

MoCRA Private Label Launch Checklist

Complete before you print labels or list your product. Numbers in brackets refer to the sources below.

Brand

Date

BEFORE LAUNCH

- ☐ Label names the responsible person with "Distributed by" or "Manufactured for" and a full place of business [5]
- ☐ Label includes a U.S. address, U.S. phone number or website for adverse event reports [8]
- ☐ Supply agreement says who lists the product and who keeps which safety data
- ☐ Manufacturer's FDA facility registration number on file and current [1]
- ☐ Safety substantiation file complete before launch [6]
- ☐ Product listed with ingredients within 120 days of first sale [1]
- ☐ Process to send serious adverse events to FDA within 15 business days [2]
- ☐ Adverse event records kept 6 years (3 for qualifying small businesses) [2]
- ☐ Yearly listing update and 2-year registration renewal on the calendar [1][3]
- ☐ Small business exemption checked, including the product-type exceptions [10]

Notes

SOURCES

1. 21 U.S.C. § 364c, Registration and product listing
2. 21 U.S.C. § 364a, Adverse events
3. FDA, "Registration and Listing of Cosmetic Product Facilities and Products"
4. 21 U.S.C. § 364, Definitions
5. 21 CFR 701.12, Name and place of business of manufacturer, packer, or distributor
6. 21 U.S.C. § 364d, Safety substantiation
7. Foley & Lardner, "How MoCRA Is Reshaping FDA Oversight of Cosmetics in 2026" (March 2026)
8. 21 U.S.C. § 364e, Labeling
9. FDA, "Modernization of Cosmetics Regulation Act of 2022 (MoCRA)"
10. 21 U.S.C. § 364h, Small businesses
11. Crowell & Moring, "Cosmetics Under the Microscope: FDA's Expanding Regulatory Reach Under MoCRA" (April 8, 2026)
12. PMG, homepage FAQ
13. PMG, "Private Label vs Custom Formulation"

General planning aid, not legal or regulatory advice. Confirm requirements with your manufacturer and regulatory reviewer.