PRE-LAUNCH COMPLIANCE CHECKLIST

Cosmetic Regulatory Requirements

Canada · United States · European Union

2026 Edition — Updated for MoCRA, Health Canada CNP & EU CPNP

Use this checklist before launching any cosmetic product in Canada, the United States, or the European Union. Work through each phase in order — regulatory requirements must be met **before** your product reaches consumers. Consult a regulatory affairs specialist for products making drug-cosmetic claims (e.g., SPF, anti-dandruff, teeth whitening).

PHASE 1

Before Formulation

- ■ Define your product category (cosmetic vs. drug-cosmetic) for each target market

  SPF, anti-dandruff, and teeth-whitening products are regulated as drugs in Canada and the US.

- ■ Confirm your target markets: Canada, USA, EU — or a combination

  Each market has distinct notification, labelling, and ingredient requirements.

- ■ Review the prohibited and restricted ingredient lists for each target market

  Health Canada Cosmetic Ingredient Hotlist · FDA Prohibited Ingredients · EU Annex II/III/IV/V/VI

- ■ Verify all proposed ingredients are permitted at your intended concentrations

  EU Annex III sets maximum concentrations for restricted substances.

- ■ Confirm your contract manufacturer holds appropriate GMP certification

  ISO 22716 (Good Manufacturing Practice for Cosmetics) is the international standard.

- ■ Establish a product safety assessment process

  EU requires a formal Cosmetic Product Safety Report (CPSR) signed by a qualified assessor.

- ■ Assign a Responsible Person for EU market entry

  Required under EU Cosmetics Regulation 1223/2009 — can be a third-party service provider.

PHASE 2

Labelling & Claims

- ■ Prepare INCI ingredient list in descending order of concentration

  Required in all three markets. Use INCI names, not trade names.

- ■ Include bilingual labelling (English + French) for Canadian market

  Mandatory under the Consumer Packaging and Labelling Act.

- ■ List net quantity in metric units (Canada/EU) and both metric + imperial (USA)

Canada requires metric; USA requires both; EU requires metric only.

- ■ Include name and address of responsible party on label

Canada: manufacturer or importer · USA: manufacturer, packer, or distributor · EU: Responsible Person

- ■ Add required warnings and precautionary statements

Varies by product type — e.g., 'Keep out of reach of children', 'Avoid contact with eyes'.

- ■ Verify no prohibited claims (e.g., 'repairs DNA', 'reverses ageing')

Claims must be truthful, not misleading, and substantiated.

- ■ Confirm 2026 fragrance allergen disclosure (Canada)

New Health Canada rule requires disclosure of 26 fragrance allergens above threshold concentrations.

- ■ Review EU Regulation 2023/1545 fragrance allergen labelling requirements

Expanded list of 56 allergens requiring individual disclosure effective 2026.

PHASE 3

Pre-Market Notifications

- ■ Canada — Submit Cosmetic Notification Form (CNF) to Health Canada

Required within 10 days of first sale in Canada. Submit via the Cosmetic Notification Portal (CNP).

- ■ Canada — Ensure CNF includes product name, manufacturer, distributor, and full ingredient list

Incomplete notifications are rejected. Allow 2–4 weeks for portal processing.

- ■ USA — Register manufacturing facility with FDA under MoCRA

Mandatory for facilities that manufacture or process cosmetics sold in the US. Renew biennially.

- ■ USA — Submit product listing to FDA under MoCRA

Required for each cosmetic product. Annual renewal required. Deadline: December 29 each year.

- ■ USA — Confirm facility has a Designated Responsible Person on file with FDA

Must be a US-based contact for FDA communications.

- ■ EU — Submit pre-market notification via the Cosmetic Products Notification Portal (CPNP)

Notification must be submitted before placing product on the EU market.

- ■ EU — Compile Product Information File (PIF) and store in EU

Must be accessible to competent authorities for 10 years after last batch placed on market.

- ■ EU — Ensure Cosmetic Product Safety Report (CPSR) is complete and signed

Must be completed by a qualified safety assessor before CPNP submission.

PHASE 4

Ongoing Compliance

- ■ Maintain batch records and retain samples for each production run

Minimum 3 years in Canada; 10 years in EU from last batch date.

- ■ Establish a consumer complaint and adverse event tracking system

Required in all three markets. Serious adverse events must be reported to authorities.

■ Monitor Health Canada, FDA, and EU ingredient list updates annually

Subscribe to regulatory update services or assign a team member to monitor changes.

■ Renew FDA MoCRA product listings annually (December 29 deadline)

Failure to renew is a compliance violation and may result in enforcement action.

■ Update CNF if formulation, manufacturer, or distributor changes

Health Canada requires an updated notification within 10 days of any material change.

■ Review and update CPSR and PIF if formulation changes (EU)

Any change to ingredients, concentrations, or manufacturing process requires reassessment.

■ Conduct periodic label reviews against current regulatory requirements

Regulations evolve — schedule an annual label audit against the current prohibited claims list.

OFFICIAL REGULATORY PORTALS

Where to Submit Notifications

Market	Portal	URL
■■ Canada	Cosmetic Notification Portal (CNP)	www.canada.ca/en/health-canada/services/consumer-product-safety/cosmetics.html
■■ United States	FDA MoCRA Registration & Listing	www.fda.gov/cosmetics/cosmetics-registration-listing
■■ European Union	Cosmetic Products Notification Portal (CPNP)	ec.europa.eu/growth/tools-databases/cosing

Need help navigating regulatory requirements?
Formyoule™ Inc. provides regulatory support for Health Canada CNP submissions, FDA MoCRA registration, and EU CPNP notifications as part of our turnkey manufacturing service.

Book a free 30-minute consultation: formyouleinc.com/contact · +1 (437) 449-6951

This checklist is provided for informational purposes only and does not constitute legal or regulatory advice. Requirements change — always verify against the current regulations for each market before launch.