



RESPONSIBLE PERSON AND US AGENT SERVICES

COSMETICS EU/UK/US &
CANADA



**We create compliance for
safer markets**

**Since 1988, our mission
has been to deliver the
most effective compliance
processes to our clients**

**Your consultant and
in-country representative
on the EU, UK ,US &
CANADA markets**

**Your trusted partner for
regulatory compliance**





What is it all about?

Product compliance and sales in the EU, UK, US and Canadian 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, Health Canada, FDA facility registration and product listing,) and assume the role of your RP/US Agent – This will allow your products to be made available on the respective markets

How long will it take?

Only for the EU, UK and Canada



30 working days

*This 21-day period allows for the preparation and scheduling of the required tests.



Need a faster turnaround?

Upgrade to our VIP packages

Choose between 8-5 working days delivery

Only for the US

How long will it take?

 Pro Package 21 working days



*Basic Package excludes: Safety Substantiation Review & Label Review

Why choose Obelis?

EXPERIENCE

We provide regulatory consultancy and representative services (Responsible Person and US Agent) since 1988

With over 35 years of experience, we have helped thousands of brand owners enter the EU, UK, US and Canadian market

ISO CERTIFICATION

Our operations and procedures are certified against ISO 9001:2015 and ISO 13485:2016. Our compliance team is comprised of lawyers, chemists, toxicologists, and other regulatory experts

COMMITMENT TO COMPLIANCE

We know that our consultants can be very meticulous in their compliance review process, but our objective remains firm: to see your products on the EU, UK, US and Canadian markets without any incidents or being blocked at customs! We are invested in your success, and we are proud of seeing our customers grow their business and sales revenues through our compliance services

What services will we provide?

One-stop shop for cosmetic compliance

- ✓ Responsible Person and US Agent
- ✓ Formulation Review
- ✓ Labelling Review
- ✓ Claims Validation
- ✓ Product Information File (PIF) Verification
- ✓ Safety Assessment and Safety Substantiation
- ✓ Laboratory Testing
- ✓ Product Registration
- ✓ Alert on Ingredients Bans and Restrictions
- ✓ Post Market Surveillance & Cosmeto - Vigilance

How much will it cost?


 EU

#	Service	Number of products	Cost type	Price
	RP RETAINER FEE			
1	EU Responsible Person	Unlimited	Annual	€160/ month
	ONE TIME FEES			
2	Guarantee Deposit (refundable)			€640
	FILE REVIEW			
3	PIF Review	1 Product	One time	€230
4	CPNP Registration			
	OPTIONAL SERVICES			
5	Laboratories tests: stability, challenge & compatibility	1 Product	One time	€350
6	Safety Assessment	1 Product	One time	€270

Price Quotations are valid for 30 days

How much will it cost?



#	Service	Number of products	Cost type	Price
	RP RETAINER FEE			
1	UK Responsible Person	Unlimited	Annual	£160/ month
	ONE TIME FEES			
2	Guarantee Deposit (refundable)			£640
	FILE REVIEW			
3	PIF Review	1 Product	One time	£230
4	SCPN Registration			
	OPTIONAL SERVICES			
5	Laboratories tests: stability, challenge & compatibility	1 Product	One time	£350
6	Safety Assessment	1 Product	One time	£270

Price Quotations are valid for 30 days

How much will it cost? For Brand Owners



#	Service	Number of products	Cost type	Price
RP RETAINER FEE				
1	US Agent	Unlimited	Monthly retainer	160 USD/ month
ONE TIME FEES				
2	Guarantee Deposit (refundable)	n/a	One-time (refundable upon agreement's termination)	640 USD
FILE REVIEW				
3	Product Listing + Safety Substantiation Review	Per product	One-time	190USD/ per product

*Additional **adverse events fees** - extra 95 USD per month

* **Safety Substantiation Review + Product Listing + Label Review** 460 USD per product for products reviewed by Obelis US

Price Quotations are valid for 30 days

How much will it cost? For Facilities



#	Service	Number of products	Cost type	Price
	RP RETAINER FEE			
1	US Agent	Unlimited	Monthly retainer	160 USD/ month
	ONE TIME FEES			
2	Guarantee Deposit (refundable)	n/a	One-time (refundable upon agreement's termination)	640 USD
	FILE REVIEW			
3.a	FEI Registrations (optional service)	Per facility	One-time	100 USD
3.b	Facility Registration	Per brand	One-time	85 USD

*Additional **adverse events fees** - extra 95 USD per month

Price Quotations are valid for 30 days

How much will it cost?



#	Service	Number of products	Cost type	Price
	RP RETAINER FEE			
1	Canada Representative	Unlimited	Monthly retainer	250 CAD/month
	ONE TIME FEES			
2	Onetime deposit (fully refundable)			1,000 CAD
	FILE REVIEW			
3	PIF Review	1 Product	One time	360 CAD
4	Canada Health Notification			
	OPTIONAL SERVICES			
5	Safety Assessment Report / Evidence of Safety Compilation	1 Product	One time	425 CAD
6	Laboratory testing (stability & challenge)	1 Product	One time	550 CAD

Price Quotations are valid for 30 days

OIO Agreement



ELEMENT	DESCRIPTION
COMMISSION	2 × Monthly Fee for each client referred
PAYMENT	Paid quarterly at the start of April, July, October, and January (for the previous quarter)
ONGOING RETAINER	€10/month per client , starting after 10 clients are referred
RETAINER ACTIVATION	Begins the month after the 10th client is referred
RETAINER PAUSE RULE	Retainer is frozen if no new clients are referred for 3 consecutive months
RETAINER RESUMES	Retainer resumes the month after a new client is referred

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AN EXTENSIVE INFORMATION PLATFORM ON THE **COSMETICS REGULATIONS**

SUBSCRIBE FOR
FREE



- Alerts on ingredients ban
- Update on substances restrictions
- Access to guidance and official documents

Monthly Fee

Why do we charge a monthly retainer?

Because certain aspects of the service need to be maintained continuously such as:

- Maintaining products registration valid
- Maintaining Product Information Files readily available for inspections
- Maintaining a regulatory consultant available for support and advice
- Maintaining set-up of news, updates and alerts on regulatory changes
- Maintaining set-up for market surveillance and incident reporting support

DISCLAIMERS

- All cost projections are valid for 30 days
- The Safety Assessments and Laboratory Testing have separate timelines
- In case one (or more) of the manufacturer suppliers refuse to disclose information without a NDA with Obelis – an additional fee of 40 EUR/month will be applied to cover present and future suppliers requiring such a NDA
- The Guarantee Deposit will be reimbursed to the manufacturer after completing the steps to replace Obelis by another RP or US Agent and after all outstanding fees due to Obelis have been paid



One-Time Fees:

One-time fees explained

PIF Compilation and Verification

We ensure your documentation complies with the requirements of the EU, UK, US and Canadian legislation on cosmetic products

Certificates

Evidence that Obelis has been appointed as the Responsible Person or US Agent for your products and that they have been registered (CPNP, SCPN, Health Canada notification, FDA product listing)

RP Mandate (only for the EU and UK)

The official document between Obelis and your importers through which we officially assume the Responsible Person role that, according to the law, would automatically be theirs, unless an agreement is signed

Refundable Deposit

That will be fully refunded when the legal obligations linked to the termination of the RP or US Agent agreement are met





**One-stop shop for
cosmetic compliance**

To Summarise:

What is it all about?

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

How much will it cost?

- 160 EUR/month (EU) /160 GBP/month (UK)/ 160 USD/month (US)/ 250 CAD/month (Canada)

How long will it take?

- 30 working days under our basic package (EU, UK and Canada)
- 8-5 working days if you upgrade to one our VIP packages (EU, UK and Canada)

Why choose Obelis?

- More than 35 years of service
- Highest standard of service
- One-stop shop for cosmetic compliance
- Commitment to compliance and to our customers



**Request our
Service Agreement today!**

Questions?



sales@obelis.net



www.obelis.net



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**One-stop shop for
cosmetic compliance**

**EU/UK/Canada RP - US
Agent
CPNP/SCPN/Health
Canada/FDA listing
Labelling
Ingredient Alerts
Safety
Assessment/Evidence of
Safety
Laboratory Testing**

