines both drugs and cosmetics submission requirements and saves time and effort. DUNS number is only a required field if you create a CDER Direct account or a combined account (CDER Direct and Cosmetics Direct). DUNS number is NOT required but requested if you create only a Cosmetics Direct account.
ORGANIZATION INFORMATION
Name: *
DUNS:
ORGANIZATION ADDRESS
Country: *
United States
Street Address: *
City: *
State: *
-Select State-
Postal Code: *
CONTACT INFORMATION
First Name: *
Middle Name:
Last Name: *
Job Title:
Contact Email: *
CONTACT PHONE
Country Code: *
United States (+1)
Phone Number: *
Phone Extension:
COSMETICS DIRECT ACCESS
With a COSMETICS Direct account, the following submissions can be made to the FDA.
COSMETIC REGISTRATION AND LISTING
• REGISTRATION OF COSMETIC PRODUCT FACILITY
• COSMETIC PRODUCT LISTING
Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.
I have read and agree to the Terms and Conditions stated above.
SUBMIT
CANCEL
FDA Home | Browser Requirements | Resources | Tutorials | Help Desk | FAQs
Follow FDA | FDA Voice Blog | Privacy | Vulnerability Disclosure Policy

SUBMIT SPL | SAVE AS DRAFT | SAVE AND VALIDATE | DELETE | << RETURN

Note: Click on the Data Element Name for each field below to display instructions and helpful hints for filling out this Registration of Cosmetic Product Facility submission form. A red asterisk (*) indicates a required field.

For assistance with validation errors and general questions regarding electronic registration and listing of cosmetic product facilities and products, contact cosmeticsdirect@fda.hhs.gov.

DOCUMENT TYPE DETAILS

Document Type: *	COSMETIC FACILITY REGISTRATION		
Set ID: *	10137f18-4742-6c51-e063-6294a90af5cb Generate New	Version Number: *	1
Root ID: *	10137f18-4743-6c51-e063-6294a90af5cb Generate New	Effective Date: *	01-29-2024

REGISTRATION DETAILS

Is this a facility registration for a small business (optional registration)?: ☐ Yes ☐ No

Facility Name: *	xxx	Facility Country: *	Italy
Facility FEI Number: *	1234567890	Facility Street Address: *	Via Roma 1
Facility D&B D-U-N-S Number:		Facility City: *	Milano
Parent Company Name (If applicable):		Facility State or Province:	
		Facility Zip/Postal Code: *	20122

FACILITY CONTACT DETAILS

Name of the Owner and/or Operator of the Facility: *	Mario Rossi	Facility Phone Number (Include Country/Area Code): *	0039-02-123456
Facility Email: *	email@xxx.it		

US AGENT

U.S. Agent Name (for foreign facilities): *	Angel Consulting USA LLC	U.S. Agent Phone Number (Include Country/Area Code): *	1-445-289-0011
U.S. Agent Email (if not available, enter "N/A"): *	USagent@angelconsulting.eu	U.S. Agent Phone Extension:	

FACILITY BRAND NAMES

ADD BRAND NAME

There are currently no Brand Names associated with this facility. To add a Brand Name, select "Add Brand Name".

CONFIRMATION STATEMENT

The data and information in this submission have been reviewed and, to the best of my knowledge, are certified to be true and accurate. I agree to report changes to this information and renew as required under section 607 of the Federal Food, Drug and Cosmetic Act.

WARNING: A willfully false statement is a criminal offense, U.S. Code, Title 18, Section 1001.

☐ I Agree

Date

Name of Submitter

ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT

Additional Contact Name:		Phone Number (Include Country/Area Code):	
Email:		Phone Extension:	

SAVE BRAND RETURN

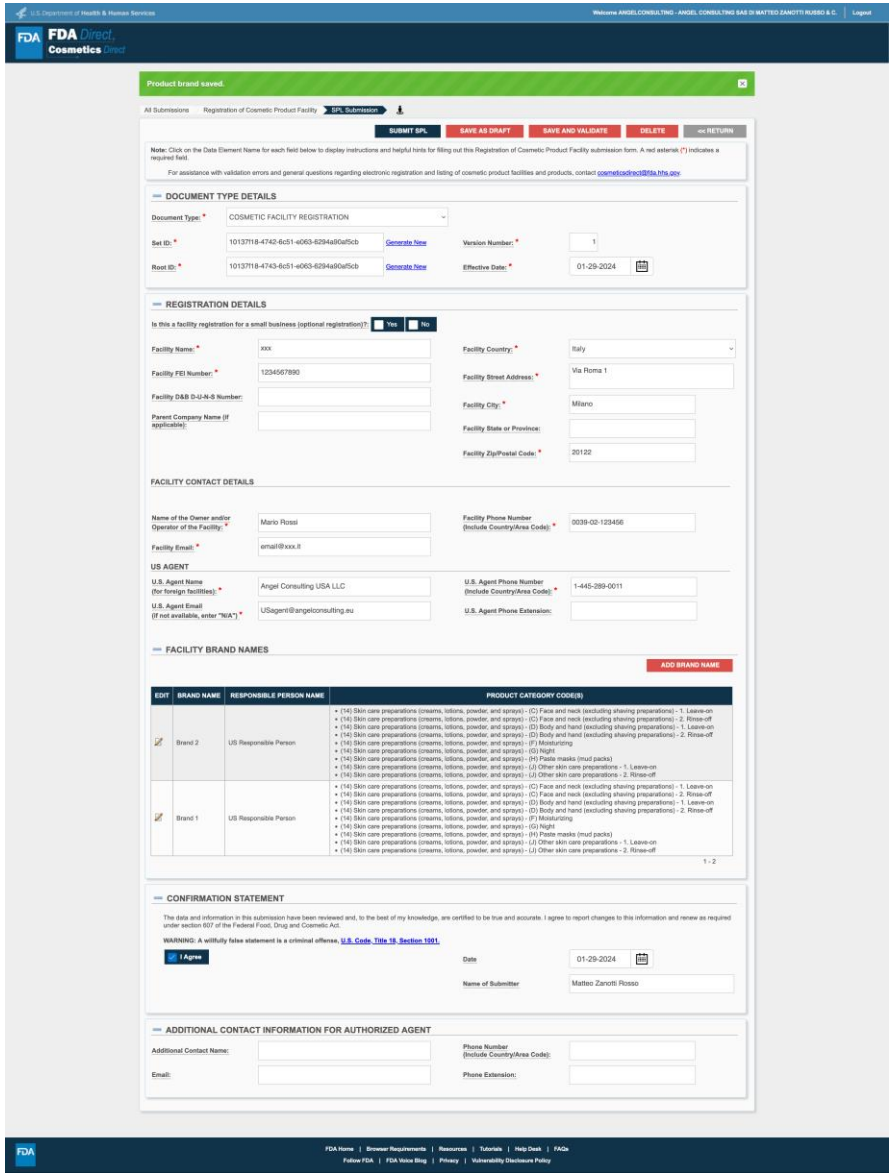
BRAND INFORMATION

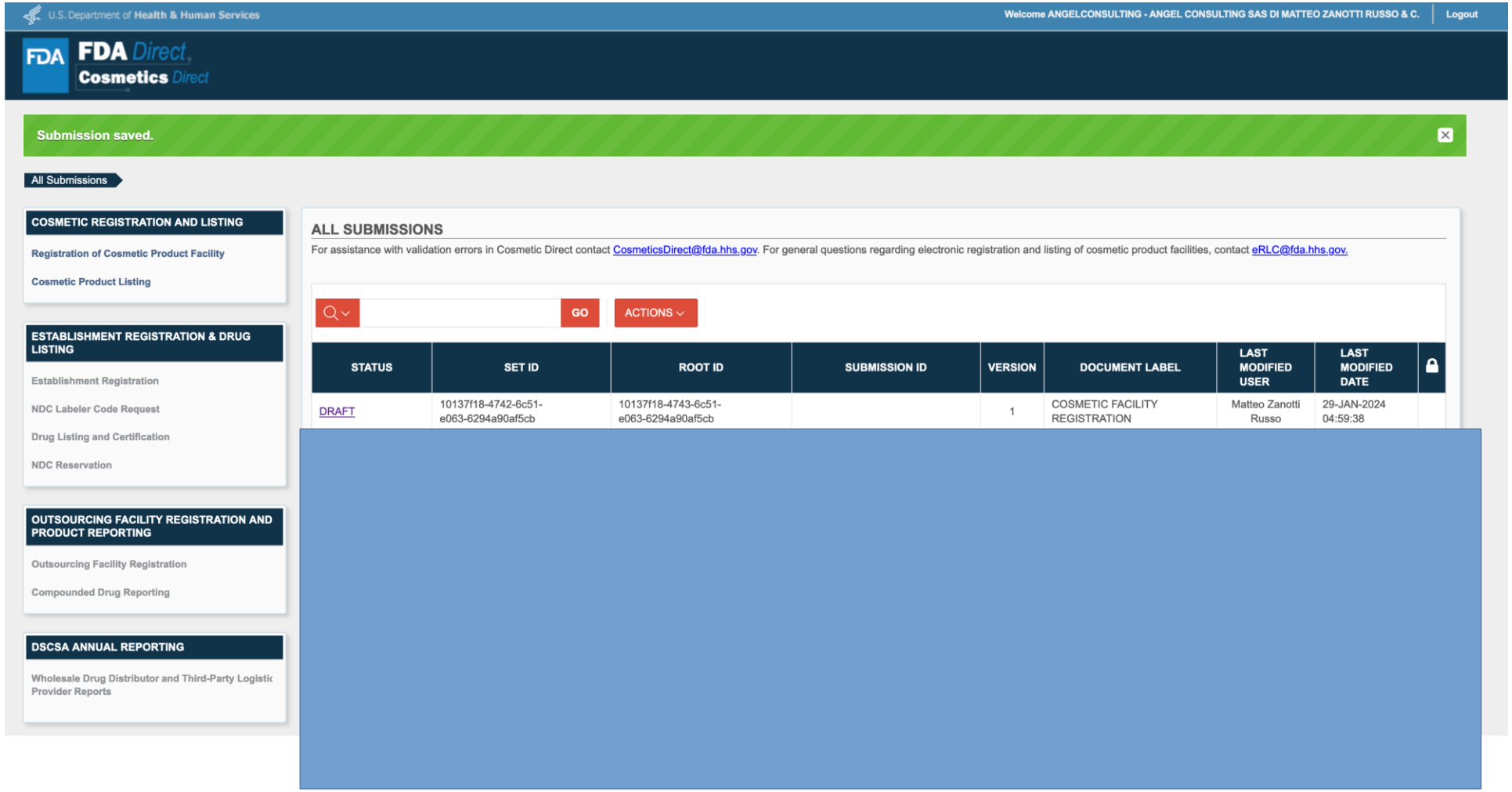
Brand Name of Cosmetic Products: *

Responsible Person (As listed on the label): *

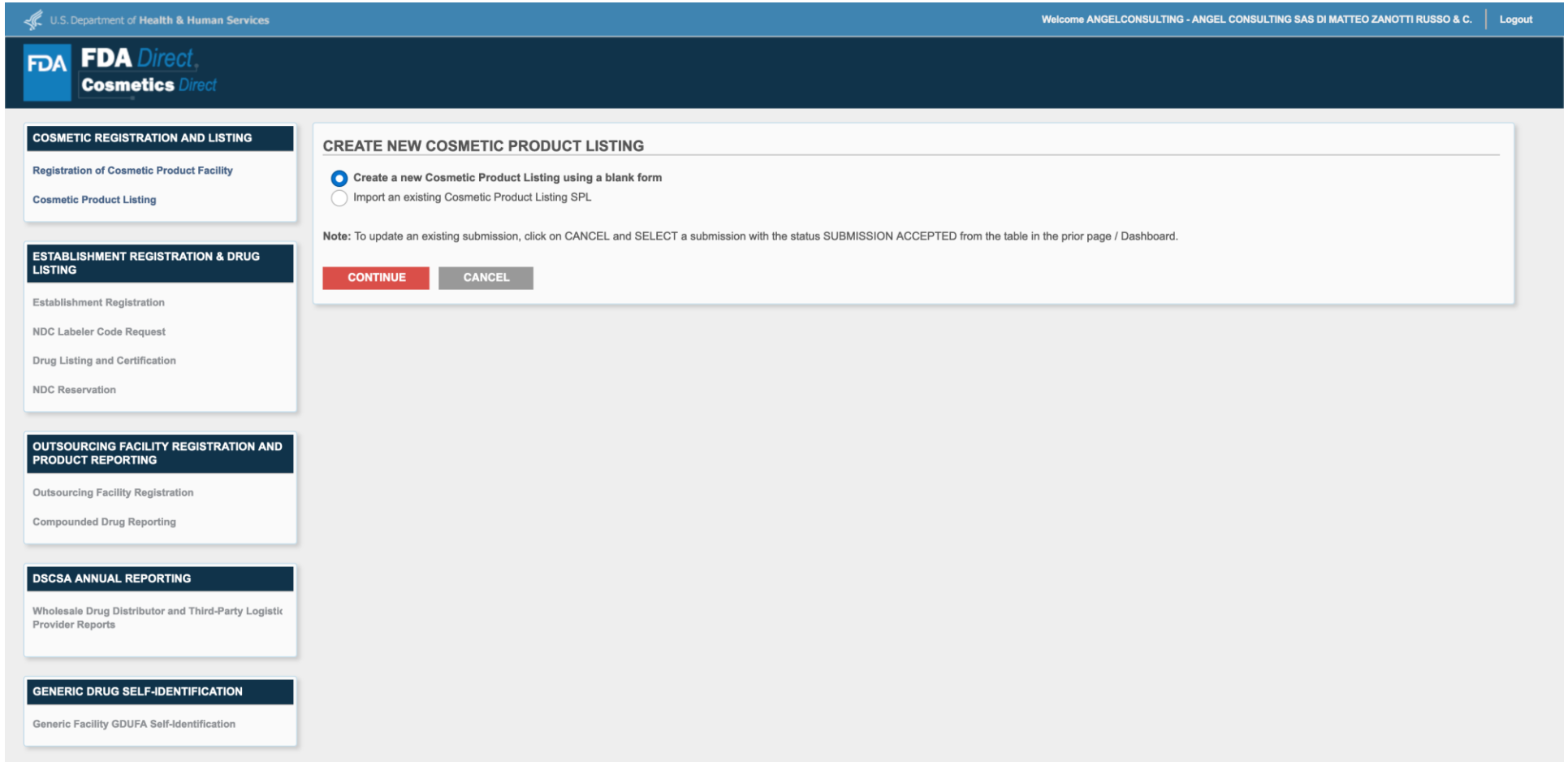
Product Category Code(s) (Select all that apply): *

- (01) Baby products
- (02) Bath preparations
- (03) Eye makeup preparations (other than children's eye makeup preparations)
- (04) Children's eye makeup preparations
- (05) Fragrance preparations
- (06) Hair preparations (non-coloring)
- (07) Hair coloring preparations
- (08) Makeup preparations (not eye)(other than makeup preparations for children)
- (09) Makeup preparations for children (not eye)
- (10) Manicuring preparations
- (11) Oral products
- (12) Personal cleanliness
- (13) Shaving preparations
- (14) Skin care preparations (creams, lotions, powder, and sprays)
- (15) Suntan preparations
- (16) Tattoo preparations
- ☐ (17) Other preparations (i.e., those preparations that do not fit another category)


FDA Direct, Cosmetics Direct
Welcome ANGELCONSULTING - ANGEL CONSULTING SAS DI MATTEO ZANOTTI RUSSO & C.
Logout
Product brand saved.
All Submissions
Registration of Cosmetic Product Facility
SPL Submission
SUBMIT SPL
SAVE AS DRAFT
SAVE AND VALIDATE
DELETE
<< RETURN
Note: Click on the Data Element Name for each field below to display instructions and helpful hints for filling out this Registration of Cosmetic Product Facility submission form. A red asterisk (*) indicates a required field.
For assistance with validation errors and general questions regarding electronic registration and listing of cosmetic product facilities and products, contact cosmeticsdirect@fda.hhs.gov.
DOCUMENT TYPE DETAILS
Document Type: * COSMETIC FACILITY REGISTRATION
Set ID: * 10137f18-4742-6c51-e063-6294a90af5cb Generate New
Version Number: * 1
Root ID: * 10137f18-4743-6c51-e063-6294a90af5cb Generate New
Effective Date: * 01-29-2024
REGISTRATION DETAILS
Is this a facility registration for a small business (optional registration)? Yes No
Facility Name: * xxx
Facility FEI Number: * 1234567890
Facility D&B D-U-N-S Number:
Parent Company Name (if applicable):
Facility Country: * Italy
Facility Street Address: * Via Roma 1
Facility City: * Milano
Facility State or Province:
Facility Zip/Postal Code: * 20122
FACILITY CONTACT DETAILS
Name of the Owner and/or Operator of the Facility: * Mario Rossi
Facility Email: * email@xxx.it
Facility Phone Number (Include Country/Area Code): * 0039-02-123456
US AGENT
U.S. Agent Name (for foreign facilities): * Angel Consulting USA LLC
U.S. Agent Email (If not available, enter "N/A") * USagent@angelconsulting.eu
U.S. Agent Phone Number (Include Country/Area Code): * 1-445-289-0011
U.S. Agent Phone Extension:
FACILITY BRAND NAMES
ADD BRAND NAME
EDIT
BRAND NAME
RESPONSIBLE PERSON NAME
PRODUCT CATEGORY CODE(S)
Brand 2
US Responsible Person
• (14) Skin care preparations (creams, lotions, powder, and sprays) - (C) Face and neck (excluding shaving preparations) - 1. Leave-on
• (14) Skin care preparations (creams, lotions, powder, and sprays) - (C) Face and neck (excluding shaving preparations) - 2. Rinse-off
• (14) Skin care preparations (creams, lotions, powder, and sprays) - (D) Body and hand (excluding shaving preparations) - 1. Leave-on
• (14) Skin care preparations (creams, lotions, powder, and sprays) - (D) Body and hand (excluding shaving preparations) - 2. Rinse-off
• (14) Skin care preparations (creams, lotions, powder, and sprays) - (F) Moisturizing
• (14) Skin care preparations (creams, lotions, powder, and sprays) - (G) Night
• (14) Skin care preparations (creams, lotions, powder, and sprays) - (H) Paste masks (mud packs)
• (14) Skin care preparations (creams, lotions, powder, and sprays) - (J) Other skin care preparations - 1. Leave-on
• (14) Skin care preparations (creams, lotions, powder, and sprays) - (J) Other skin care preparations - 2. Rinse-off
Brand 1
US Responsible Person
• (14) Skin care preparations (creams, lotions, powder, and sprays) - (C) Face and neck (excluding shaving preparations) - 1. Leave-on
• (14) Skin care preparations (creams, lotions, powder, and sprays) - (C) Face and neck (excluding shaving preparations) - 2. Rinse-off
• (14) Skin care preparations (creams, lotions, powder, and sprays) - (D) Body and hand (excluding shaving preparations) - 1. Leave-on
• (14) Skin care preparations (creams, lotions, powder, and sprays) - (D) Body and hand (excluding shaving preparations) - 2. Rinse-off
• (14) Skin care preparations (creams, lotions, powder, and sprays) - (F) Moisturizing
• (14) Skin care preparations (creams, lotions, powder, and sprays) - (G) Night
• (14) Skin care preparations (creams, lotions, powder, and sprays) - (H) Paste masks (mud packs)
• (14) Skin care preparations (creams, lotions, powder, and sprays) - (J) Other skin care preparations - 1. Leave-on
• (14) Skin care preparations (creams, lotions, powder, and sprays) - (J) Other skin care preparations - 2. Rinse-off
1 - 2
CONFIRMATION STATEMENT
The data and information in this submission have been reviewed and, to the best of my knowledge, are certified to be true and accurate. I agree to report changes to this information and renew as required under section 607 of the Federal Food, Drug and Cosmetic Act.
WARNING: A willfully false statement is a criminal offense, U.S. Code, Title 18, Section 1001.
I Agree
Date 01-29-2024
Name of Submitter Matteo Zanotti Rosso
ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT
Additional Contact Name:
Email:
Phone Number (Include Country/Area Code):
Phone Extension:
FDA Home | Browser Requirements | Resources | Tutorials | Help Desk | FAQs
Follow FDA | FDA Voice Blog | Privacy | Vulnerability Disclosure Policy


U.S. Department of Health & Human Services
Welcome ANGELCONSULTING - ANGEL CONSULTING SAS DI MATTEO ZANOTTI RUSSO & C.
Logout
FDA Direct, Cosmetics Direct
Submission saved.
All Submissions
COSMETIC REGISTRATION AND LISTING
Registration of Cosmetic Product Facility
Cosmetic Product Listing
ESTABLISHMENT REGISTRATION & DRUG LISTING
Establishment Registration
NDC Labeler Code Request
Drug Listing and Certification
NDC Reservation
OUTSOURCING FACILITY REGISTRATION AND PRODUCT REPORTING
Outsourcing Facility Registration
Compounded Drug Reporting
DSCSA ANNUAL REPORTING
Wholesale Drug Distributor and Third-Party Logistic Provider Reports
ALL SUBMISSIONS
For assistance with validation errors in Cosmetic Direct contact CosmeticsDirect@fda.hhs.gov. For general questions regarding electronic registration and listing of cosmetic product facilities, contact eRLC@fda.hhs.gov.
GO
ACTIONS
STATUS
SET ID
ROOT ID
SUBMISSION ID
VERSION
DOCUMENT LABEL
LAST MODIFIED USER
LAST MODIFIED DATE
DRAFT
10137f18-4742-6c51-e063-6294a90af5cb
10137f18-4743-6c51-e063-6294a90af5cb
1
COSMETIC FACILITY REGISTRATION
Matteo Zanotti Russo
29-JAN-2024 04:59:38

PRODUCT LISTING


U.S. Department of Health & Human Services
Welcome ANGELCONSULTING - ANGEL CONSULTING SAS DI MATTEO ZANOTTI RUSSO & C.
Logout
FDA Direct,
Cosmetics Direct
COSMETIC REGISTRATION AND LISTING
Registration of Cosmetic Product Facility
Cosmetic Product Listing
ESTABLISHMENT REGISTRATION & DRUG LISTING
Establishment Registration
NDC Labeler Code Request
Drug Listing and Certification
NDC Reservation
OUTSOURCING FACILITY REGISTRATION AND PRODUCT REPORTING
Outsourcing Facility Registration
Compounded Drug Reporting
DSCSA ANNUAL REPORTING
Wholesale Drug Distributor and Third-Party Logistic Provider Reports
GENERIC DRUG SELF-IDENTIFICATION
Generic Facility GDUFA Self-Identification
CREATE NEW COSMETIC PRODUCT LISTING
Create a new Cosmetic Product Listing using a blank form
Import an existing Cosmetic Product Listing SPL
Note: To update an existing submission, click on CANCEL and SELECT a submission with the status SUBMISSION ACCEPTED from the table in the prior page / Dashboard.
CONTINUE
CANCEL

Note: Click on the Data Element Name for each field below to display instructions and helpful hints for filling out this Registration of Cosmetic Product Facility submission form. A red asterisk (*) indicates a required field.

For assistance with validation errors and general questions regarding electronic registration and listing of cosmetic product facilities and products, contact cosmeticsdirect@fda.hhs.gov.

DOCUMENT TYPE DETAILS

Document Type: * COSMETIC PRODUCT LISTING

Set ID: * 101433ce-971e-5aaa-e063-6394a90abadc Generate New

Version Number: * 1

Root ID: * 101433ce-971f-5aaa-e063-6394a90abadc Generate New

Effective Date: * 01-29-2024

PRODUCT, INGREDIENT AND FACILITY LISTING OF THE COSMETIC PRODUCT

Is this a product listing for a small business (optional product listing)?: ☐ Yes ☐ No

Responsible Person (as listed on label):

Type of Business: ☐ MANUFACTURER ☐ PACKER ☐ DISTRIBUTOR

Responsible Person Name (as listed on label): * US Responsible Person

Responsible Person Phone Number (Include Country/Area Code): * 1-445-289-0011

Parent Company Name (if applicable):

Responsible Person D&B D-U-N-S Number for Address Listed on the Product Label:

PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)

ADD PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)

Add all required information by selecting ADD PRODUCT(S), INGREDIENT(S), AND FACILITY(IES).

CONFIRMATION STATEMENT

The data and information in this submission have been reviewed and, to the best of my knowledge, are certified to be true and accurate. I agree to report changes to this information as required under section 607 of the Federal Food, Drug, and Cosmetic Act.

WARNING: A willfully false statement is a criminal offense, U.S. Code, Title 18, Section 1001.

☐ I Agree

SAVE PRODUCT | << RETURN

COSMETIC PRODUCTS

Cosmetic Product Listing Number:

Product Name (As listed on label): *

Product Webpage Link:

Fragrance or Flavor: * -- Select --

Professional Use Only : -- Select --

PRODUCT CATEGORY CODE(S)

MANAGE CATEGORIES

INGREDIENTS

Note that any update regarding Fragrance and/or Flavor made through the ingredient upload tool, will automatically update the above "Fragrance or Flavor" selection field in the previous section.

MANAGE INGREDIENTS

LIST OF FACILITIES WHERE THE COSMETIC IS MANUFACTURED OR PROCESSED

ADD FACILITY

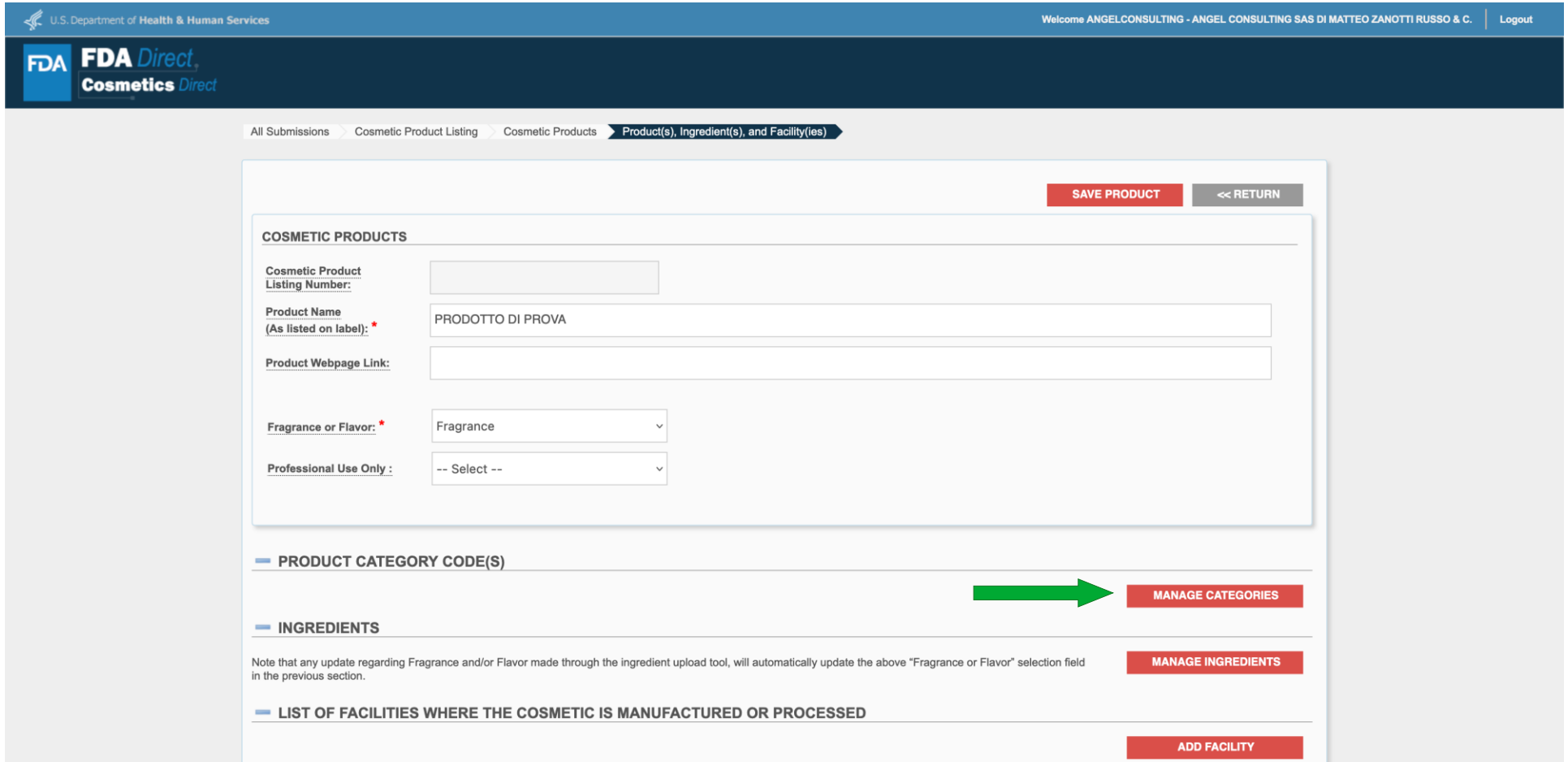
PRODUCT IMAGES

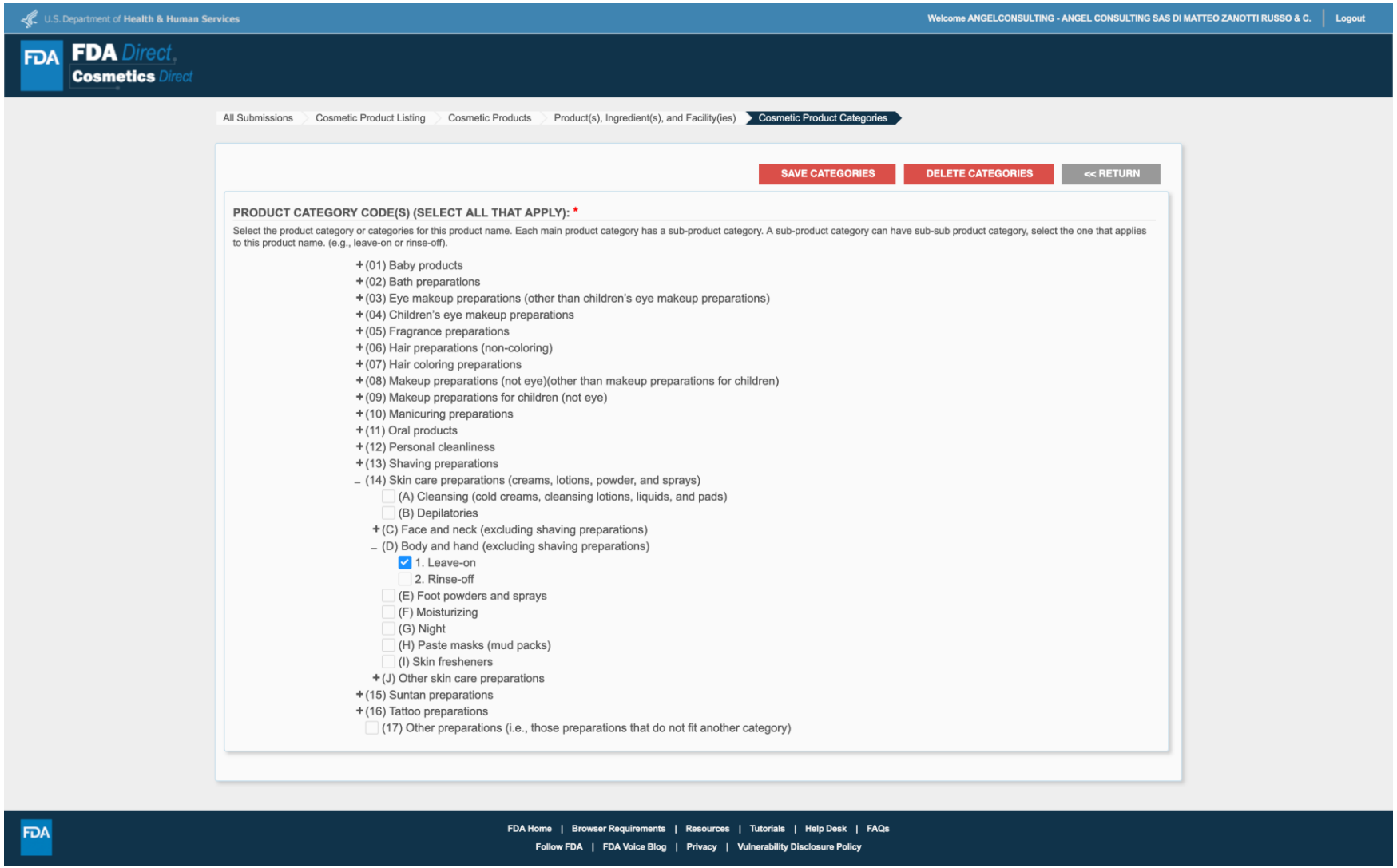
Upload image(s) of the label, any sides of the label whether it front, back or sides.

Drag and Drop

Image of Product Label (Attach images of the front and back product labels by selecting the icon).

UPLOAD | CANCEL


U.S. Department of Health & Human Services
Welcome ANGELCONSULTING - ANGEL CONSULTING SAS DI MATTEO ZANOTTI RUSSO & C.
Logout
FDA Direct, Cosmetics Direct
All Submissions
Cosmetic Product Listing
Cosmetic Products
Product(s), Ingredient(s), and Facility(ies)
SAVE PRODUCT
<< RETURN
COSMETIC PRODUCTS
Cosmetic Product Listing Number:
Product Name (As listed on label): *
PRODOTTO DI PROVA
Product Webpage Link:
Fragrance or Flavor: *
Fragrance
Professional Use Only :
-- Select --
PRODUCT CATEGORY CODE(S)
MANAGE CATEGORIES
INGREDIENTS
Note that any update regarding Fragrance and/or Flavor made through the ingredient upload tool, will automatically update the above "Fragrance or Flavor" selection field in the previous section.
MANAGE INGREDIENTS
LIST OF FACILITIES WHERE THE COSMETIC IS MANUFACTURED OR PROCESSED
ADD FACILITY


U.S. Department of Health & Human Services
Welcome ANGELCONSULTING - ANGEL CONSULTING SAS DI MATTEO ZANOTTI RUSSO & C.
Logout
FDA Direct
Cosmetics Direct
All Submissions
Cosmetic Product Listing
Cosmetic Products
Product(s), Ingredient(s), and Facility(ies)
Cosmetic Product Categories
SAVE CATEGORIES
DELETE CATEGORIES
<< RETURN
PRODUCT CATEGORY CODE(S) (SELECT ALL THAT APPLY): *
Select the product category or categories for this product name. Each main product category has a sub-product category. A sub-product category can have sub-sub product category, select the one that applies to this product name. (e.g., leave-on or rinse-off).
+ (01) Baby products
+ (02) Bath preparations
+ (03) Eye makeup preparations (other than children's eye makeup preparations)
+ (04) Children's eye makeup preparations
+ (05) Fragrance preparations
+ (06) Hair preparations (non-coloring)
+ (07) Hair coloring preparations
+ (08) Makeup preparations (not eye)(other than makeup preparations for children)
+ (09) Makeup preparations for children (not eye)
+ (10) Manicuring preparations
+ (11) Oral products
+ (12) Personal cleanliness
+ (13) Shaving preparations
– (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)
– (D) Body and hand (excluding shaving preparations)
1. Leave-on
2. Rinse-off
(E) Foot powders and sprays
(F) Moisturizing
(G) Night
(H) Paste masks (mud packs)
(I) Skin fresheners
+ (J) Other skin care preparations
+ (15) Suntan preparations
+ (16) Tattoo preparations
(17) Other preparations (i.e., those preparations that do not fit another category)
FDA
FDA Home | Browser Requirements | Resources | Tutorials | Help Desk | FAQs
Follow FDA | FDA Voice Blog | Privacy | Vulnerability Disclosure Policy

FDA Direct
Cosmetics Direct

Product categories saved.

All Submissions > Cosmetic Product Listing > Cosmetic Products > Product(s), Ingredient(s), and Facility(ies)

SAVE PRODUCT | DELETE | << RETURN

COSMETIC PRODUCTS

Cosmetic Product Listing Number:

Product Name (As listed on label): * PRODOTTO DI PROVA

Product Webpage Link:

Fragrance or Flavor: * Fragrance

Professional Use Only : -- Select --

PRODUCT CATEGORY CODE(S)

MANAGE CATEGORIES

PRODUCT CATEGORIES
• (14) Skin care preparations (creams, lotions, powder, and sprays) - (D) Body and hand (excluding shaving preparations) - 1. Leave-on

1 - 1

INGREDIENTS

Note that any update regarding Fragrance and/or Flavor made through the ingredient upload tool, will automatically update the above "Fragrance or Flavor" selection field in the previous section.

MANAGE INGREDIENTS

INGREDIENT UNII CODE(S)	COMMON, USUAL OR CHEMICAL NAME (AS LISTED ON THE LABEL)
	FRAGRANCE

row(s) 1 - 1 of 1

LIST OF FACILITIES WHERE THE COSMETIC IS MANUFACTURED OR PROCESSED

ADD FACILITY

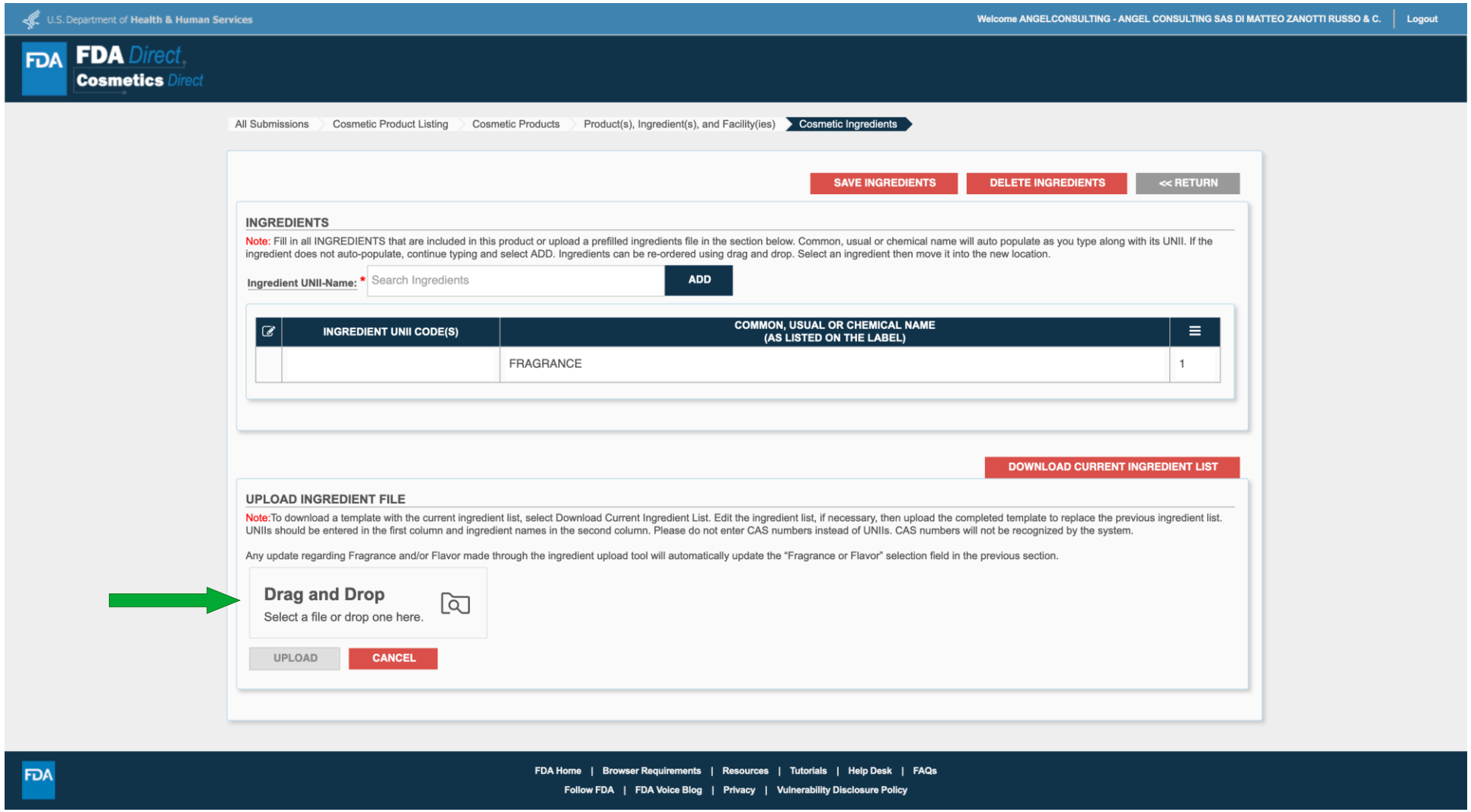
PRODUCT IMAGES

Upload image(s) of the label, any sides of the label whether it front, back or sides.

Drag and Drop

Image of Product Label (Attach images of the front and back product labels by selecting the icon).

UPLOAD | CANCEL


U.S. Department of Health & Human Services
Welcome ANGELCONSULTING - ANGEL CONSULTING SAS DI MATTEO ZANOTTI RUSSO & C.
Logout
FDA Direct
Cosmetics Direct
All Submissions
Cosmetic Product Listing
Cosmetic Products
Product(s), Ingredient(s), and Facility(ies)
Cosmetic Ingredients
SAVE INGREDIENTS
DELETE INGREDIENTS
<< RETURN
INGREDIENTS
Note: Fill in all INGREDIENTS that are included in this product or upload a prefilled ingredients file in the section below. Common, usual or chemical name will auto populate as you type along with its UNII. If the ingredient does not auto-populate, continue typing and select ADD. Ingredients can be re-ordered using drag and drop. Select an ingredient then move it into the new location.
Ingredient UNII-Name: *
Search Ingredients
ADD
INGREDIENT UNII CODE(S)
COMMON, USUAL OR CHEMICAL NAME (AS LISTED ON THE LABEL)
FRAGRANCE
1
DOWNLOAD CURRENT INGREDIENT LIST
UPLOAD INGREDIENT FILE
Note:To download a template with the current ingredient list, select Download Current Ingredient List. Edit the ingredient list, if necessary, then upload the completed template to replace the previous ingredient list. UNIIs should be entered in the first column and ingredient names in the second column. Please do not enter CAS numbers instead of UNIIs. CAS numbers will not be recognized by the system.
Any update regarding Fragrance and/or Flavor made through the ingredient upload tool will automatically update the "Fragrance or Flavor" selection field in the previous section.
Drag and Drop
Select a file or drop one here.
UPLOAD
CANCEL
FDA Home | Browser Requirements | Resources | Tutorials | Help Desk | FAQs
Follow FDA | FDA Voice Blog | Privacy | Vulnerability Disclosure Policy

	B	C	D	E	F	G
1	**COMMON, USUAL OR CHEMICAL NAME**					
2	WATER					
3	ETHYLHEXYL PALMITATE					
4	ISODODECANE					
5	GLYCERIN					
6	ETHYLHEXYLGLYCERIN					
7	PHENOXYETHANOL					
8	FRAGRANCE					
9						
10						
11						
12						

Product Ingredients Saved.

All Submissions > Cosmetic Product Listing > Cosmetic Products > Product(s), Ingredient(s), and Facility(ies)

SAVE PRODUCT | DELETE | << RETURN

COSMETIC PRODUCTS

Cosmetic Product Listing Number:

Product Name (As listed on label): * PRODOTTO DI PROVA

Product Webpage Link:

Fragrance or Flavor: * Fragrance

Professional Use Only : No

PRODUCT CATEGORY CODE(S)

MANAGE CATEGORIES

PRODUCT CATEGORIES
• (14) Skin care preparations (creams, lotions, powder, and sprays) - (D) Body and hand (excluding shaving preparations) - 1. Leave-on

1 - 1

INGREDIENTS

Note that any update regarding Fragrance and/or Flavor made through the ingredient upload tool, will automatically update the above "Fragrance or Flavor" selection field in the previous section.

MANAGE INGREDIENTS

INGREDIENT UNII CODE(S)	COMMON, USUAL OR CHEMICAL NAME (AS LISTED ON THE LABEL)
059QF0KO0R	WATER
2865993309	ETHYLHEXYL PALMITATE
A8289P68Y2	ISODODECANE
PDC6A3C0OX	GLYCERIN
147D247K3P	ETHYLHEXYLGLYCERIN
HIE492ZZ3T	PHENOXYETHANOL
	FRAGRANCE

row(s) 1 - 7 of 7

LIST OF FACILITIES WHERE THE COSMETIC IS MANUFACTURED OR PROCESSED

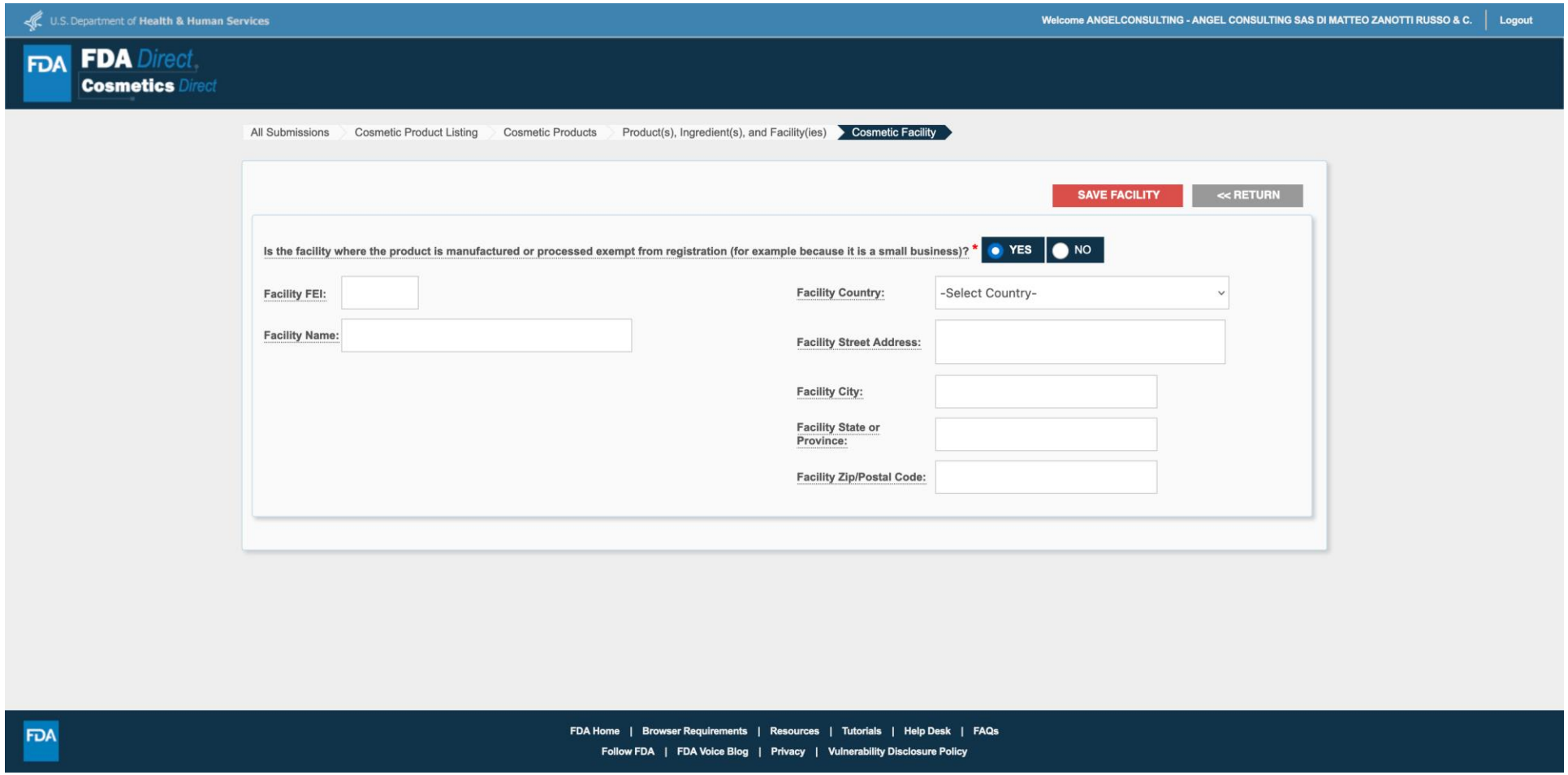
ADD FACILITY

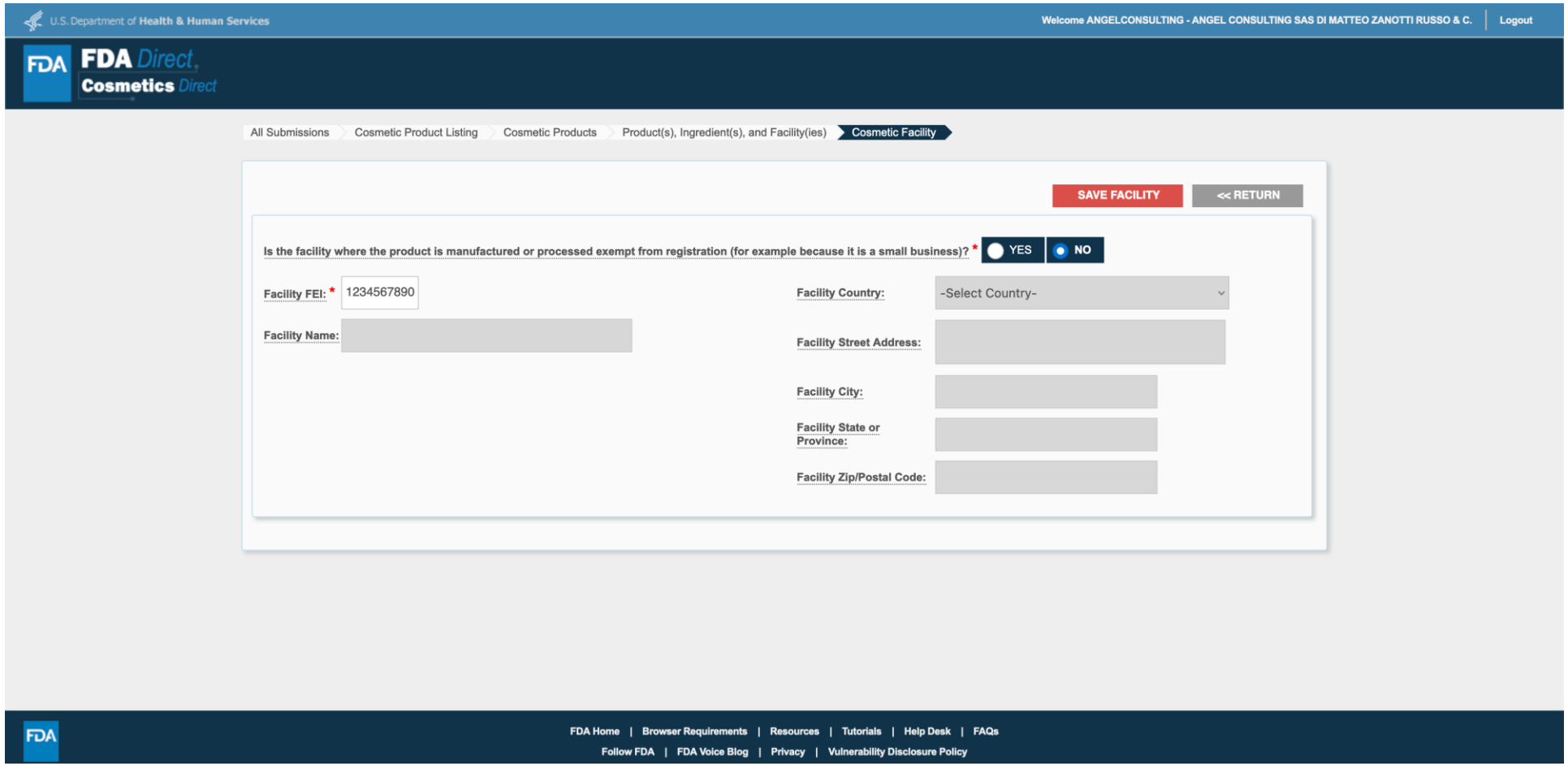
PRODUCT IMAGES

Upload image(s) of the label, any sides of the label whether it front, back or sides.

Drag and Drop
Image of Product Label (Attach images of the front and back product labels by selecting the icon).

UPLOAD | CANCEL


U.S. Department of Health & Human Services
Welcome ANGELCONSULTING - ANGEL CONSULTING SAS DI MATTEO ZANOTTI RUSSO & C.
Logout
FDA Direct, Cosmetics Direct
All Submissions
Cosmetic Product Listing
Cosmetic Products
Product(s), Ingredient(s), and Facility(ies)
Cosmetic Facility
SAVE FACILITY
<< RETURN
Is the facility where the product is manufactured or processed exempt from registration (for example because it is a small business)? *
YES
NO
Facility FEI:
Facility Name:
Facility Country:
-Select Country-
Facility Street Address:
Facility City:
Facility State or Province:
Facility Zip/Postal Code:
FDA Home | Browser Requirements | Resources | Tutorials | Help Desk | FAQs
Follow FDA | FDA Voice Blog | Privacy | Vulnerability Disclosure Policy


U.S. Department of Health & Human Services
Welcome ANGELCONSULTING - ANGEL CONSULTING SAS DI MATTEO ZANOTTI RUSSO & C.
Logout
FDA Direct
Cosmetics Direct
All Submissions
Cosmetic Product Listing
Cosmetic Products
Product(s), Ingredient(s), and Facility(ies)
Cosmetic Facility
SAVE FACILITY
<< RETURN
Is the facility where the product is manufactured or processed exempt from registration (for example because it is a small business)? *
YES
NO
Facility FEI: *
1234567890
Facility Name:
Facility Country:
-Select Country-
Facility Street Address:
Facility City:
Facility State or Province:
Facility Zip/Postal Code:
FDA Home | Browser Requirements | Resources | Tutorials | Help Desk | FAQs
Follow FDA | FDA Voice Blog | Privacy | Vulnerability Disclosure Policy

Cosmetic Product Facility Saved.

All Submissions > Cosmetic Product Listing > Cosmetic Products > Product(s), Ingredient(s), and Facility(ies)

SAVE PRODUCT | DELETE | << RETURN

COSMETIC PRODUCTS

Cosmetic Product Listing Number:

Product Name (As listed on label): * PRODOTTO DI PROVA

Product Webpage Link:

Fragrance or Flavor: * Fragrance

Professional Use Only : No

PRODUCT CATEGORY CODE(S)

MANAGE CATEGORIES

PRODUCT CATEGORIES
• (14) Skin care preparations (creams, lotions, powder, and sprays) - (D) Body and hand (excluding shaving preparations) - 1. Leave-on

1 - 1

INGREDIENTS

Note that any update regarding Fragrance and/or Flavor made through the ingredient upload tool, will automatically update the above "Fragrance or Flavor" selection field in the previous section.

MANAGE INGREDIENTS

INGREDIENT UNII CODE(S)	COMMON, USUAL OR CHEMICAL NAME (AS LISTED ON THE LABEL)
059QF0KO0R	WATER
2865993309	ETHYLHEXYL PALMITATE
A8289P68Y2	ISODODECANE
PDC6A3C0OX	GLYCERIN
147D247K3P	ETHYLHEXYLGLYCERIN
HIE492ZZ3T	PHENOXYETHANOL
	FRAGRANCE

row(s) 1 - 7 of 7

LIST OF FACILITIES WHERE THE COSMETIC IS MANUFACTURED OR PROCESSED

ADD FACILITY

EDIT	IS THIS FACILITY SMALL BUSINESS?	FACILITY FEI	FACILITY NAME	FACILITY ADDRESS
	No	1234567890		

1 - 1

PRODUCT IMAGES

Upload image(s) of the label, any sides of the label whether it front, back or sides.

Drag and Drop
Image of Product Label (Attach images of the front and back product labels by selecting the icon).

UPLOAD | CANCEL

FDA Direct

Intuitivo
Rapido
Elenco INCI
…poco dettagliato!

Etichettatura

stesso frame di riferimento pregresso

Principal display panel (PDP) e *Information Panels* (IP)

prodotti per uso professionale: warning in etichetta

Etichettatura

Allergeni delle fragranze

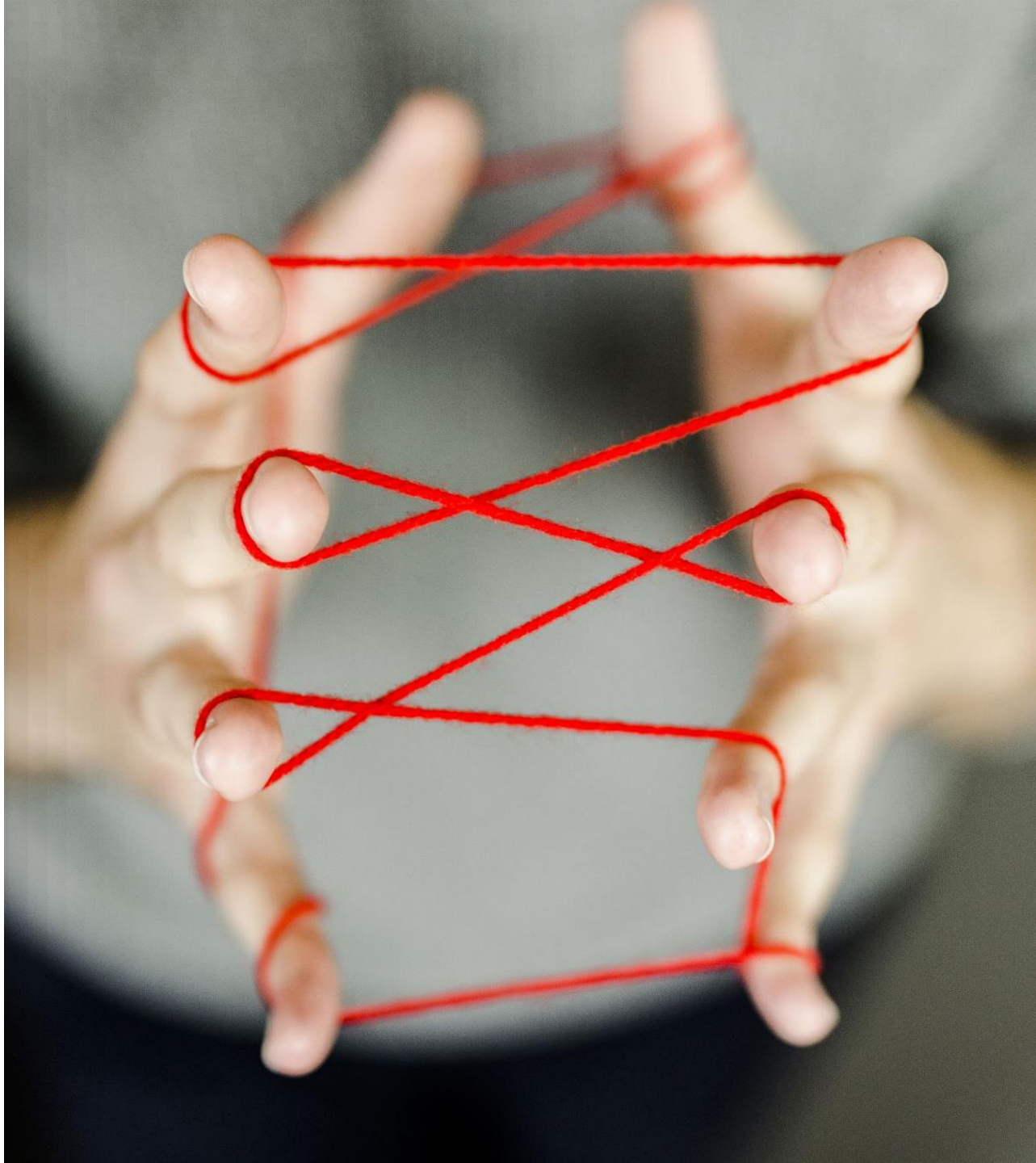
(elenco da definire, plausibile allineamento con l'elenco europeo)

Informazioni di contatto della U.S. *Responsible Person*

(indirizzo, telefono, email, sito web)

Altri aspetti

Experiencing MoCRA….



I. Adverse Events

Serious Adverse Events

Gestione degli Adverse Events

Gestione degli Adverse Events

Definizione di Serious Adverse Events

Obblighi della US RP

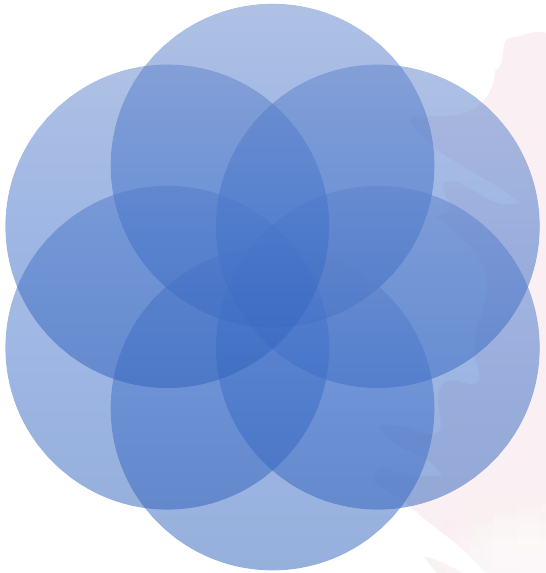
Cosmetic Survey

Rapporto US RP – FDA

Azioni della FDA

RECORD ACCESS → Safety Data, Cosmetic Survey

Mandatory Recall Authority → l'FDA può richiedere il ritiro dal mercato di un prodotto o provvedere essa stessa al richiamo



Serious Adverse Events

- definizione simile all'***effetto indesiderato grave*** (SUE) della norma EU

- la **U.S. *Responsible Person*** deve:
  - *report: inviare relazione e copia dell'etichettatura del prodotto, entro 15 giorni dalla ricezione della segnalazione*
  - *aggiornamento medico (New Medical Information): per 1 anno dall'evento, entro 15 giorni dalla ricezione degli ulteriori dati*
  - *ricezione delle segnalazioni: agli indirizzi (fisico, email e sito web) della US RP*
  - *mantenimento dei record per 6 anni*
  - *accesso a personale autorizzato del Department of Health and Human Services*

- **FDA: sospetto su componenti** della fragranza
  - *può richiedere l'elenco di tutti i prodotti che le contengono*
  - *la U.S. Responsible Person deve fornire l'elenco entro 30 giorni*

- **RUOLO DELLO US AGENT!**
  - *Tramite!*

Serious Adverse Events: Gestione

- Tutto bene, grazie…
- Ringraziando il cielo: No Events!
- Knock the wood/Toccare ferro (o altro…)
- Veda di non portare sf-ortuna…
- Lo scopo della vita: NON ricevere segnalazioni.

AEM: in pratica

- **US RP (voi!)**:
  - Ruoli e Formazione
  - Procedure
  - Organizzazione

- **Adverse Event:**
  - Flusso delle informationi
  - Event Management
  - Coordinazione!

- **AEM come strumento:**
  - Incrementa la sicurezza
  - Performance del prodotto

Definizione operativa di AEM-MoCRA e Cosmetic Survey-EU

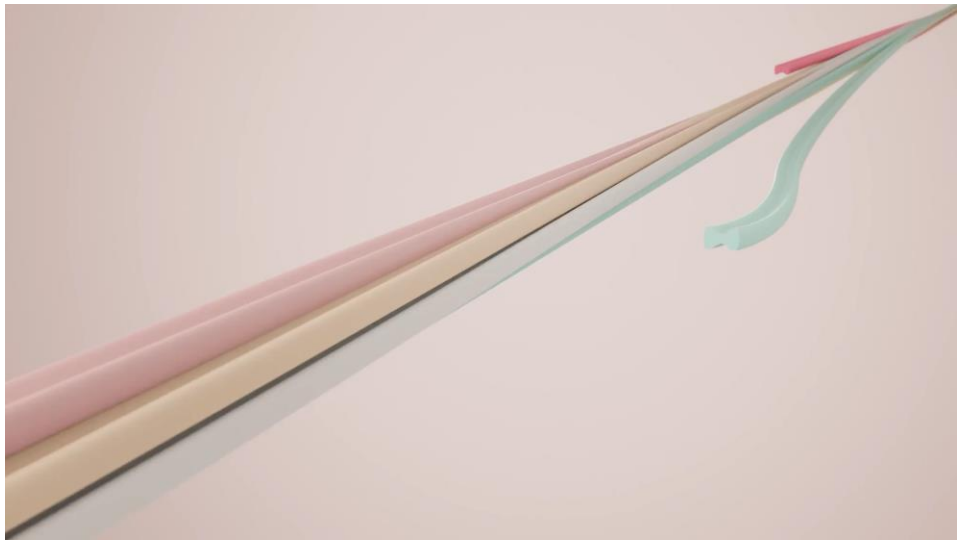
La dimostrazione documentata della EU/US RP di gestire la gli Adverse Events/Undesirable Effect.

Il punto di partenza: la Cosmetovigilanza in EU (la vostra, com'è?)

- Reg.1223/2009: art 23, Annex I (CPSR)
- EU Resolution AP(2006)1
- SUE form (EU Commission: SUE reporting guidelines 2012)
- Cosmetics Europe: Management of Undesiderable Effect Report – 2016

Causality Assessment

→ European Commission Guidelines on Reporting of SUEs, Appendix I



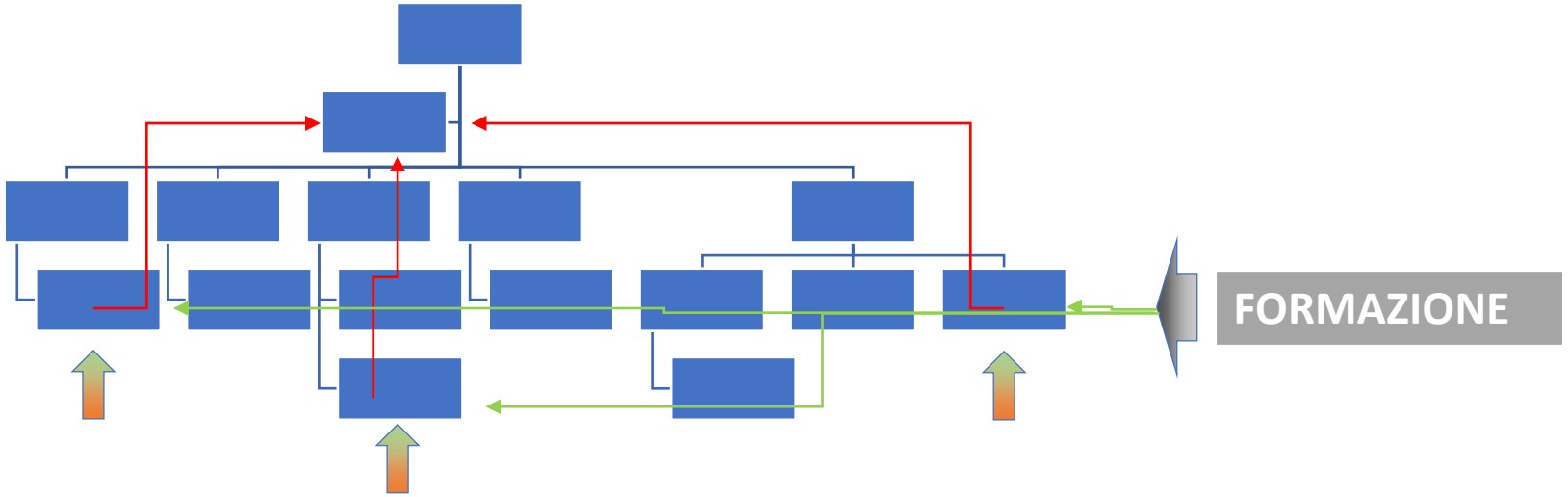
Siete una brava EU/US RP?

SOP : le basi

- Ricezione e Registrazione
- Raccolta di informazioni e documentazione interna
- Azioni verso il consumatore/dichiarante
- Azioni verso l'Autorità Competente - Modello di Segnalazione
- **Valutazione del Nesso Causale**
- Follow-up e Tempistica

Ricezione

- → Reports: mail, email, telefonate, distributori, centri di vendita.



→ Flusso verso la persona appropriata..
→ Raccolta di informazioni
→ Documentazione (moduli)
→ **Formazione!**

Ruoli e Funzioni

- **Customer care:**
  - Data collection: Screening of reports (customer service) and contact with the consumer
  - **Identification of critical reports**
- **Safety Assessor:**
  - Processing/Evaluation of correlation
  - Updating of CPSR **(Safety Substantiation)**
- **Responsible Person (USRP):**
  - Interface with authorities **(US Agent)**
  - Crisis Management

SERIOUS ADVERSE EVENTS

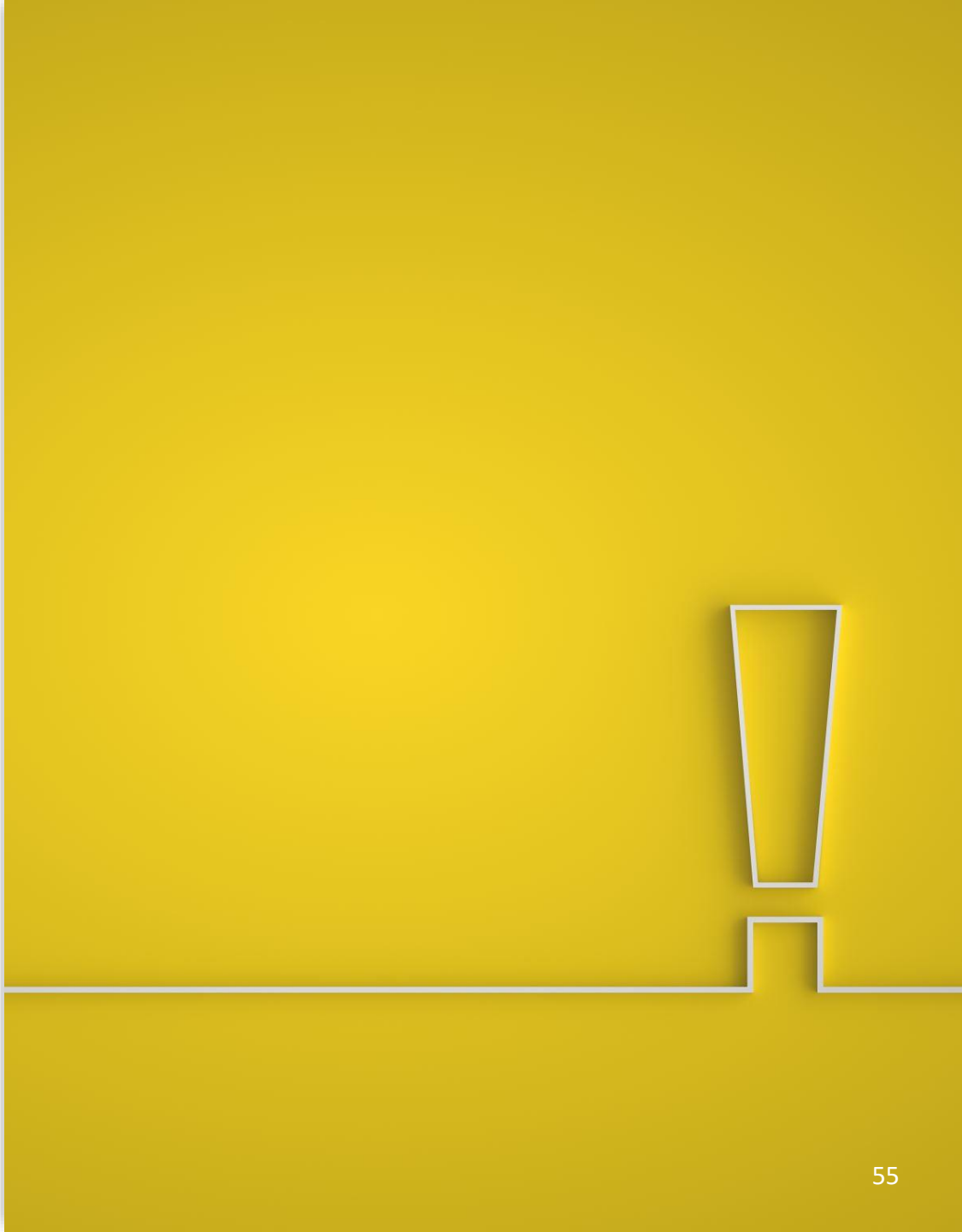
- NON SIGNIFICA CHE IL PRODOTTO SIA PERICOLOSO/DIFFORME!

Serious Adverse Events

(A) results in:

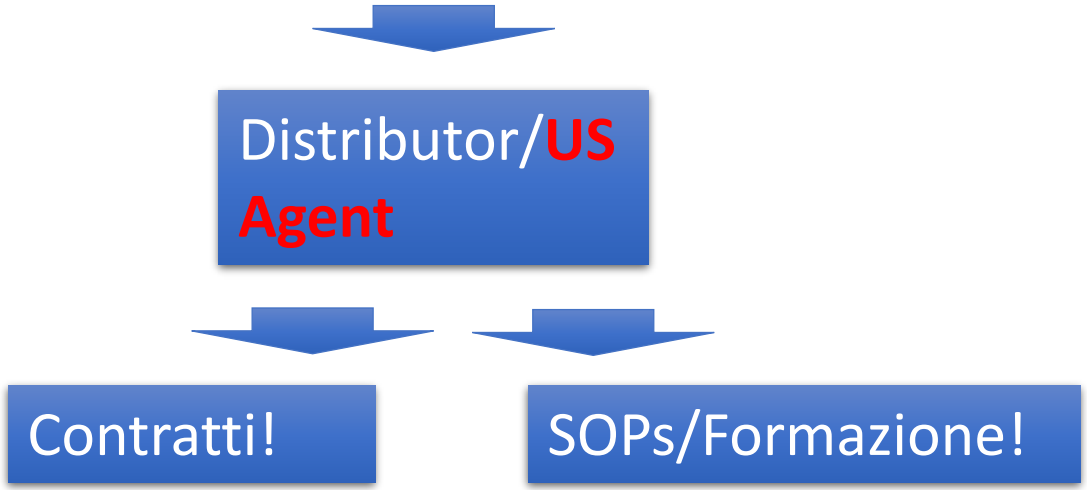
- death;
- a life-threatening experience;
- inpatient hospitalization;
- a persistent or significant disability or incapacity;
- a congenital anomaly or birth defect;
- an infection; or
- significant disfigurement (including serious and persistent rashes, second- or third-degree burns, significant hair loss, or persistent or significant alteration of appearance), other than as intended under conditions of use that are customary or usual; or

(B) requires, based on reasonable medical judgment, a medical or surgical intervention to prevent an outcome described in (A) above.



MoCRA: Reporting SAE/SUE

- Alla ricezione di una segnalazione di un Evento Avverso Serio (SUE), il Responsabile deve segnalarlo all'Autorità Nazionale Competente (CA) (alla FDA per MoCRA) nel luogo in cui si è verificato l'effetto avverso, utilizzando il modulo standardizzato per la segnalazione degli effetti avversi gravi.



MoCRA - Reportistica

US-RP (con il supporto dello US Agent): report entro 15 giorni dall'evento

Copia dell'etichetta o dell'immagine del packaging

Mantenere aggiornato l'FDA per 1 anno su qualsiasi sviluppo significativo

Form 3500A

Segnalazione, a: CosmeticAERS@fda.hhs.gov

Reset Form

FDA

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

MEDWATCH
FORM 3500A

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Form Approved: OMB No. 0910-0291
Expires: 6-30-2025
See PRA statement on page 6.

FDA USE ONLY	
Mfr report #	
UF/Importer Report #	
Exemption/Variance #	

Note: For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year; for example, 01-JAN-1900.

A. PATIENT INFORMATION

1. **Patient Identifier** *(In confidence)*

2. Age
☐ Year(s) ☐ Week(s)
☐ Month(s) ☐ Day(s)

or Date of Birth *(e.g., 01-Jan-1900)*

3a. **Sex:** Enter the patient's sex at birth *(the sex that a person has or was assigned to at birth).*
☐ Male ☐ Undifferentiated
☐ Female ☐ Decline to answer

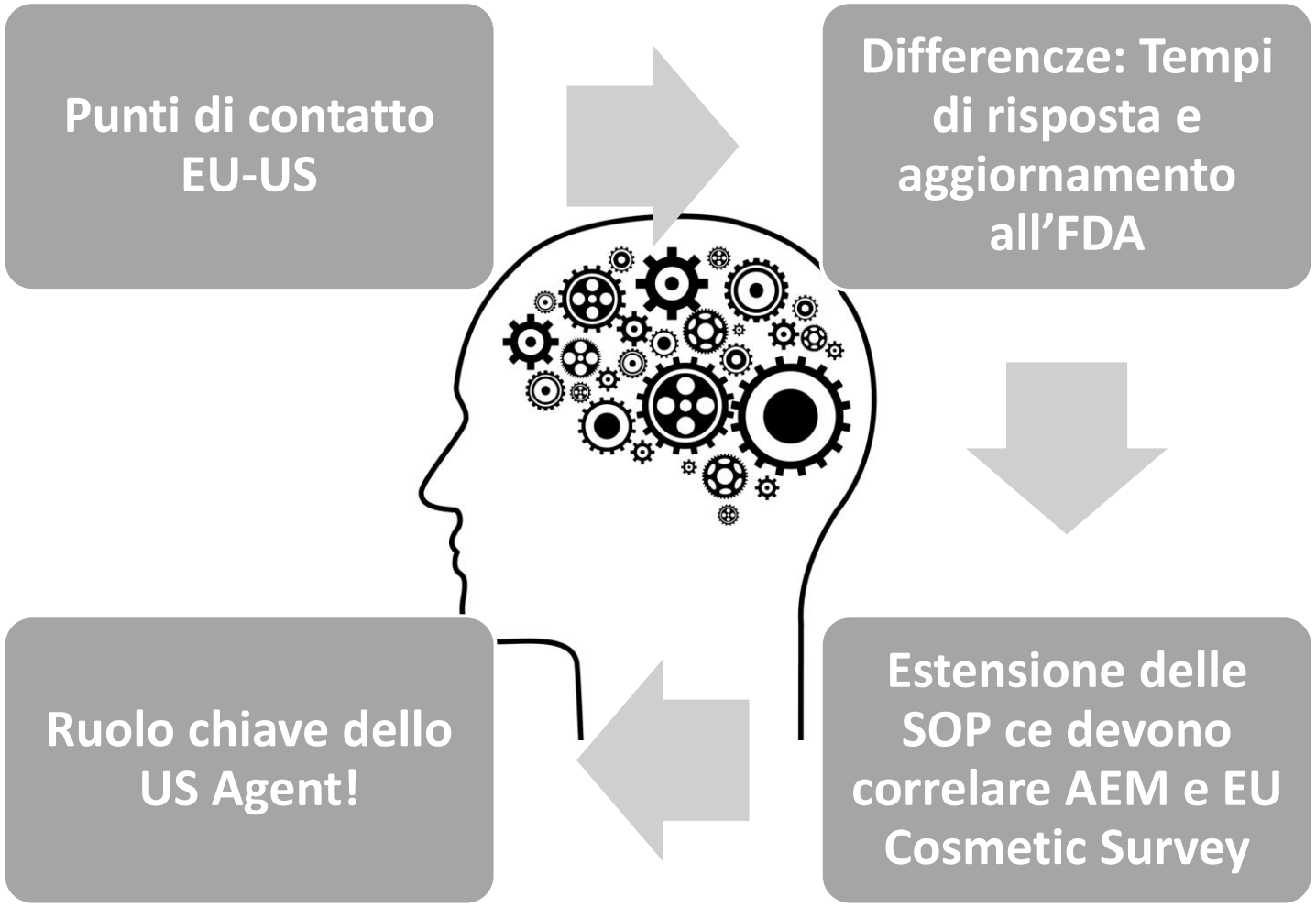
3b. **Gender:** Enter the patient's current gender *(how the patient thinks of themself).*
☐ Cisgender man/boy (gender corresponds with birth sex)
☐ Cisgender woman/girl (gender corresponds with birth sex)
☐ Transgender man/trans man/ female-to-male (FTM)
☐ Transgender woman/trans woman/ male-to-female (MTF)
☐ Other gender category; please specify:
☐ Decline to answer

4. **Weight**
☐ lb
☐ kg

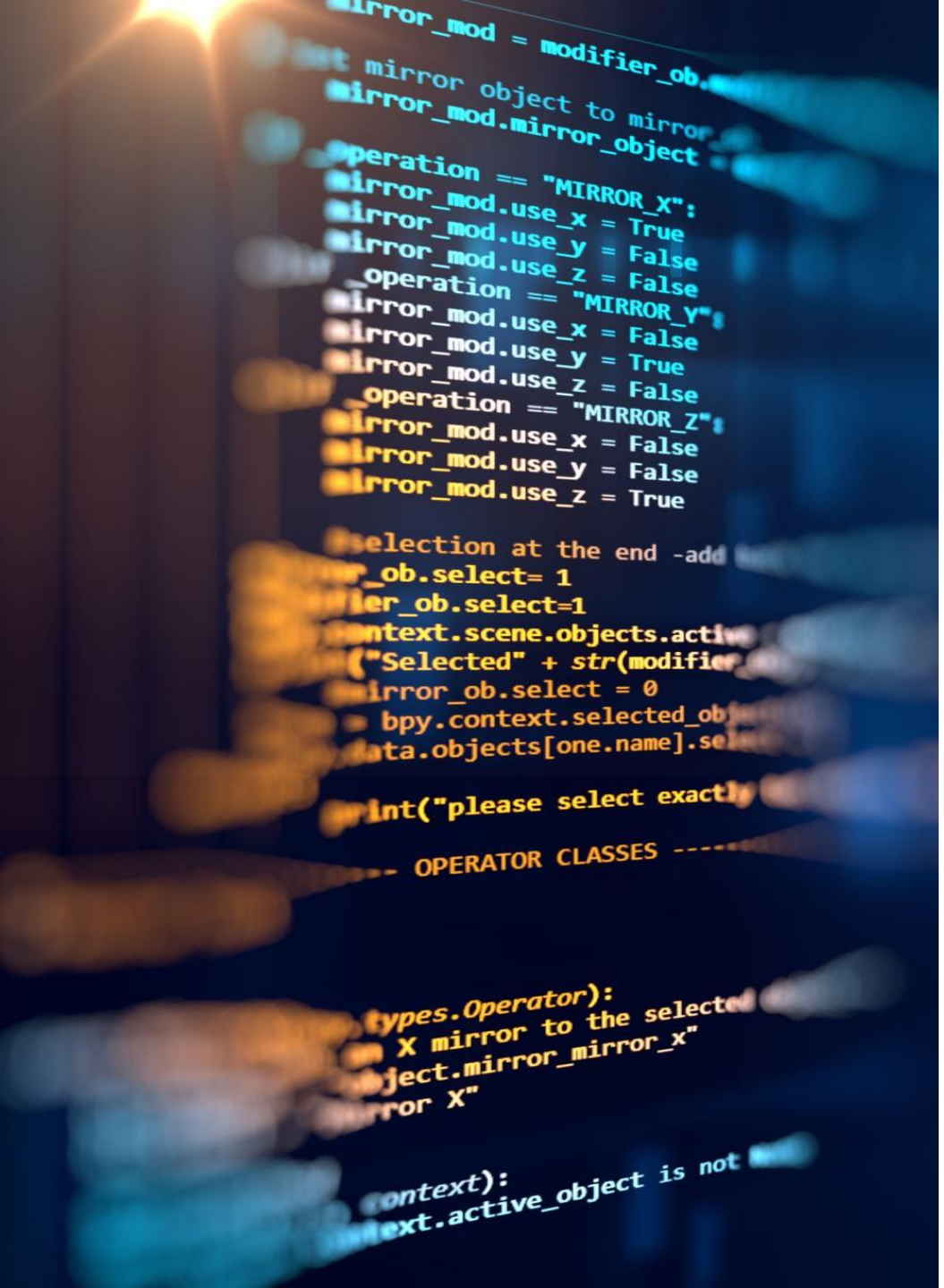
5. **Ethnicity** *(Check one)*
☐ Hispanic/Latino
☐ Not Hispanic/Latino

6. **Race** *(check all that apply)*
☐ American Indian/Alaska Native
☐ Asian
☐ Black or African American
☐ Native Hawaiian/ Other Pacific Islander
☐ White

Dalla EU-Cosmetic Survey alla AEM-MoCRA



II. Safety Substantiation



II. Safety Substatiation/PIF

Differenze

Errori comuni

Safety Substantiation: chi ha detto PIF?

Dimostrazione scientifica sulla sicurezza del prodotto e degli ingredienti

Documentata

Aggiornata

Tramite studi, test, analisi, prove, informazioni → **dati tossicologici!**

Esperto Qualificato con competenza documentata ed esperienza → **Safety Assessor**

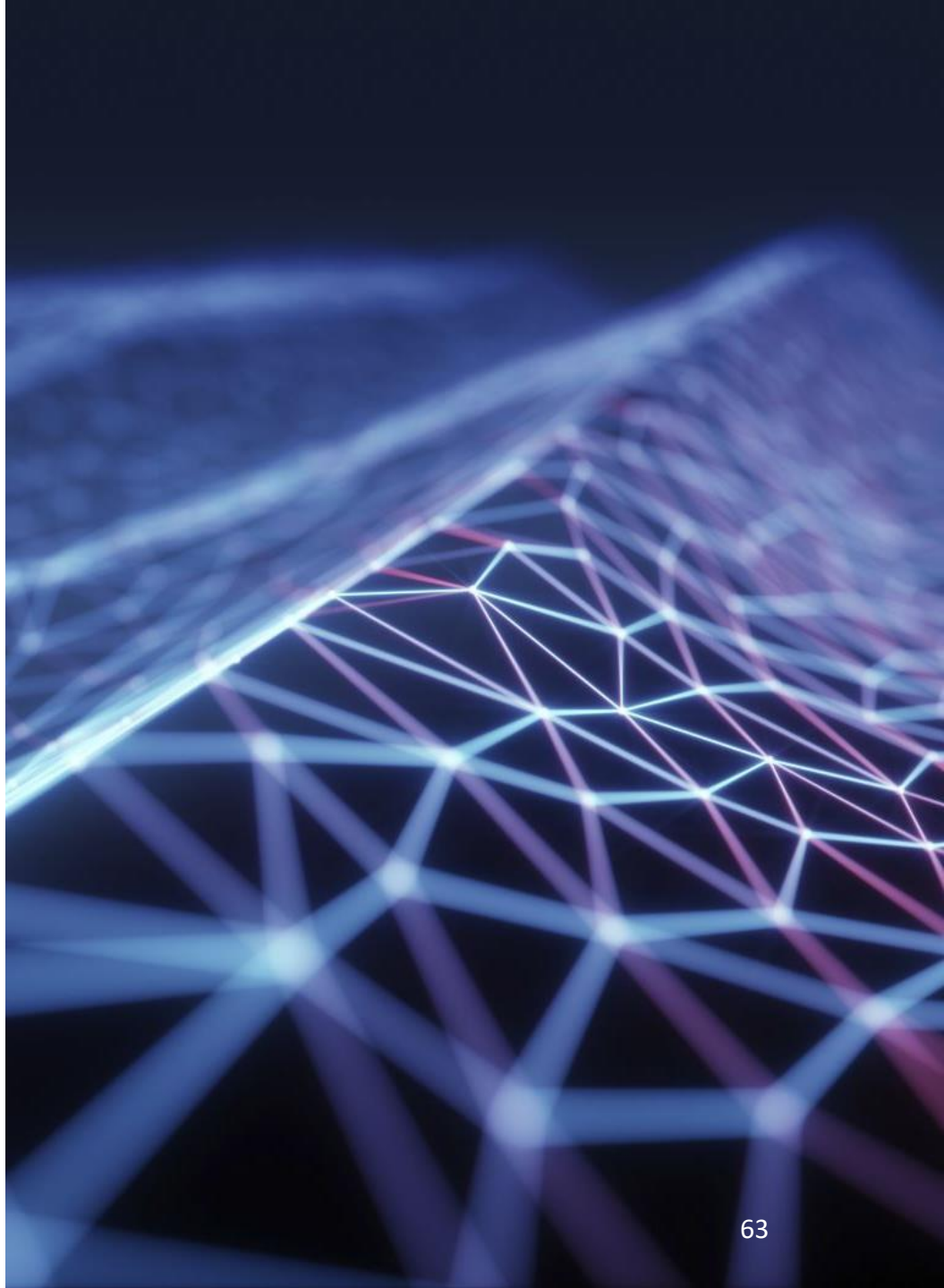
Valutazione della Sicurezza inerente il prodotto e gli ingredienti → **dati tossicologici!**

Safety Substantiation: cosa dice il MoCRA?

Companies must maintain records substantiating a product's safety, which can include tests, studies, research, and expert evidence

Adequate substantiation of safety involves evidence considered sufficient by **qualified scientific experts**.

This includes tests, studies, research, analyses, or other information that supports a reasonable certainty that a cosmetic product is safe



Come? (MoCRA)

Manufacturers can use safety data that is already available on individual ingredients and on products with similar formulations.

Sources:

Safety data may be published in scientific journals (**sources include PubMed and TOXNET**).

The **Cosmetic Ingredient Review (CIR)** websiteExternal Link Disclaimer disclaimer iconhas information on the safety of cosmetic ingredients that they have reviewed.

FDA: Dati ulteriori!

- Microbiological Methods for Cosmetics.
- Does “Natural” Mean “Safe”?
- Guidance for Industry: Safety of Nanomaterials in Cosmetic Products
- Potential Contaminants

Safety Substantiation Vs CPSR, Q&A

La Safety Substantiation è solo un CPSR ridotto?

Un CPSR è accettabile come Safety Substantiation, tal quale?

Un EU/UK-Safety Assessor è riconosciuto in USA?

Dal CPSR alla Safety Susbtantiation

CPSR aggiornato come punto di partenza

Dati Tossicologici: Pubmed and CIR opinions!

Database: MoCRA Ready!

Molte parti del CPSR influenzano la sicurezza, anche se non esplicitamente menzionati nel MoCRA Act! (stabilità, impurezze, packaging…)

UnCPSR aggiornato, completo, in inglese, può essere presentato come una Safety Substantiation!

Chi è responsabile per la sicurezza dei cosmetici?

- La US RP (voi), ma…
- **L’FDA può coinvolgere la Facility**
- **Ruolo-chiave dello US Agent**

III.GMP in USA
Giochi senza frontiere

GMP in USA

- **ISO 22716: punto di partenza**
- **in fase di definizione**
- **work in progress: team di esperti *on track! (anche italiani dal brutto carattere)***
- **Final Rule entro il 29 dicembre 2024**
- **obbligo di applicazione: 29 dicembre 2025**

MoCRA on track

in azione!

US Agent: un nome, più ruoli

MoCRA/EU: Attenzione alle differenze!

- US RP residente ovunque
- Controllo diretto della filiera da parte dell'FDA (con possibilità di contattare tutti gli attori!)
- Responsabilità maggiormente delocalizzata fra US RP e Facilities
- US Agent: ruolo fondamentale come *server* delle informazioni US RP/Facilities-FDA
- US Agent: ruolo fondamentale per gli Adverse Events

Azione!

Now!
(dal 29 dicembre 2023…)

- ✓ avere uno **US Agent qualificato!**
- ✓ Organizzare la gestione degli Adverse Effects (**Cosmetic Survey**)
- ✓ ***Safety Substantiation*** *- documentata, in inglese, aggiornata, dati -*
- ✓ **etichettatura** *- conforme -*

In Progress!

- ✓ **registrazione** dei prodotti (con *listing* ingredienti), produttori e attori della filiera

Coming Soon

- ✓ **ispezioni** e contatti da parte dell'FDA - *be ready!*

Conclusioni

Le aziende (EU RP) con un alto livello di conformità e organizzazione sono notevolmente agevolati → verifica di conformità del CPSR!

EU/UK Vs MoCRA → la catena di fornitura e le responsabilità: EU RP (US RP)-**US Agent**-FDA

FDA Direct: non male! (ma occorre che il pregresso sia *a posto*!!)

Conclusioni

MoCRA

E se fosse una buona occasione per migliorare?

COSMETICA ITALIA SERVIZI

MoCRA e FDA Cosmetics Direct. Come presidiare correttamente i nuovi requisiti regolatori USA
Dr. Matteo Zanotti Russo

GRAZIE PER L'ATTENZIONE!